

Norplant: 'The Five-Year Needle'

An Investigation of the Bangladesh Trial

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Norplant, a contraceptive subdermal implant was introduced for clinical trials in Bangladesh as early as 1981. However, partly because of resistance from conscious groups the trial was abandoned. Four years later, the Bangladesh Fertility Research Programme with other international organisations and a pharmaceutical company once again initiated the trial. This is a report of investigations conducted by a concerned group in Bangladesh.

NORPLANT is the registered trade mark of the Population Council for contraceptive subdermal implants. It consists of flexible, nonbiodegradable tubes filled with levonorgestrel, a synthetic hormone of the progestin family. The implants are placed under the skin on the inside of a woman's upper or lower arm. The hormone is slowly released at an almost constant rate for several years.

Norplant implants come in two forms. The first, called simply Norplant, consists of six hollow silastic (silicone rubber) capsules, each capsule is 34 mm long, with a diameter of 2.4 mm, and contains 36 mg levonorgestrel. The ends of the capsules are sealed shut with silastic adhesive. This is the most widely used of the two systems. In Bangladesh, this system is being used.

The other system called Norplant-2, consists of two solid silastic rods, each 44 mm long. A total of 70 mg levonorgestrel is dispersed in the matrix of each rod. (PRS, 1987).

The promoters of the system are a coalition of heterogeneous partners, (1) Population Council, New York, USA working through its International Committee for Contraceptive Research (ICCR) and (2) Leires Pharmaceuticals Company, Finland. In Bangladesh the preintroductory trial is being carried out by Population Council and Family Health International (FHI) through the Bangladesh Fertility Research Programme (BFRP).

Norplant Trial in Bangladesh

In this section we shall provide some information regarding the history of Norplant trial in Bangladesh which began as early as 1981.

The 16th meeting of the National Council for Population Control and Family Planning was held on February 7, 1981 at Bangabhaban and was presided over by the late president Ziaur Rahman. In this meeting, among other matters, it was discussed that, Norplant, a sub-dermal contraceptive which is easier and more effective than sterilisation should be introduced on a trial basis (National Council, 1981). Accordingly, a steering committee was formed on Norplant for introduction and examination of suitability and acceptability in Bangladesh. In August 22, 1981 a meeting of the subvention committee, Population Control and Family Planning Division, was held. The meeting considered the project proposal of BFRP on 'Clinical Study of Norplant Reversible Hormone Implant Contraception'. It was approved in principle and a sum of Tk. 7,43,000 including US 20,000 in foreign exchange was recommended for the project to be paid in phases. On October 4, 1981, BFRP put an advertisement

in the *Bangladesh Observer and Holiday*, a daily and weekly newspaper respectively:

A new birth control method

NORPLANT

A wonderful innovation of modern science

- This method is for women
- This can be implanted under the skin of arm
- This will ensure sterility for 5 years
- When removed, can have child again.

Get more information:

Bangladesh Fertility Research Programme
3/7, Asad Avenue, (1st Floor), Mohammadpur, Dhaka.

Immediately, there was resistance from conscious groups who pointed out the unethical aspect of the advertisement. An article was published on October 25, 1981, where several issues were raised. A brief text of the article is presented below:

... So far as we know through reliable sources that the Technical Advisory Committee in Bangladesh did not approve its use in Bangladesh. However, the BFRP has successfully bypassed the Technical Advisory Committee and announced and advertised its use.

It should be noted here that the BFRP was also the pioneer in using Depo-provera and Norigest in Bangladesh.

Finally, some comments on the BFRP advertisement for Norplant. First, the advertisement says "Norplant-a wonderful innovation of modern science" Hard to believe because we do not have any scientific evidence.

Secondly, *the method is for use by women.* As women are politically less dangerous.

Thirdly, *it will be implemented under the skin of the arm.* Will ensure identification for coercion.

Fourthly, *this method will ensure infertility for five years:* A safe method for the population controllers and not the users.

Fifthly, *when removed will ensure fertility again:* Nobody knows (Norplant, 1981).

The trial was then postponed, as it was known through sources in government that the Population Council was not interested in being involved with controversial issues. A group of 151 doctors and pharmacists made a petition to the minister for health and population control to stop such an unethical trial. This part of the information seems to be lost in the present document of BFRP. There is no mention of the attempt of the trial in 1981. The BFRP documents now shows that they have initiated the clinical trial on Norplant in February 1985 under the financial and technical assistance

from Population Council and Family Health International (FHI) (FERP, 1986).

In an article by Dr. Halida Hanum Akhter, the present director of BFRP, it was mentioned that the BFRP has initiated the study after obtaining clearance from the Directorate of Drug Administration "to assess the acceptability and effectiveness of the new method among Bangladeshi women through government controlled hospitals and clinics such as the Institute of Post-Graduate Medicine and Research (IPGMR), Dhaka Medical College Hospital (DMCH) and Mohammadpur Fertility services and Training Centre (MFSTC)" (New Nation, 1987).

Earlier BFRP had obtained clearance from its 19 member executive council headed by the secretary ministry of health and family planning and consisting of members from various government and non-government research organisations. University departments and ob gyn departments of medical colleges.

The advisory committee was constituted by the Bangladesh government in February, 1985 to make major policy decision relating to the clinical trials and use of Norplant as a contraceptive, to decide the mode of Norplant study and monitor the acceptability of the new method of female contraception and to decide on the use of Norplant in large scale in the family planning programme cleared the use of Norplant in Bangladesh. The BFRP initiated the pre-introduction clinical trials only after the World Health Organisation decided at its Special Technical Review in November, 1984 that the Norplant was an effective and reversible, long-term birth control method which has proved to be superior to all other reversible methods.

It has been found by researchers that contraceptive pills containing progestin and more commonly used other reversible methods necessitate continuous motivational involvement of the user. In a country like Bangladesh this fact is more true than in the developed world. It is, therefore, necessary to introduce methods in Bangladesh which can continue to be effective for long periods without continuous motivation by Family Planning Workers. Norplant is perhaps the most effective method which is likely to prove successful here.

The articles does not say anything about the study on the safety aspects of the research. Again, when BFRP is quoting the WHO special Technical Review decision (which also says nothing about safety) it only emphasises the effectivity and the superiority over other methods.

The BFRP protocol of research does not have the objective of looking into the safety aspects of the method. An effective method means that the method can ensure birth control; but it does not necessarily mean that by being effective it is safe for user's health. The safety aspects are directly relevant for women's health, while the effectivity only deals with population control programme aspects.

It is interesting to note that even before BFRP undertook the trial in February 1985; the Third Five Year Plan had incorporated the use of Norplant. It says:

This long lasting method has the potential advantage of not requiring day-to-day use and therefore may be particularly suitable for our semi-literate population. It is proposed to introduce this method initially on trial basis, and the programme for its wider use can be decided according to the experience of the trial (TFUR, 1985). Here again, the effectivity question is mentioned and is specially targeted towards the semi-literate population, in other words, the poorer section of the population, so that population control can be ensured.

The BFRP had started promoting Norplant even before the trial was completed. While the trial began in 1985, the BFRP started making the following claims:

The Norplant contraceptive system is suitable for most women of reproductive age. (BFRP, 1986).

Norplant is a contraceptive system which is still under scientific investigation or trial. Because of the known and

unknown health hazards of administering long acting hormonal implants scientists and women's groups all over the world as well as concerned individuals are resisting even the trial of this system. The trial was attempted secretly in Brazil. Later when it became a public scandal and had started facing resistance the experimentation was stopped.

It is important to briefly state the scientific status of Norplant. Here's a critique of the 'Facts About an Implantable Contraceptive' published in the *Bulletin of the World Health Organisation* 63(3): 485-494 (1985).

A. Insufficient Animal Experiment:

1. Levonorgestrol and the half as active, Norgestrol isomer are used interchangeably. Only the investigations referring to levonorgestrol are relevant. The interchangeable use of the two substances is confusing, and it is not known how far results for one substance are valid for the other substance.

2. The comparison of the doses given to animals and humans is misleading because there are big differences in the bioavailability and terminal half-lives of the drug between different species.

Table 1: Bioavailability and Terminal Half Life of Drug between Species

Species	Bioavailability	Terminal Half Life
Rat	9	0.5
Dog (Beagle)	22-6	1.2-0.3
Rhesus Monkey	9-4	4.4-0.5
Women	100	26.4-72

3. Although it is accepted that the beagle bitch is an unsuitable model for studying progestagens, experiments with this animal are included and no replacement experiments were carried out.

4. In the majority of experiments, 1/levonorgestrol was given by the oral route. The comparison with implanted doeses is misleading because there is a difference in bioavailability.

5. Experiments are included which were carried-out for approval as an oral contraceptive.

6. Although the rat appears to be a poor model for the testing of implants (local sarcomas) it is nevertheless used in animal experiments.

B. Insufficient Clinical Research:

1. The effect of Norplant on lipid metabolism—the experiments carried out to date are contradictory. Fat metabolism is associated with the development of cardiac problems.

2. The relationship between Norplant use and an abnormal glucose tolerance test. (This was only examined in six women according to WHO report.)

3. The safety of long term use of Norplant.

4. The effect of Norplant on blood coagulation.

5. The use of Norplant during lactation. Its effect on the growth and development of the child.

6. The use of Norplant during pregnancy.

7. The effect of Norplant on the levels of testosterone and rostenedione. The experiments carried out to date are contradictory.

8. The effect of Norplant on systolic and diastolic blood pressure in the fourth and fifth year of use.

C. Inadequacy of Relevant Area of Investigation:

1. In general, investigations were carried out with young, healthy, non-smokers. By 'healthy' is understood: without cardiovascular disease, without diabetes (also preferably not in the family), not overweight, without liver disease. Common causes of this are alcohol and poor nutrition. Women who had used injectable contraceptives were eliminated from some experimental series. Thus, not a good cross section of the population.

2. Frequently results are compared with those of women who use oral contraceptives, instead of comparison with women who use no hormonal contraception.

3. Some side effects (although not frequent ones) were not included in the WHO report. More implants were removed as a result of 'other medical reasons' than because of menstrual problems (6.5 per cent of 5.6 per cent), while menstrual problems occur more frequently. Some of these side effects are depression (1 per cent), more than 10 kg weight loss (2 per cent in Thailand); and epilepsy. (study in family planning).

Therefore, the claim of suitability for most women of reproductive age is not based on facts and is misleading.

UBINIG's Involvement in Study

Since 1981 UBINIG has raised the question of ethics of the research which is conducted on human beings. There are specified guidelines for bio-medical research, which must be followed. But it has been observed that the research ethics was violated in several ways. UBINIG's main concern is the health of women and that women, specially the poorer women, because of their vulnerable condition, should not become the victims of such research. From this commitment UBINIG has always pointed out the lapses found in the research in order to improve the situation.

In 1985, UBINIG was informed of the trial on Norplant by a development worker working with women in the slum areas of Dhaka city. She wrote a brief account of her experience with the trial:

One of our group members (Jahanara) had four children. She became pregnant again and was worried. She went to several family planning centres for abortion (MR), but failed. Finally she told me everything and sought my help.

On 15th December, 1985 I took her to Mohammadpur Fertility Clinic for MR services. We were told that abortion cannot be done because it is already 11 weeks of pregnancy. But soon they said that MR can only be done if she takes ligation operation simultaneously. Jahanara did not want to take ligation. So she was refused by the centre.

I, then, took her to the medical college and met with the counsellor. Jahanara told the counsellor that she would prefer to take an IUD (plastic coil) after the MR. She said that she would not be able to take rest at least for three days after the ligation operation. She has to work. So it is better not to do it now. Then the counsellor told her about an injection. I remembered the side-effects about injectables so I said 'injections have possible side-effects'. The counsellor said: "You are talking about injectables with 2/3 months duration. But here is another injectable which is of 5 years duration. It does not have any side-effects."

I was confused, because earlier I heard of Norplant which is of 5 years duration, but the counsellor did not say that it was Norplant. During our conversation, the counsellor opened up a form and asked Jahanara to put her fingerprint on the paper. I could read what was written in it, although the counsellor did not make any effort to read the text to Jahanara which was meant for her. It said: I am completely aware of the method of menstrual regulation. I know about

the problem such as infection, bleeding and perforation of uterus and yet I have requested for the MR.

Jahanara put her fingerprint on the paper without knowing what was written on it.

Then we came downstairs. I saw that several clients were sitting, while two motivators were trying to motivate the clients. A doctor came out of the room and asked, "Did you find a client?" The motivators said, "No". The doctor said, "Try to motivate them".

I asked the motivators about the 5-year injectables. They said that it was called Norplant. They also informed me that it is given in the PG hospital, the medical college and Mohammadpur Fertility Clinic and through Dr. Firoza Begum. They also mentioned that Norplant was being given through some private clinics. I became very worried and went to the room where Jahanara had her MR. I told her not to take Norplant. The I went to the doctor and requested her to let us go on that day. We would come back later. In this way Jahanara was saved from Norplant.

After this, we tried to find out more about Norplant. UBINIG research team found that most of the clients in the PG hospital were being motivated for accepting Norplant. However, they were found to have been asked questions such as, whether the woman was a lactating mother or not. One Aya thought that the research team was there as client. She suggested that if they take Norplant, then they could be given Tk 30.00 [app. Rs 60] and some medicine during the first visit. The client could come back in case of any problem and would receive Tk. 30 and medicine. In the PG hospital, we collected a leaflet which was distributed to the clients. The leaflet said:

Facts About Norplant

1. Norplant is a new temporary family family planning method. It is effective for 5 years.
 2. Its use is relatively easier.
 3. It is given under the skin of the arm with an injection needle.
 4. Generally the side-effects of this method are less than that of the pill.
 5. It is 100 per cent effective as sterilisation.
 6. The user can take out the norplant whenever she wants.
 7. The return of fertility after taking out Norplant is after one year.
 8. It is possible to carry out normal movement and works when it is in the body.
 9. There is no need of taking any other method when the method is in use.
 10. The doctor will examine the client before the method is given.
- To know more about Norplant, contact the doctor
(Collected From IPGMR on December 24, 1985.)

If we evaluate the points mentioned in the leaflet, we find that it actually violates the ethics by providing false information to the clients. A few examples of the falsity of the information are given below:

Point 1: The claim of effectiveness is not completely true, because according to BFRP newsletter the rate of accidental pregnancies during the first year was 0.4 pregnancies per 1000 users. The WHO records indicate a gross cumulative pregnancy rate at 5 years of 2.6 per 100 women years. The annual pregnancy rate during the first 5 years ranged from 0.2 to 1.3. ('Facts about an Implantable Contraceptive', WHO Bulletin 63(3)-p. 485-494 (1985).)

Point 2: Its use is not easier because it needs surgical approach to put the capsules under the skin. The WHO recommends that to minimise the risk of infection, both insertion and removal should be performed in a clinical setting. It is of utmost importance that sterile techniques be maintained throughout both procedures.

The above two examples also indicate the violation of ethics by trying to motivate women with false information.

We have tried to collect more information but were not

successful because of the non-cooperation from the research organisations. In November 1986, a conference was organised by BFRP on "Contraceptive Technology Update", among other issues. Norplant research was discussed. A preliminary report was presented by S. Firoza Begum. According to her report 600 clients were admitted under the study within the period February 1985 to April 1986, but the total number that remained in the period Jan-April 1986 was 187 i.e. 31 per cent of all those admitted. She listed a number of reasons for removal (Table 2).

From the users' satisfaction point of view Firoza Begum had pointed out that 40 per cent have liked the method because it lasts for 5 years, while 30.7 per cent liked it for easiness. About 56 per cent disliked it because of its effects on the change in menstrual pattern. 82 per cent have said that they have received 'enough' information about the method, while 17.8 per cent have not. One wonders what 'enough' means. If the above leaflet is the only source of information it cannot reach all the users because many of them are illiterate.

UBINIG Study on Norplant-Clients

We found out the clients of Norplant during our study on the injectables in urban slum areas. In the area of Mohammadpur, Tikkapara slum we identified women who have taken injectables. We also went to Basila village which is a semi-urban village and found a number of injectable clients. During the interview we discovered one injectable client with Norplant. The client told us that she has taken a 'five-year needle'. Then she showed her arm having the capsules. Gradually we found more women in the same village who have taken the 'Five-Year Needle'. We have interviewed 10 women who have taken Norplant.

Three centres were visited by the UBINIG research team in order to get information about the trial. These centres are: (1) Mohammadpur Fertility Services and Training Centre, commonly known as Mohammadpur Model Clinic or the Mohammadpur Fertility Centre; (2) Dhaka Medical College Hospital, DMCH; (3) Institute of Post Graduate Medicine and Research, IPGMR.

Table 2: Reasons for Removal

Reasons	(N=32)	
	No	Per Cent
1. Pregnancy Related:		
Luteals Phase*	2	6.2
Planned Pregnancy	1	3.1
2. Change in Menstrual Pattern:		
Amenorrhoea	4	12.5
Polymenorrhoea	6	18.8
Menorrhagia	2	6.2
Irregular Bleeding/Spotting	5	15.6
3. Medical Reasons:		
Body Pain	1	3.1
Headache/Nausea/Burning Sensation	3	9.4
Loss of Libido	2	6.2
Weight Gain	1	3.1
Serum Hepatitis	1	3.1
Infection at Insertion Site	1	3.1
Jaundice	1	3.1
4. Personal Reasons:		
Husband Went Abroad	2	6.2

* In these two cases women were pregnant at the time of admission.
Source: Report of Firoza Begum (1986).

The information obtained from (1) Dr. Hosna Ara Ali, deputy director and Ms. Pervin (a family planning worker) in the Mohammadpur Model Clinic, (2) Dr. Kohinoor, gynaec specialist and directly working with the Norplant study in Dhaka Medical College Hospital and Ms. Nadira Begum, a family planning counsellor in IPGMR.

It was known that about 616 women were given Norplant in three centres. Except in IPGMR the other two centres had 200 clients each, while in IPGMR it was 216. The counsellor reported that another 14 clients will be given Norplant within one month of the interview (i.e. January 1988).

Information received from Mohammadpur Model Clinic shows that the age range of the clients is between 18 and 40 years. The Norplant is given within 1-7 days of menstruation. Women who are not breast feeding their babies are given the method. All medical check-up is done for the clients so that no disease such as jaundice, hypertension, diabetes is found in her. If the clients fall sick after the use of the method then it is taken out and she is admitted to the hospital.

The follow-up is done within 1.3 and 6 months of insertion. Those who have taken Norplant have come from Dhaka mostly, although a few have gone to Chittagong and Comilla after the insertion. However, they have stopped inserting any further Norplant since last one year.

In the Dhaka Medical College, the criteria of the Norplant recipients in terms of age was same as the other two centres i.e. between 18 and 40 years. In addition to that, the gynaec specialist said that one should use Norplant after one child is born. The breastfeeding mothers should not use it, because according to Dr. Kohinoor, "the hormone which is in Norplant may pass from mother to the child through breastmilk and can cause harmful affects on the baby." In response to the question, how do they get the clients Dr. Kohinoor said, "When women come here for taking a contraceptive method we give them a leaflet where the good and bad effects of Norplant use are written. But the women must get the consent of their husband". About follow-up she said that each and every client has a card. If the women do not turn up for follow-up care then workers go and visit them at their homes.

No insertion is made without complete medical checkups. Those who have hypertension should not be given, nor those having jaundice and diabetes.

As for side-effects, the most common side-effect is amenorrhoea. "However, this is not a serious side-effect", she said. "It is better for the health to have amenorrhoea. Because it saves the blood which would have gone through menstruation every month. Therefore there is no chance of having anaemia. You know these women are already malnourished Norplant is better for their health," she added. According to her 95 per cent of the clients belong to very poor class. "They are responsible for giving 4 to 5 births each. Since they cannot remember to take birth control method; like pills, every day, long acting methods are better for them. On the other hand, women in the upper class are intelligent and can take any other method".

Finally she said, "In order to get a good thing there is a trade off. If 2/3 women die what's the problem? The population will reduce and 70 per cent of our research has been successful. In every birth control method there are good and bad sides. This has, too."

The doctor in the PG hospital has only joined recently, so she could not give much information.

Every centre we visited referred us to BFRP. But BFRP refused to give information on the ground that we will 'misinterpret them'. We have requested the director in writing.

Profile of Norplant Users

Below we shall provide a brief picture of the users of Norplant in the village Basila, in Dhaka city. There were 10 women, who were found to take Norplant from Mohammadpur Fertility Centre.

(i) *Economic Condition*: According to the information available about occupation of the husbands of users, and by direct observation of their household conditions, the economic status of the users is poor (6) and lower middle (4). Those who are poor are working as boatmen, fish sellers, day labour and small business. The average daily income is Tk. 40.00 to Tk. 50.00. They have no land and have to depend on selling labour for earning their livelihood. The lower middle families are mainly engaged in small business such as ~~and~~ groceries. The families are also found to be involved in brick business.

(ii) *Education*: Eight out of 10 users are illiterate; one has read upto primary level, and another has got secondary education.

(iii) *Age*: Two users are in the age range of 15-20 years, three are in 26-30 years, one is in 31-34 years and four users over 35 years of age. The highest age was found to be 45 years, while the lowest age is 18 years.

The age was determined by our investigators by asking the user about her age; about the age at marriage; about her menstrual situation at the time of marriage and about the age of her first child.

All this information together helped the investigators to come to a figure for age of the user. This age information is more or less accurate. In the centres where Norplant is given, the age limit is said to be 18 to 40 years and is noted only by asking the user about her age. In our sample, we find that a woman over 40 years has been given the method.

It is interesting to note that the draft protocol of the Norplant study does not say anything about age of the users. Moreover, the preliminary report submitted by Firoza Begum does not mention anything about the age level of the 600 users of Norplant. The question is whether the researchers are not taking the issue of "age of the user" as an important criterion of the research, whereas Norplant as a "long-acting contraceptive" method must have a limit for age for the method to be effective.

(iv) *Marriage and Child Birth Information*: (a) *Duration of married life*: Six women had a long-married life of 20 to 30 years, while others had between 10 and 20 years. Only 2 young women were married in 1981. It is somewhat related to the age of the user. Most of the users (8) were married at an age of 13 to 16 years, and only 2 were married at the age of 18 years.

(b) *Number of living children and children ever born*: The average number of children for all the users (N=10) is 4.3, while maximum number is 8 and minimum is one child. As is known from national statistics, the number of child births is higher than the number of living children. The average

number of child births is 4.7 (the maximum is 9).

(c) *Age at first child birth*: Three women have got children before they reached 15 years, while 7 had children between 16 and 20 years of age.

(d) *Time gap of first child birth and marriage*: Five women got children only after a year of marriage, 4 had between 2 and 3 years and one had 5 years of time gap after marriage before the first child birth.

(e) *Average gaps between child birth*: The average gap between child births were found to be 2.1 years, with 4 years as the maximum gap.

(v) *Information on Contraceptive Acceptance*: Except 3, seven users have accepted other methods before taking Norplant. These other methods are pill and injection. Norplant has been used as a method of switch from other methods or other methods were taken after Norplant use. This is shown in Table 3.

Table 3: Use of Norplant and Other Methods

Category I	No of Users
I Norplant as the first method and no switch	3
II Norplant as the first method but switched to other methods	1
III Norplant after using other methods	6

That is most of the users have switched to Norplant as a change of contraceptive method from other methods. One woman in the category II has already changed from Norplant to other method such as pill. In category I, one woman has taken off Norplant and has not taken any other method. In category III, one woman has taken off Norplant. Out of 10, the drop out of Norplant is 3.

Those who used other methods have started using the methods since 1976. The Norplant was given in 1985. Only one woman has taken Norplant in 1986.

(vi) *Present Health Condition of User*: We have taken weight, height, blood pressure, pulse, anaemia etc. as minimum indications of health condition of the user. We shall provide the information in terms of average and maximum and minimum figures.

Height:	Average	4.11	N=10
	Maximum	5.1	
	Minimum	4.9	
Weight:	Average	42.3 kg	N=10
	Maximum	48.0 kg	
	Minimum	38.0 kg	
Blood pressure:		90/60	N=10
	Minimum Normal Level		
Plus rate:	65-80 per minute	5	N=10
	More than 80 per minute	5	
Anaemics:	Normal	2	N=10
	Mild anaemic	2	
	Moderate anaemic	4	
	Severe anaemic	2	

(vii) *Health Condition before Use of Norplant*: We have asked questions whether they had any specific health problems before the use of Norplant, we got the following response.

There was no problem 8

Irregular Menstruation 2 N=10

That is, women having amenorrhoea and irregular menstruation were given Norplant, which aggravated their problem

even further. We could not however get information on health conditions for which Norplant is contraindicated such as jaundice, diabetes etc. So we abstain from making any analysis of it.

(viii) *Health Conditions after Use of Norplant*: All the 10 Norplant users were facing problems since they have taken Norplant. These were as they have expressed:

"No menstruation since 1 to 1½ years"

"Once menstruation is started continues for 15 to 20 days"

"Irregular bleeding, spotting" etc.

In addition to this the other problems are loss of appetite, vertigo, burning feeling in hand and feet, body ache, weakness, leucorrhoea, etc. If we order the health complaints in terms of the frequency of reporting, then the following pattern emerges:

	N=10
1. Amenorrhoea*	10
2. Irregular menstruation	4
3. Burning sensation	3
4. Excessive Bleeding, White Discharge, Body ache 2	
5. Tiredness	1

* Almost all the clients suffered from amenorrhoea for different periods of time and most of them developed irregular, or excessive bleeding in between.

Here by amenorrhoea is meant long period without menstruation, even more than 45 days. According to some clients they had no menstruation for one year or more.

A few examples of the users' complaints:

(a) "After I have taken the "Six" (the needle), I felt aches in my body after six months. I cannot look up, I do not have any appetite, I am going to die. The menstruation is very irregular, and during last Shabe-Barat (a religious occasion) I had menstruation for 2 months at a stretch", Anwara Khatun (30 years).

b. "I did not get menstruation for 2 year since I have taken this 5 year needle. Now I have aches in my hands, legs; I feel weak, I cannot explain; it is a terrible feeling", Fulbanu (35 years).

c. "Since I have taken the needle, I get menstruation which continues for 12 + 13 days together. When I took the 3 month needle, I had regular menstruation but now I had bleeding; clots of bloods going at the time of menstruation. I feel pain in the body. I put kerosene oil on my body; when I go near the stove to cook; I see things double. I cannot go near the fire". Nawab Banu (38 years).

Three women who could not tolerate the problems insisted on taking the Norplant off, and finally could succeed in convincing the centre to take it off.

For health problems, the users have gone to the centre to express the problems; but they were given only 30 vitamin tablets and in some cases a prescription to buy medicine from outside. No other treatment was done from the centre. But they had to go to some doctor. For example 2 have gone to a qualified allopath doctor, 3 have gone to traditional healers, called the kabiraj, and one to a quack allopath doctor. Five women did not go to any doctor because they did not have the money to spend.

(ix) *How was Norplant Taken by Users?*: The users first heard of injectables, the 3 month dose, from the family planning workers but later they heard from the neighbours that there is a needle for 5 years. They heard that it was better than the 3 month injection so it would be better for them

to take the 5 year needle instead of the 3 month one. From their village, it is difficult to go to the centre frequently, so it was better if they could have a method of 5-year duration. One woman said that every woman goes to take Norplant is asked to talk about the benefits of Norplant to their neighbour, and that they should send their neighbours to take the method. None of the user has mentioned that they were using the method as a trial. The only information which was given to the clients was that Norplant was a 'needle for 5 years'.

(x) *State of Lactation, Pregnancy and Affects by other Contraceptives*: We have received information which is vital before a contraceptive like Norplant is taken by women. Table 4 is the representation of the situation.

Table 4: Status of Women before Taking Norplant

State of Client's Condition at the Time of Norplant Acceptance	Number of Clients
Breastfeeding	3
Pregnant	3
Already had problems due to use of other contraceptive methods	3
Both breastfeeding and affected by other methods	3
None	3

Six out of 10 women were breastfeeding out of which two women had a child below one year of age. One of these clients had her last baby with the age of 1½ months only. Four women were still breastfeeding their child even though the child was over 1 year of age. In Bangladesh, the average length of breastfeeding is about 18 months.

Table 5 shows that there is no sign of using Norplant as a trial, it is used as a contraceptive method, like the injectables, IUD etc. The clients are not included under the trial with their informed consent nor any proper care is being taken for the health problems of the clients. However, the centres are selectively doing urine tests for some clients and not all of them. It is assumed that they want to eliminate the cases where the women are not coming within 1-7 days of menstruation. By urine tests they want to be sure about pregnancy.

Here again, the evidence suggest that the rules for trial were not followed although the workers are found to be aware of certain rules. Violations are particularly made in taking informed consent, in the selection of clients for the method and in the follow-up care. Information on the monetary incentives for follow-up monitoring was received from IPGMR Hospital. The doctor told us that they give Tk. 20.00 to each client for motivating the clients for visiting the centre for follow-up monitoring. They also reported that the clients are given Tk. 50.00 at the time of first insertion of the method. While the centres try to motivate the clients to come for follow-up visits the clients reported the contrary. According to the clients, there was rather discouragement for reporting health problems. The centre workers are friendly in their attitude before insertion of the method, but afterwards 'they do not even want to talk'. The family planning workers at the centre do not appreciate the clients' health problems at all and they also do not want to take it off. Since the method is clinical, and the clients cannot take it off by themselves, they feel helpless and therefore have to go to the centre and plead for taking off the method. It is upto the decision of the workers whether it would be taken off or not. This is

a helpless situation for the clients.

The clients also become discouraged to go to the centre for follow-up care because they are not given any treatment. They are given 'slip' only i.e. prescription. The centre workers says that there is no medicine for treatment of the clients.

Discussion

If the trial is for acceptability and effectivity, the methodology is inadequate to prove either. The research methodology is directed more towards getting women so that the method can be inserted. Women are not considered as a human and social being. Therefore, no information is being shared with her except the information which will only lead to the insertion.

Women who are motivated to take Norplant are supposed to be motivated with full knowledge of the method as a trial. This is not happening. This can be proved not only by the

Table 6: Discrepancy and Similarities Found in Information Given by Centre and Information Received from Clients

Centre	Clients
a. Norplant is given within 1-7 days of menstruation	All the clients reported of same time period after menstruation.
b. Women who are breastfeeding are not given the method	Six out of 10 users were breastfeeding at the time of taking Norplant.
c. Norplant is taken out as soon as any side-effect is noticed.	Three clients have taken out Norplant. But their experience is that the centre did not want to take it off for first 2-3 times. Then when they insisted further, then it was taken off. In the words of a client, "when I had problems, and could not bear it anymore, then I went to the centre, but they refused to take it off. They said why did you take it?" Next time I went and made a lie by saying that my two children are drowned in the river and my husband wants another child. This time they took it off. The rest seven clients are having side effects but the method is not taken off.
d. All pre-medical tests are done. These include checking of disease like hypertension, jaundice, asthma, etc.	The clients have reported only urine test, blood pressure checking, irregular p/y exam and weight as the premedical test done for them. But these were also not done for all the clients.
e. Norplant is given to women between 18 and 40 years of age.	One client was 16 years and one client was 45 years. The rest were within 18 to 40 years of age.
f. The follow-up procedure is the following: 1st follow-up after one month of insertion, 2nd and 3rd follow-up after three months of insertion. Fourth onwards follow-up in after six months of insertion. Dates of follow-up visits are written on the card. If they do not come then the centre workers go to the clients' houses to see how they are.	The clients reported that they are asked to go to the centre after every 2-3 months. They know that the date is written on the card, but they have not seen any worker coming to their houses for follow-up care.
g. A leaflet is made with the information of good and bad effects of Norplant. This is read out to the clients; and then if they decide to take it then the method is given.	No client has reported of such information.
h. Women having post-partum amenorrhoea, are not given Norplant.	All the 10 women who have received Norplant during normal menstruation cycle.
i. The clients must have at least one child at the time of taking Norplant.	The clients reported that they were asked about the number of children they have.
j. Those women who have taken pills, must wait six months before they take Norplant.	Two clients were taking pill before taking Norplant. One of them has taken Norplant only after 2 months of stopping pills.
k. Clients must get consent of their husbands before taking Norplant.	Only six clients have taken consent and four did not.

Table 7: An Examination of Rules to be Followed for Trials

Rules	Whether It Was Followed by the Trial
a. Informing the clients about the method and that it is on trial	None of the sample clients know that the method was on trial. The information which was given to the clients was that: "It is one of the contraceptive methods and it is of 5 years' duration".
b. Informing the clients about the side-effects	Two clients were told that "there will be some disturbances in the menstruation cycle, either it will stop or may be there will be more bleeding. There will be no other problem". Two clients were asked to come "if there is any problem". One client was told that "if you take this needle, there will be no problem, but if you get sick, we will check". One client was asked to take milk, banana and other good food. Four clients were not given any information.
c. Taking consent of the clients after providing all the information	No information was found which will reveal that an informed consent was taken. The clients were not even told of the name of the method. Only one client knew that the method was called "Norplant" and the rest knew that it was a 5 year injection.
d. Pre-medical examination of the client	Urine test and blood pressure checking was done for 2 clients, weight and blood pressure was taken for 8 clients.
e. Medical support to clients having side-effects after taking the method	Six clients reported that when they went to the centre to report about their health problem, the centre gave them prescription on plain white paper and asked them to buy medicine from outside. According to a client, "I have gone to the centre 2-3 times, they gave us slips only and asked me to buy from outside. I asked them, why should I buy medicine from outside when I have taken the needle from here. I want my treatment to be done here. The big doctor told me that the govt. did not give medicine for us. If I talk about my health problems more, they suggest I go for ligation operation". One client was given 30 vitamin tablets, another client got pain killer tablets once.

(Contd on page 108)

Obsession with Socialism

rohit j oza

I AM attempting underneath to answer some of Anant R.S.'s criticism (*RJH* II: 1-2, June-September, 1987) by quoting an article from the December 1987 issue of the Russian magazine *Sputnik*. The journal comments: "Problems posed by health service [in Soviet Union] of late have come in for criticism. The truth is that the health service has been obsessed by the quantity of services [the widely available and almost free medical care referred to by Anant] rather than quality of these services." Anant's reference to "these stupid civilisations [of capitalist countries] spending more on health-care" can be well answered by the *Sputnik* article and I quote "Health service has been dominated by conservatism in economic management, thus creating serious problems". Further, the article says, "the success stories of principles of medical aid as practised in USSR should not be ignored. But what was good yesterday will not necessarily be found satisfactory tomorrow". As for Anant's attempt to locate "the indicator to find out what percentage of medical needs are being met and in what manner", the *Sputnik* article has quoted the USSR Minister of Public Health as saying, "we will dismiss specialists for whom medicine has been a random choice of career and who refuse to treat the job seriously". (And this, Anant, in spite of the Soviet Union's population of 1.2 million doctors—the largest number as compared to any country in the world.)

In the words of Anant: "A rough opinion in a proper direction is better than a precise obsessed opinion in a wrong direction." The "information" needed to "draw valid conclusions" is well provided in the *Sputnik* article: "By 1990 almost a million people will have died of lung cancer in the USSR and most of these smokers". (So much for the healthy

Soviet way of life as compared to the unhealthy American way of life.)

With reference to the "wrong work environment and wrong social environment", Anant should note the following sentences in the *Sputnik* article: "A quarter of water supply is without adequate cleansing"; "from 1965 to 1985 the incidence of lung cancer doubled in Soviet Union"; "forty per cent of sixteen-year olds smoke"; and "medical specialists pay little attention to the propagation of a healthy way of life as a whole".

In the end, I would like to quote five more sentences from the *Sputnik* article to start, if possible, another 'Dialogue':

- (1) "In Soviet Union, it is intended, by ^{to increase} ~~to double~~ the volume of Pay Services available."
- (2) "It is worth considering the question of large enterprises or big organisations paying at least partly for the treatment of their employees (workers)."
- (3) "It would be just to levy a specific tax on smoking. Such additional charge (income) could be used for the treatment of smoking related diseases."
- (4) "The present situation [in the Soviet Union] can no longer be tolerated by the party, the government and the people. Nor indeed by us in the medical profession."
- (5) "The patient should also have a right to choose a doctor whom he trusts?"

The Soviet Union is restructuring all spheres of its economy, culture and life. It is high time Anant also 'restructured' his obsessions. Remember, all that glitters is not gold.

(Contd from page 107)

10 samples but also from the discussion with the centre workers about their methodology. Therefore, it cannot be proved with the number of drop outs that once they realise the problems they are no more interested in it.

The follow-up monitoring is done to note down the problems but with little care of the clients. The problems such as amenorrhoea are found to be frequent, but the tendency of the centre is to justify the problem rather than giving remedies for it.

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