RESEARCH REPORT
NORPLANT, THE FIVE YEAR NEEDLE: AN INVESTIGATION OF THE NORPLANT TRIAL IN BANGLADESH FROM THE USER'S PERSPECTIVE

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Synopsis — Trials of new contraceptive drugs and devices continue to be undertaken by family planning research organisations on poor women in developing countries. They are being carried out as if the drugs being tested were part of the regular family planning programme. Consequently, the subjects of the research do not get adequate information about the real status of the drug and believe they are accepting approved contraceptives. In so doing, the ethics of biomedical research are violated. Not only do the women, serve unknowingly, as guinea pigs in a medical trial, they are also subjected to an unsafe contraceptive as a means of population control. The UBINIG investigation into the Norplant trial in Bangladesh highlights gross violations of ethics, an inadequate research practice and a lack of care for health of the women to whom Norplant was administered.

Synopsis —

গরিব মহিলাদের শরীরে নূতন জন্মনিয়ন্ত্রণ পদ্ধতি ও ওষুধের পরীক্ষা চালানো যেন উন্নয়নশীল দেশের নিয়মিত ব্যাপার হয়ে দাঁড়িয়েছে। এমন ভাবে এই পরীক্ষা চালানো হচ্ছে যেন বা এটা পরিবার পরিকল্পনা কর্মসূচীরই কাজ। ফলে এই গবেষণার যারা লক্ষ্যবস্তু সেই মহিলাদের জানানো হয়না যে, এটা তাদের শরীরে পরীক্ষা করা হচ্ছে। তারা নূতন পদ্ধতি গ্রহণ করেন অনুমোদিত পদ্ধতি ভেবেই। এভাবে বায়ো–মেডিকেল গবেষণার জন্যে আর্ন্তজাতিক নৈতিক নীতিমালা ভয়ানকভাবে লংঘিত হচ্ছে। এদেশের নারীদের শুধু গবেষণার জন্যে গিনিপিগ হিসেবে ব্যবহার করা হচ্ছে তাই নয়, জনসংখ্যা নিয়ন্ত্রণের নামে ক্ষতিকর পদ্ধতিও তাদের শরীরে অহরহ ব্যবহার করা হচ্ছে। উবিনীগের এই গবেষণায় দেখানো হয়েছে বাংলাদেশের নরপ্ল্যান্ট গবেষণায় কিভাবে নৈতিক নীতিমালা লংঘিত হচ্ছে, গবেষণা পদ্ধতিও কিভাবে অসম্পূর্ণ এবং গ্রহীতা মহিলাদের শারীরিক সমস্যার প্রতিও কিভাবে কোন মনোযোগ দেয়া হচ্ছে না।

INTRODUCTION

Norplant is the registered trademark of the Population Council for contraceptive sub-dermal implants. It consists of flexible, non-biodegradable tubes filled with levonorgestrel a synthetic hormone of the progestin family. The implants are family. The implants are placed under the skin on the inside of a woman's upper or lower arm, where the hormone is slowly released at an almost constant rate for several years.

This report was originally written in February 1988 and was updated in May 1989. We thank the women in the villages and slums who have provided us with information despite their bad experiences with people who asked them questions while their health problems remained the same.

We also thank the family planning doctors and workers at the Dhaka Medical College Hospital, the Institute of Post Graduate Medicine and Research Hospital, and the Mohammadpur Fertility Research and Training Centre for providing us with useful information.

Norplant implants come in two types. 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 types and the one that is used in Bangladesh. The other type is called Norplant-2. It consists of two solid Silastic rods, each 44-mm long. A total of 70 mg of levonorgestrel is dispersed in the matrix of each rod (Population Report, 1987, P.K-58). The promoter of the two types is the Population Council, located in New York, working through its International Committee for Contraceptive Research (ICCR). The manufacturer of the drug is the company Leiras Pharmaceutical, Finland.

A BRIEF HISTORY OF THE NORPLANT TRIAL IN BANGLADESH

The history of the Norplant trial in Bangladesh dates back to as early as 1981. Norplant became an item on the national agenda in the 16th Meeting of the National Council for Population Control and Family Planning held on 7 February 1981, at Bangabhavan and presided over by the late President Ziaur Rahman. In this meeting, among other matters, the following decision was made:

> Norplant, a subdermal contraceptive which is easier and *more effective than sterilisation* should be introduced on a trial basis. (Emphasis ours; *GOB Proceedings,* 1981a, p. 000)

From the beginning, Norplant was promoted to the Government of Bangladesh as *more effective than sterilisation.* This despite the fact that, according to Dr. Wayner Bardin, Vice President of the Population Council and Director of its Centre for Biomedical Research, sterilisation fails at a rate of 1 per 1,000 people per year, whereas Norplant implants fail at a rate of 3 per 1,000 (*Economic Times*, 1985).

In accordance with the decision of the 7 February meeting, a steering committee was formed to investigate the introduction of Norplant in Bangladesh by examining its suitability and acceptability. On 22 August 1981, a meeting of the so-called subvention committee of the Population Control and Family Planning Division was held. The committee considered a project proposal by the Bangladesh Fertility Research Programme (BFRP) — the national family planning and biomedical research organisation in Bangladesh — for a "Clinical Study of Norplant Reversible Hormone Implant Contraception." It was approved in principle and a sum of Tk. 743,000 including US$ 20,000 in foreign exchange was recommended for the project to be paid in phases (1US$ equals Tk 30; *GOB Proceedings*, 1981b).

On 4 October 1981, BFRP placed an advertisement in the *Bangladesh Observer* and *Holiday,* a daily and weekly newspaper respectively. The advertisement was in Bengali. The English translation reads as follows:

A new birth control method
NORPLANT
A wonderful innovation
of modern science

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

Get more information from:

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

This advertisement for the mass promotion of Norplant, while its scientific status was still

under investigation, was the first attempt to initiate a Norplant trial in Bangladesh. Immediately after publication of the advertisement, there were protests from people who were aware of the status of the drug with regard to its safety as well as the methods used in trials in other countries. The strikingly unethical aspect of the advertisement, in particular the attempt at mass promotion of the device through advertisement in the public press, was of special concern. One hundred fifty-one concerned doctors, pharmacists, and health workers sent a petition to the Minister for Health and Population Control to stop the trial.

An article by Farida Akhter of UBINIG was published on 25 October 1981, in the weekly *Holiday,* raising a number of issues for public discussion. A brief summary reads as follows (Akhter, 1981): The recent advertisement for the contraceptive by the Bangladesh Fertility Research Programme has raised confusion among the people because it describes Norplant as "a wonderful innovation of modern science" without adding "it is still on trial." According to medical ethics and the Helsinki Declaration of 1964, the volunteer of a new drug should know that it is on trial and that he/she will be compensated for any damage caused by the drug.

Will the users of Norplant ever be told that (1) it is on trial; (2) animal tests of the drug have not yet been completed; (3) it is not approved by the FDA in the USA; and (4) it may cause health hazards to the users?

Reliable sources inform us 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 Noresterat in Bangladesh.

Finally, some comments on the 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 for this claim.

Second, *the method is for use by women*: are women politically less dangerous? (This point was necessary to emphasise by the promoters to make Norplant acceptable to the people and the government because exclusion of man makes the method politically safe.)

Third, *it will be implanted under the skin of the arm*: will this ensure identification for coercion purposes?.

Fourth, *this method will ensure infertility for 5 years*: a safe method for the population controllers—*not* the users!

Fifth, *when removed it will ensure fertility again*: nobody knows.

Above all, the main question is, how much longer will the women of Bangladesh and other poor countries have to serve as guinea pigs for testing drugs that are produced in developed countries? Why do countries like Bangladesh have to solve their population problem by risking the lives of their women?

Following this protest, the trial was postponed. Reliable government sources revealed that the Population Council did not like the prospect of being involved in a controversy. Nevertheless, despite this successful resistance, BFRP brought up the Norplant trial again in 1985. Astonishingly, they remained silent about their first attempt in 1981 — the 1985 document made no mention of that earlier attempt. What is claimed was that they were *now* initiating the clinical trial of Norplant with the financial and technical assistance from the Population Council and Family Health International (BFRP, 1986). In other words, no trace is left of their attempt to begin trials as early as 1981 by means of the unethical advertisement in the mass media that reflected the organisation's lack of concern for medical ethics and social responsibility. What BFRP did-or attempted to do in 1981 — remains a mystery. This silence, it seems to us,

is serious cause for concern: why this silence about the past attempt?

WHAT THE TRIAL WAS ABOUT

In an article by Dr. Halida Hanum Akhter, the present Director of BFRP, it was mentioned that BFRP initiated the trial after obtaining clearance from the Directorate of Drug Administration:

> . . . to assess the acceptability and effectiveness of this new method of contraception 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)

The article explained clearly how the clearance was obtained. The objectives of the trial were also revealed:

1. To assess the acceptability and effectiveness of the new method among Bangladeshi women.
2. To decide about the use of Norplant on a large scale in the family planning programme.

The article did not say anything about the *safety aspects* of the trial. It quoted the WHO Special Technical Review (WHO Bulletin, 1985) of 1985 only with regard to the method's effectiveness and the supposed superiority of Norplant over other methods, but did to repeat the points about safety measures *(WHO Bulletin,* 1985).

An effective method can indeed ensure birth control, but it does not necessarily mean that it is safe for its users. Nor does it mean that it is advisable as a contraceptive at all. It is quite clear that the objective of the proposed BFRP research protocol for the trial was *not* to look into the *safety aspects* of Norplant. The objective of the research was to create the conditions for the *mass promotion* of Norplant within the family planning programme of Bangladesh. Interestingly, this is also the explicit objective of the Population Council. What it means in reality is that research about the safety aspects of Norplant has been systematically bypassed and the *research* that is conducted is essentially an exercise to ensure its mass promotion.

NORPLANT AND THE STATE POLICY OF BANGLADESH

It is interesting to note that even before BFRP undertook the trial in February 1985, the Third Five-Year Plan (TFYP) of the government of Bangladesh had incorporated the use of Norplant. The TFYP said:

> 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 a trial basis, and the programme for its wider use can be decided according to the experience of the trial. (Emphasis ours; TFYP, 1985)

Here the safety question is conspicuously absent from the considerations of the government. The class bias and the eugenic premises of the government policy are also clear in its emphasis on the suitability of the method for the *semi-literate* population: unwanted people whose numbers need to be limited. The targeting of a particular unwanted section of the population does not seem to require any considerations about safety.

FALSE PROPAGANDA FOR NORPLANT

BFRP had started promoting Norplant even before the trial was completed. After the trial had begun in 1985, BFRP began making the

following claim in 1986 in its BFRP Bulletin *News & Views*: "The Norplant contraceptive system is suitable for most women of reproductive age."

This claim is obviously false as Norplant is a contraceptive agent which remains under scientific investigation. In fact, because of the known *and* the unknown health hazards of administering long-acting hormonal implants, scientists and women's groups all over the world, as well as concerned individuals, resist even trial of this contraceptive (see Breijer, 1986). When a clinical trial was attempted secretly in Brazil, the experimentation was stopped upon its discovery which became a public scandal (see Gomez dos Reis, 1990).

The falsity of this claim lies not only in the incomplete scientific evidence or noncompliance with the ethical norms of scientific research (because such claims can be made only *after* the research is completed), but also because the suitability of Norplant or any other contraceptive method can be decided only in the context of the economic, social, and cultural situation of the women who use it. But this is an area which always was — and continues to be — consistently and systematically disregarded by the promoters of modern contraceptives.

SCIENTIFIC FACTS ABOUT NORPLANT

Much remains to be determined about the scientific status of Norplant because it continues to be an experimental contraceptive. We will discuss some of the scientific facts by presenting a critique of the "Facts About an Implant-able Contraceptive," published 1985 in the *Bulletin of the World Health Organisation.* This is a memorandum issued on the occasion of a meeting convened by the World Health Organisation in October 1984 in Geneva, which, in essence, was a consultation with the Population Council, Leiras Pharmaceutical and scientists engaged in population control research and aimed at justifying the promotion of Norplant through family planning programmes. The WHO memorandum discusses the results of research undertaken in animals and human subjects on Norplant. However, the conclusions it draws are not consistent with the scientific documents it reviews. A critique is, therefore, necessary to demonstrate this inconsistency. Many of the points in our critique have already been raised earlier by others (Breijer, 1986).

Insufficient animal experimentation

1. In the review, levonorgestrel and the half as active D,L-norgestrel isomer are used interchangeably. But only the investigations referring to levonorgestrel 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.
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 drugs between different species (see Table 1).
3. The memorandum states clearly that, "the beagle dog is an unsuitable toxicologic model for the study of progestogens" (p. 486). Nevertheless, experiments with this animal continue to be quoted to prove that there are "no adverse effects relevant to human use" (p.486) because they have not been noticed in beagles. This is an example of conscious mystification of inadequate and irrelevant animal data.
4. In the majority of experiments, D,L-levonorgestrel was given to the animal by the oral route. The comparison with implanted doses is misleading because there is a difference in bioavailability.
5. In order to mystify the facts and to mislead the judgement on the status of animal experimentation with Norplant, data from

6. experiments are included which were carried out for approval of levonorgestrel as an *oral contraceptive*!.
7. Impervious or semipermeable subcutaneous implants induce local sarcomas in rats. Therefore, the rat is a poor model for the testing of implants. It is nevertheless used in animal experimentation.

Insufficient clinical research

1. The memorandum admits that "studies on lipid metabolism have given inconsistent results" (p. 489). The experiments carried out up to date are contradictory. Because fat metabolism is associated with the development of cardiac problems, the information in this regard is insufficient to determine
   the *safety* of levonorgestrel implants.
2. The relationship between Norplant used and an abnormal glucose tolerance test was only examined in nine women. Two of them tested positive. It was claimed, however, that the two women had a history of family diabetes. Although the memorandum admits that "the data are limited" (p. 489), it still claims that "Norplant *appears* to have no deleterious effect on carbohydrate metabolism" (p. 489) (emphasis ours). Note the mystification of the fact by the word *appears.*
3. There are no studies about the long-term safety of the product and in fact, the memorandum says this clearly: ". . . because the method is only now becoming widely available, there have, as yet, been no epidemiological studies of long-term safety" (p. 489).
4. The study of the effect of Norplant on blood coagulation is still very inadequate. Only one study has been cited (Shaaban, 1984, p. 489).
5. The use of Norplant during lactation and its effect on the growth and development of the child is still unknown.
6. The effect of Norplant on the levels of testosterone and androstenedione is unclear. The experiments carried out to date are contradictory.
7. The effect of Norplant on systolic and diastolic blood pressure in the fourth and fifth year of use is not known because, according to the memorandum, "no data are available for a longer duration of use" (p. 490).

Danger of method failure: Effect of Norplant on pregnant women

The WHO Memorandum states that a total of 11 pregnancies have been reported as method failure. Of these, two were ectopic pregnancies. In other words, Norplant users might have to face the danger of an ectopic pregnancy if the method fails. Indeed the memorandum states clearly: "should a pregnancy occur in a woman using Norplant, attention must be paid to the possibility of an ectopic pregnancy" (p. 489). It is obvious that data on the effect of Norplant on pregnancy are inadequate and incomplete. The actual danger of the method as well as the percentage of women who will be exposed to ectopic pregnancies may be much higher.

Table 1. Bioavilablity and terminal half-life of the drug between species (from Breijer 1986

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
Homo sapiens (women)	100	26.4–72.0

Inadequacy of investigations

1. In general, investigations were carried out on young, healthy, nonsmoking women. *Healthy,* in the memorandum, is defined as: without cardiovascular disease, without diabetes (also preferably not in the family), not overweight, without liver disease. Women who had previously used injectable contraceptives were also eliminated from some experimental series. Clearly, this is not a good cross-section of the population. The data are therefore inadequate to determine the safety of the method to be used in a family planning programme where acceptors are not going to be only young, healthy, and nonsmoking women.
2. The results are compared mainly with the data from women who use oral contraceptives, instead of a comparison with women who use *no* hormonal contraception. This plays down the negative aspects of the method. Consequently, the scientific status of Norplant has remained by and large indeterminate. Such comparisons are poor science.
3. It is surprising that some *known* side effects were not included in the WHO memorandum. In a study under review it was found that by the end of the fourth year, 13 out of 100 women had the Norplant implants removed for adverse effects categorised as "other medical reasons" (Sivin *et al.,* 1983). More implants were removed as a result of "other medical reasons" than because of menstrual problems (6.5%), despite the fact that menstrual problems occur more frequently. Some of these side effects are: depression (1 %), more than 10 kg weight loss (2% in Thailand), and epilepsy.
4. The continuation rate is clearly inconsistent with the claim of high use-effectiveness of Norplant. A clinical trial is cited where after four years of use only 49 women out of 100 have continued the method (WHO Bulletin, 1985, p. 489). This means more than half of the Norplant acceptors do not continue with it. It also shows the unsatisfactory acceptance of the method by the women and therefore demonstrates its unsuitability in family planning programmes.

SOME IMPORTANT INFORMATION ON NORPLANT

The Population Report from Johns Hopkins University (Series K Number 3, March–April 1987) made several recommendations for the use of Norplant, in particular specifying some of the advantages and disadvantages of the method.

The insertion and removal of the Norplant capsules requires sophisticated equipment and in addition, careful and trained health personnel. It is, therefore, important to quote the Population Report on the question of insertion and removal in order to evaluate the situation in a country like Bangladesh where there are problems with effective management.

According to the Population Report (1987, p. K-62): Implants are inserted on the inside of the upper or lower arm 6 to 8 cm above or below the elbow. Inserted through a single incision, the six Norplant capsules form a fan shape, with its base toward the incision. Special care must be taken during insertion to place the implants just under the skin. If the implants are inserted too deeply, locating and removing them can be difficult. Maintaining sterile techniques throughout the procedure is essential to prevent infection.

Removing the implants is usually more difficult than inserting them. Problems can occur if the insertion was done improperly — that is, if the implant was placed too deep in the tissue — or when fibrous tissue has grown around the implants, as often happens. Practitioners should work gently, carefully and patiently to avoid injuring the skin of the arm

The report also suggests that it may be difficult — and painful — to remove the capsules. It says (1987, p. K-62):

> If an implant cannot be removed, the woman should return to the clinic in about two to four weeks. Removing the remaining implants is easier when the arm has healed.

The report lists advantages and disadvantages of Norplant in the following manner (1987, p. K-60):

ADVANTAGES AND DISADVANTAGES OF NORPLANT

Advantages

1. Norplant is highly effective.
2. Once in place, the implants require no further action until removal.
3. The six-capsule system provides continuous protection for 5 years.
4. The implants have no estrogen side effects.
5. The contraceptive effect of the implants ends soon after they are removed.
6. The implants release progestin at a fairly constant, low rate, avoiding the high initial dose typical of injectables and the daily surge of hormones with oral contraceptives.
7. Norplant may help to prevent anemia.

Disadvantages

1. Norplant must be inserted and removed by health professionals.
2. Health workers need special training and practice to insert and remove implants.
3. Norplant implants are initially more expensive than oral contraceptives and other short-term methods.
4. Norplant often changes bleeding patterns.
5. Women cannot discontinue use on their own.
6. Some women may be reluctant to use an unfamiliar method.
7. Implants may be visible.

UBINIG'S INVESTIGATION OF THE NORPLANT TRIAL

In line with the ongoing work of our research group to critically assess population control measures, in particular, contraceptive methods, we were very alarmed by BFRP's first attempt to introduce Norplant on a mass-scale in 1981. However, as described earlier in this report, despite successful community resistance to the Norplant trial in 1981, BFRP initiated a second round of research on Norplant in 1985. This was done in a very secretive fashion. UBINIG only heard of the new trial by chance from a development worker working with the women in slum areas of Dhaka City, who wrote a brief account of her experience with the trial (our translation):

> One of the group members (Jahanara) had four children. She became pregnant again and was worried. She went to several family planning centres for an abortion (Menstrual Regulation), but was refused. Finally she sought my help.
>
> On 15 December 1985,1 took her to the Mohammadpur Fertility Clinic for Menstrual Regulation (MR) services. First we were told that an abortion could not be performed because she was already 11 weeks pregnant. But then they said that MR can be done, but only if she undergoes a ligation operation at the same time. Jahanara did not want to have a ligation. So the centre refused her MR.
>
> I then took her to Dhaka Medical College and we met with a counsellor. Jahanara told the counsellor that she would like to have an IUD (plastic coil) inserted after the MR. The counsellor said, "Why not have a ligation?" Jahanara said she would not be able to take a rest for at least 3 days after the operation. She has to work. So she did not agree to have a ligation.

Then the counsellor told her about an injection she might consider. I remembered the side-effects about injectables so I said, "Injections have possible side-effects." The counsellor answered, "You are talking about the injectables with 2 to 3 months' duration. But this is another injectable one that is of 5 years' duration. It does not have any side-effects."

I was confused, because I had 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, without reading out the text to Jahanara asked her to put her fingerprint on the paper. But I could read what was written in it. It said:

> I am completely aware of the method of menstrual regulation. I know about the problems such as infection, bleeding and perforation of the uterus and yet I have requested MR.

Jahanara put her fingerprint on the paper without knowing what was written on it. Then we went downstairs. Several clients were waiting, while two motivators were obviously trying to motivate them for something. A doctor came out of the room and asked, "Have you found a client?" The motivators said, "No." The doctor said, 'Try to motivate them."

I asked the motivators about the 5-year injectable. They said that it was called Norplant. They informed me that it was administered in the Institute of Postgraduate Medicine and Research Hospital (also called the PG Hospital); Dhaka Medical College; 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 the MR. I told her not to take Norplant. Then I went to the doctor and said we would come back later. In this way Jahanara was saved from Norplant. (Lina, 1987)

Alarmed by this account that indicated that a new round of Norplant trials had begun, we immediately started our own investigation. On 24 December 1985, an UBINIG research team went to the PG Hospital and found that most of the clients for family planning were being motivated to accept Norplant. One *Ay a* (the female attendants at the clinic) thought that the members of the UBINIG team were clients. She suggested that if they take Norplant, they will be given Tk. 30.00 (Tk. 30.00 equals US $1.00) and some medicine during the first visit. We also collected a leaflet which was distributed to the clients. Originally in Bengali, it said:

Facts About Norplant:

1. Norplant is a new temporary family planning method. It is effective for 5 years.
2. Its use is relatively easier [than other contraceptives].
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% effective, as sterilization is.
6. The user can take out the Norplant whenever she wants.
7. After taking out Norplant, fertility returns after 1 year.
8. It is possible to carry out normal movements and work when it is in the body.
9. There is no need to use any other method with Norplant.
10. The doctor will examine the client before the method is given.

To know more about Norplant, contact the doctors at the PG Hospital.

If we evaluate the points mentioned in the leaflet, we find that they provide false information. They thus constitute an example of violation of medical ethics. Two examples substantiate our claim:

1. The claim of effectiveness is incorrect. According to a BFRP newsletter (1986), the rate of accidental pregnancies during the first year was 0.4 pregnancies per 1000 users. The previously quoted WHO memorandum indicates a gross cumulative pregnancy rate after 5 years of 2.6 per 100 women. The annual pregnancy rates during the first 5 years ranged from 0.2 to 1.3 *(WHO Bulletin,* 1985, p. 490).
2. The use of Norplant is not relatively easier than other contraceptives because a surgical procedure is needed to insert the capsules under the skin. The Population Report previously mentioned and the World Health Organisation Memorandum recommend that to minimize the risk of infection, both insertion and removal should be performed in a clinical setting. They also say that it is of utmost importance that sterile techniques be maintained throughout both procedures.

After our visit to the PG Hospital, we tried to collect more information on the new trial, without much success because of the non-cooperation of the research organisations. In November 1986, a conference was organised by BFRP on "Contraceptive Technology Update." Among other issues, the research on Norplant was discussed. A preliminary report was presented by Prof. (Retdj S. Firoza Begum. According to her report, 600 clients were admitted into the study from February 1985 to April 1986, but in the period of January to April 1986 only 187, that is 31 % of the originally admitted women continued on Norplant (Begum, 1986).

With regard to the *removal* of Norplant Dr. Begum listed a number of reasons, outlined in Table 2. It must be pointed out that in this study 30% of the removals happened for medical reasons: an interesting comparison with the approximately 11% cited by Sivin *et al.* (1983, p. 89).

From the users' point of view of satisfaction, Prof. Begum said that 40% liked Norplant because it lasts for 5 years, while 30.7% liked it for its ease of use. About 56% disliked it because of its effects on their menstrual pattern. Eighty-two percent said that they had received *enough* information about the method, while 17.8% said that they had not.

It is interesting to speculate what *enough* information really means. The above mentioned leaflet is not just inaccurate — if it is the only source of information provided it could not have reached all the potential users in the community because many of the women cannot read.

Table 2. (from Begum, 1986)

Reasons for removal	No. (N = 32)	%
Pregnancy related		
Luteals phase[a]	2	6.2
Planned pregnancy	1	3.1
Change in menstrual pattern		
Amenorrhoea	4	12.5
Polymenorrhoea	6	18.8
Menorrhagia	2	6.2
Irregular bleeding/spotting	5	15.6
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
Personal reasons		
Husband went abroad	2	6.2

[a]In these two cases women were pregnant at the time of admission.

Because the Norplant study which began in 1985 had been conducted silently — if not secretly — we received no cooperation from the medical centres who took part in the trial when we asked to speak to women who had the Norplant capsules implanted. Consequently, it was a rather difficult task to

locate such women. From our visits to the clinics at which the Norplant study was conducted, we knew that the new method was being used experimentally upon poor women living in the urban slums. Accordingly, we began our investigation by looking for women who were on Depo-Provera in Tikkapara, a slum area of Mohammadpur and in Basila, a semi-urban village where Depo-Provera has been used widely. By identifying women who had accepted the injectable Depo-Provera in Tikkapara, it was easy to locate Norplant users, because to the poor women of the slum Norplant is also an injection. It was in Basila that we first discovered one "injectable" client with Norplant. The woman told us that she had taken a "5-year needle." Then she showed us the arm where she had the capsules implanted. Gradually we found more women in the same village who were on the 5-year needle.

We interviewed 10 women who were on Norplant and also visited the three centres where it was administered. Our findings are stated below.

Information from the centres where Norplant is administered

The UBINIG research team visited three centres in order to get information about the Norplant trial: (a) Mohammadpur Fertility Services and Training Centre, commonly known as Mohammadpur Model Clinic or the Mohammadpur Fertility Centre; (b) Dhaka Medical College Hospital (DMCH); Institute of Post Graduate Medicine and Research Hospital Dhaka; (c) (IPGMR, also known as PG Hospital). We learned that about 616 women were given Norplant in the three centres. IPGMR had 216 clients, while the other two centres had 200 clients each.

According to the Mohammadpur Model Clinic, the age range of the clients was between 18 and 40 years. Norplant was administered within 1 to 7 days of the onset of the menstrual period. New mothers who were not breastfeeding their babies were also given the 5-year needle. The clinic claimed that the medical check-up before implantation of the capsules was very thorough so that no users of Norplant would have jaundice, hypertension, or diabetes. Should the client fall sick after the use of Norplant, the capsules would be removed and she would be admitted to the hospital.

We were told that check-ups took place after 1, 3, and 6 months of the insertion. The women on Norplant were mostly from Dhaka, although a few went to other cities after the insertion. Interestingly, our research team was told that the Mohammadpur Model Clinic had stopped inserting Norplant. No reason for this decision was given.

In the Dhaka Medical College, the criteria for Norplant recipients in terms of age was the same as at the othe two centres, between 18 and 40 years. Gynecological specialist Dr. Kohinoor also told us that women should use Norplant after the birth of their first child. However, 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 the breast-milk and might cause harm to the baby." No insertion was made without complete medical checkups, she claimed. Women who suffer from hypertension should not be given Norplant, nor those with jaundice and diabetes.

In response to our question, how they would find their clients Dr. Kohinoor said:

> When women come here for contraception we give them a leaflet where the good and bad effects of Norplant are described. But they must also get the consent of their husband.

We have already discussed the leaflet she mentioned. It is worth pointing out that it does not list "bad effects" of Norplant.

When we asked her about follow-up care, Dr. Kohinoor pointed out that each and every

client had a card. If the women did not turn up for scheduled appointments, the clinic workers would go and visit them at their homes.

Asked about side-effects, Dr. Kohinoor said the following:

> The most common is amenorrhoea. However, this is not a serious side-effect. Health-wise it is better to have amenorrhoea because it saves the blood which would be lost with menstruation every month. Therefore there is less chance of developing anaemia. Norplant is better for the women's health than having monthly periods. You know these women are already suffering from malnutrition . . . 95 % of our clients belong to the very poor class. They are responsible for giving birth four to five times. Since they cannot remember to take birth control pills every day, long-acting contraceptives are much better for them. On the other hand, women in the upper class are intelligent and can use any other method.

She concluded by saying:

> In order to have a good thing there is always a price to pay. If two or three women die — what's the problem? The population will be reduced . . . 70% of our research has been successful. Every birth control method has a good and a bad side. This one has also.
>
> The doctor we interviewed in the IP-GMR hospital had joined only recently, so she could not provide much information about their practices regarding Norplant. We did find out, however, that another 14 clients would be given Norplant within 1 month of our interview (January 1988).
>
> All of the three centres referred us to BFRP as the research organisation, but the Bangladesh Fertility Research Programme refused to give us information on the grounds that we will "misinterpret it."

Information from the women who use Norplant

We were able to locate 10 women on Norplant in the village of Basila, situated in the outskirts of Dhaka City. The socioeconomic conditions and other relevant information of the Norplant users are discussed below.

Economic conditions. The information obtained about the occupations of the husbands of the women who used Norplant and direct observation of their household conditions led us to conclude that their economic status is poor (6) and lower middle class (4). The husbands of those who were classified as poor were working as boatmen, fish sellers, day labourers, or engaged in small business. Their average daily income was Tk. 40.00 to Tk. 50.00 (the equivalent to US $1.50). They have no land and essentially depend on selling their labour to earn their livelihood. The lower middle class families were mainly engaged in small business, such as the selling of rice and groceries and the purchasing and selling of brick.

Education. Eight out of the ten Norplant users did not know how to read and write. Among the literate, one had a primary level of education, and another had reached the secondary level.

Age. The following information helped our investigators to figure out more or less accurately how old the Norplant users were. We asked each woman about her age, her age at marriage, her menstrual situation at the time of her marriage, the age of her first child.

We found that two women were between 15 and 20, three between 26 and 30, one was in the age range of 31 to 34 years, and four users were over 35 years of age. The oldest woman was 45, while the youngest was 16.

In the three centres where Norplant is promoted, we were told that the Norplant users were between 18 to 40 years and that this was

established by asking the women about their age. Already in our small sample of 10, we found that one woman under 18 and one over 40 years had been administered the implant.

It is interesting to note that the preliminary report of the Norplant trial submitted by Prof. Begum in 1986 does not mention the age of the 600 users (nor did a draft protocol of the Norplant study we obtained despite the fact that BFRP did not send it to us). It seems to us that the age of the women using Norplant should be of concern to the promoters of this long-acting contraceptive.

Marriage and childbirth information. Duration of marriage: Six women had been married for as long as 20 to 30 years, while two others had been married for 10 to 20 years. Two young women were married in 1981. Most of the users (8) had been married for between 13 and 16 years; the remaining two married at the age of 18 years.

Number of live children and children ever born: The average number of children for all 10 users was 4.3. The maximum number per woman is eight, the minimum one child. The number of children born was higher than the number of living children (average 4.7, maximum 9).

Age at birth of the first child: Three women gave birth before they were 15, while seven had children between 16 and 20 years of age.

Time between marriage and the first child: Five women gave birth after 1 year of marriage, four had their first child between 2 and 3 years after getting married, and one was married for 5 years before she had a child.

Average time between childbirths: The average time between childbirths was 2.1 years; 4 years was the maximum time between children.

Information on contraceptive acceptance. Norplant was the first contraceptive for three women, while the other seven had previously used the pill and/or Depro-Provera. But our study also revealed that one of the first-time users of Norplant had removed Norplant and was using no other contraception. One of the women who had been on Depo-Provera previously managed to remove Norplant after side-effects and began taking the pill. A third woman who had used other methods before also could not tolerate Norplant and had it removed. *In sum, we found that out of 10 women, 3 had stopped using Norplant already.*

Lactation and pregnancy at the time of accepting Norplant: Information about lactation and pregnancy is vital before a contraceptive like Norplant is implanted. As stated earlier, it appears that Norplant should not be given to a woman in either category.

None of the women in our study had been pregnant at the time of accepting Norplant. However, we found that *6 out of the 10 women in our sample were breastfeeding.* Out of these six, one woman's child was less than 1-year-old and another had a baby that was only l½-months-old. Four women were breastfeeding although their children were older than 1 year (in Bangladesh, the average duration of breastfeeding is about 18 months). This finding is very alarming when compared with Dr. Kohinoor's statement that Norplant should not be administered to breastfeeding women, "as it might cause harm to the baby." In our view, it is a further indication of the violation of medical ethics which characterises the Norplant trial in Bangladesh.

Health condition before the use of Norplant: When we asked questions about whether the women had any specific health problems before the use of Norplant, we got the following responses: no problem, 8; amenorrhoea, 1; and irregular menstruation, 1. That is, women with amenorrhoea and irregular menstruation were also given Norplant, which, as we noted when checking their current health condition aggravated their problem even further. We could not, however, get information on health conditions for which

Norplant is contraindicated, such as jaundice and diabetes.

Current health conditions of the Norplant users: We checked the weight, height, blood pressure, pulse rate, and anaemic condition of the Norplant users to establish a minimum indication of their health conditions.

Height:	Average 4 ft. 11 in.	
	Maximum 5 ft.l in.	
	Minimum 4 ft. 9 in.	
Weight:	Average 42.4 kg	
	Maximum 48.0 kg	
	Minimum 38.0 kg	
Blood pressure:	90/60	
Pulse rate:	65–80 per minute	5
	more the 80 per minute	5
Anaemia:	None	2
	Mild	2
	Moderate	4
	Severe	2

Health conditions since the use of Norplant: All 10 Norplant users had faced health problems since they had been on Norplant. As they put it: "I had no menstruation in the last 1 to 1½ years"; "Once menstruation starts it continues for 15 to 20 days"; "Lots of irregular bleeding and spotting."

Other problems include: loss of appetite, vertigo, burning sensations in hands and feet, general body aches and weakness, leukorrhoea. When arranging the health complaints in terms of their frequency of reporting, the following pattern emerges:

1. Amenorrhoea	10
2. Irregular menstruation	4
3. Burning sensation in hands/feet	3
4. Excessive bleeding	2
5. White discharge	2
6. Body aches	2
7. Tiredness	1

In sum, *all* the clients were suffering from amenorrhoea for different periods of time and most of them developed irregular or excessive bleeding in between. Amenorrhoea is defined as a long period without menstruation, that is more than 45 days. According to some women they had no menstruation for 1 year or more.

Other examples of users' complaints included:

> Six months after I had taken the six needles, I felt aches in my body. Now I cannot look up, I do not have any appetite, I am going to die. My period is very irregular, and during last Shabe-Barat [an Islamic religious occasion], I menstruated for 2 months without stopping.
>
> —Anwara Khatun (30 years)

> I did not get a period for 2 years since I have taken this 5-year needle. Now I have aches in my hands and legs. I feel weak, I cannot begin to explain how I feel; it is a terrible feeling.
>
> —Fulbanu (35 years)

> Since I have taken the needle, my period continues for 12 to 13 days. When I took the 3-month needle [meaning Depo-Provera], I had a regular menstruation but now I have too much bleeding: clots of bloods coming out at the time of menstruation. I feel pain in my 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 having the capsules removed and finally succeeded in convincing: their clinic to remove them. Other women told us that when they went to the clinic that had implanted the capsules and complained about health problems the only treatment they revived were 30 vitamin tablets and in some cases a prescription to buy medicine elsewhere. Most of the women went to see another doctor. Two went to a qualified

allopath doctor, three to traditional healers, called *kabiraj*[1] and one to a *quack*[2] allopath doctor. Four women did not go to any doctor because ;hey did not have the money.

How did the women find out about Norolant? The women who used Norplant told us [hat they had first heard of contraceptive injectables such as Depo-Provera and Noristerate. These injectables are generally known to women as injection of needles, and they hardly know the differences between the different lands of injectables. From the family-planning workers the women knew that this injection had to be taken at a 3-month interval. (In this area Depo-Provera was used more frequently than Noristerate, which is a 2-month iose.) Later, they informed us, their neighbours told them about a needle[3] for 5 years. They heard that it was better than the 3-month injection. Also, given the known side effects and sufferings with the injection — that is, Depo-Provera — they thought it would be better for them to take the 5-year needle. Also, as it was difficult to go to any of the centres who administered the injection from their village, a method that lasted for 5 years seemed a preferable solution. One woman told us that every woman who goes to take Norplant is asked by the centre to talk about its benefits to her neighbours, so that they too would go and have the new type of needle. Alarmingly, none of the women or Norplant was told that this method was used on a trial basis and that, in effect, they were the guinea pigs of medical research. The only information they were given was that Norplant was a "needle of 5 years."

An examination of the rules supposed to be adhered to in a medical trial: The organisations who were carrying out the trial maintain that they follow certain ethical rules in the trial based on an internationally agreed upon code for biomedical research. We will examine some of these rules and compare them with our findings about the Norplant trial.

Rule: Acceptors of a method under investigation should be informed that it is on trial and that they are the subjects of biomedical research.

Finding: None of the women in our study knew that Norplant was still on trial. The only information given to them was that "it is one of the contraceptive methods and it lasts for 5 years."

Rule: Research subjects must be thoroughly informed about known and possible side effects.

Finding: Of our sample of 10, 2 women were told that "there will be some disturbances in the menstrual cycle; it will either stop or there may be more bleeding." They were also told, 'There will be no other problem." Two other women were told to come back to the centre "if there is any problem." One client was told that "if you take this needle, there will be no problem, but if you do get sick, we will do a check-up." One other woman was asked to drink milk and eat bananas and other good food. Four women were not given any information.

Rule: After providing all information pertinent to the research project, consent from the research subjects must be obtained.

Finding: We could not find information that showed any sign of seeking informed consent from the women who were about to have the Norplant capsules implanted. They were not even told what this new method was called. Only one client had heard the name Norplant, the rest only knew that it was a 5-Year Needle.

Rule: *A* medical examination and screening of the research subjects should be conducted before they enter the trial.

Finding: Two women had an urine test and their blood pressure checked. Weight and blood pressure was taken in eight cases.

Rule: Medical support should be given to research subjects once they are part of the trial.

Finding: One Norplant user was given 30 vitamin tablets, another woman received pain killers. Six women told us that when they went to the centre who had administered the injection to report their health problems, they were given a prescription on plain white paper and asked to go and buy medicine outside. As one of them remembered:

> I went to the centre two or three time and they gave me a slip and told me to buy medicine elsewhere. I asked them why should I buy medicine outside the centre when they had given me the needle? I wanted my treatment done in the centre. The big doctor told me that the government did not supply medicine for us. Also, if I talked more about my health problems, they suggested I go for a ligation operation.

The above findings show that there was no sign of following the code of medical ethics required — and supposedly adhered to by the Norplant dispensers in Bangladesh — for a drug/procedure on trial. Instead, Norplant was administered as if it were an established contraceptive method, such as Depo-Provera or the IUD. The women who took Norplant did not give informed consent. Nor did they receive proper care for their health problems arising from the use of the needle. The centres were selectively doing urine tests for some clients and not for others. We assume they wanted to exclude women who did not appear at the centre within one to seven days of the end of their menstrual period. Put differently, they wanted to be sure to exclude pregnant women.

Similarities and discrepancies in the information given out by the centres and the information received by the norplant users:

Centre: A leaflet with the positive and negative sides of Norplant is read out to the clients. After this, when they decide to take Norplant, the capsules are implanted.

Clients: No client reported receiving this information.

Centre: Before implantation, the necessary medical tests are done. They include checking for hypertension, jaundice, asthma, etc.

Clients: The women in our study reported only weight checks, some urine tests, blood pressure checks, and some very few pelvic exams.

Centre: The clients must have at least one child at the time of taking Norplant.

Clients: All 10 women reported that they were asked about the number of children they had.

Centre: Clients must get the consent of their husbands before taking Norplant.

Clients: Six women had the consent but four did not.

Centre: Norplant is given within one to seven days of the onset of menstruation.

Clients: This same time period is reported.

Centre: Norplant is given to women between 18 to 40 years of age.

Clients: One woman was 16 years old and one client was 45 years of age. The rest were within the 18- to 40-year range.

Centre: Those women who previously were on the contraceptive pill must wait 6 months before they take Norplant.

Clients: Two women were taking the pill before going on Norplant. One of them started on Norplant only 2 months after stopping the contraceptive pill.

Centre: Women with postpartum amenorrhea are not given Norplant.

Clients: All the 10 women in our study received Norplant during their normal menstrual cycle.

Centre: Women who are breastfeeding should not be given the method.

Clients: **Six out of ten users were breastfeeding at the time of taking Norplant.**

Centre: The follow-up procedure is as follows: First follow-up after 1 month of the insertion, second and third follow-up after 3 months of the insertion. Fourth follow-up 6 months after insertion. The dates of follow-up visits are written on the patient card. If the women do not come to the centre then the workers visit them.

Clients: The clients reported that they were asked to go to the centre every 2 to 3 months after the insertion. They knew that the date was written on their card, but none had ever seen any worker coming to their houses for follow-up care.

Centre: Norplant is removed as soon as any side-effects are noticed.

Clients: Seven women had side-effects but the capsules were not removed. Three women had Norplant removed. But their experience was that the centre did not want to take the capsules out even though they went there two or three times and asked for its removal. Only when they insisted further, were the capsules removed. In the words of one client:

> When I had problems and could not bear it any longer, I went to the centre, but they refused to take it out. They said, "Why did you take it?" The next time I went in I told a lie and said that my two children had drowned in the river and my husband wanted another child. This time they took it out.

Again, the evidence suggests that the rules for a medical trial are followed incompletely although the workers were found to adhere to some of them. Specific violations happened in the area of informed consent, in the selection of clients and in the follow-up care.

We also received contrary information on monetary incentives for follow-up care. The doctor from IPGMR Hospital told us that they give Tk. 20.00 to each client for motivating the women to return to the centre for follow-up monitoring. They also said that the clients were given Tk. 50.00 at the time of the first insertion of Norplant. However, while the centres told us that they tried to motivate their clients to return for follow-up visits, the women themselves reported the contrary and said that they had been discouraged from reporting health problems. According to them, the family planning workers at the centre were friendly before the insertion of the capsules, but afterwards they do not even want to talk. They do not appreciate the clients' health problems at all and they also do not want to remove the capsules. Because the removal has to be done in a clinic, the women cannot remove Norplant by themselves and they feel helpless but cannot do anything else except go back to the centre and plead for removal of the capsules. It is then up to the workers whether they will take it out or not. This is an inhuman and undignified situation for the women who are suffering from the adverse effects from Norplant.

The women were further discouraged from going to the centre for follow-up care because they were not given any treatment. As mentioned earlier, they were only given a slip, that is a prescription. The centre workers said they had no medicine for the treatment of side-effects.

An analysis of a client's card: The following is our analysis of a card given to a Norplant user at the Mohammadpur Fertility Services and Training Centre. Laila gave her card to the UBINIG research team because she had stopped Norplant.

According to the card, Laila received Norplant on 16 November 1985. There is no information about her age. This raises the question of how the centre ensures that only women between 18 to 40 years of age are

given Norplant. There is also no information about the number of her children.

The dates for the follow-up visits show that Laila visited the centre on 16.12.85, 16.2.86, 16.5.86, 16.11.86, 16.5.87, and 13.6.87. It is rather surprising to see that these visits seem to have been made on the *precise* days when the check-ups were due, especially because, as we know, it was entirely up to the women to visit the centre without any previous reminder.

With regard to side-effects, it was noted on Laila's card that from the beginning she complained about amenorrhoea. Her weight and blood pressure was also recorded every time. On the day of her last visit a note was made that said, "patient wants baby . . . nothing significant."

SECRECY OF THE NORPLANT TRIAL

On 25 January 1988, UBINIG wrote a letter to the Director of BFRP requesting a copy of the interim report on the study of Norplant. BFRP replied on 27 January 1988 (our translation):

> We are continuing to conduct our research with Norplant after obtaining the necessary permission from the Health and Family Planning Ministry, External Resource Division and the Bangladesh Medical Research Council. Before we deliver any information to you we would like to know whether you have obtained the necessary permission from the relevant authorities to start your research on Norplant. Moreover, according to the conditions of the research we are promise-bound to keep the information on the Norplant acceptors secret. Therefore we can not give you any information on the acceptors right at this moment.

Our answer to BFRP of 3 February 1988, read as follows:

> The information that in order to conduct your research with Norplant you have obtained the necessary permission from the Health and Family Planning Ministry, External Resource Division and the Bangladesh Medical Research Council was already known to us through your article in *The New Nation* of January 25, 1987. We thank you for giving us this information again. However we are alarmed by the fact that no permission in a proper manner has been obtained from the poor women whose bodies are being used for the testing of Norplant. We are concerned about the life of human beings. We would like to know whether any damage is being caused to them. If so, our purpose is to inform the relevant authorities about it so that the necessary actions for the prevention of such damage can be undertaken. . . . We have been conducting our research on Norplant with the permission from the acceptors themselves. We wanted to know under what conditions they have accepted this method and whether they were aware that they were actually being used as the subjects of a biomedical research trial. Most importantly, we wanted to know if they were experiencing discomfort after the implantation of Norplant. In addition to collecting information from the Norplant acceptors we contacted the centres where the method is administered and collected necessary information from them as well. Since BFRP is the main research organisation concerned with these issues in Bangladesh, we requested you to share your information with us. What we intended to do was to present the information we received from you alongside the information we received from the Norplant acceptors. We have nothing more to say if you have a problem in sharing information on your Norplant research with us. If you are interested in receiving a copy of our report we will of course send you one.

BFRP never answered our letter.

DISCUSSION AND CONCLUSIONS

As we mentioned earlier, studying the safety aspects of Norplant in the light of its impact on the users' health was never the objective of the trial in Bangladesh. Moreover, even if the aim of the trial was to achieve acceptability and effectiveness, the way the research was conducted was entirely inadequate. From our findings it is clear that the trial was set up in order to increase the number of research subjects. The bodies of women were considered living test sites — not part of human beings with a right to dignity and integrity.

Women who were motivated to take Norplant were supposed to do so fully informed that this method was on trial and that by consenting to the implantation of the capsules they would be part of the trial. As we documented in our study, this was not happening. The only information the centres shared with the women was geared towards making them agree to have Norplant inserted. We can prove this not only from what the 10 women we interviewed told us, but also from the discussion with the centre workers about their methods of motivating women to accept Norplant. We were also very alarmed to learn that women were given Norplant who, according to the rules of the centres, did not fit the criteria of Norplant users, that is, women either too young or too old, and, importantly, women who were lactating.

Furthermore, if the women had indeed agreed to take part in the trial they would not simply have dropped out without maintaining some kind of relation with the centre. The reality is that once the users are experiencing problems with this new 5-year-needle they are no longer interested in it. But the trial did not have an inbuilt research component to follow up such cases. And the women did not know that they have a right to ask not only for medical treatment (e.g., the removal of the capsules), but also, where relevant, for financial compensation (e.g., inability to work because of severe side-effects). Because they did not know that they were part of a trial, they accepted Norplant as if it were an approved method of contraception like the pill or the IUD. This reinforces the point we made earlier, that is the eugenic aspect of this trial: semi-literate poor women are the targets of unethical population control.

The follow-up monitoring was done to record medical problems of interest to the research project but with little care for the safety of the clients. We found that amenorrhoea was a very frequent problem — all 10 women in our study suffered from it — but the tendency of the centres was to trivialise this problem and even to justify it as the price to pay for birth control. The women had to plead for the removal of the capsules, sometimes go to the centre two or three times. In this way, one could argue, more research results were accumulated: further evidence, we believe for the unethical conduct of the trial.

On 6 November 1986, UBINIG called a press conference[4] on the Norplant research in Bangladesh and appealed to the Government of Bangladesh to stop the unethical research of the Bangladesh Fertility Research Programme (BFRP). Almost all the national dailies published a summary of the relevant facts we discuss in this report and expressed their concern about the violation of research ethics. In two editorials (*Dainik Inqilab*, 1986; *Dainik No bo Abhijan*, 1986) and in a posteditorial written by Aniruddha, a well-known and highly regarded journalist (Aniruddha, 1986), the use of Bangladeshi women as "animals of biomedical experimentation" was condemned severely. However, neither the government nor BFRP responded to the issues raised by UBINIG and taken up by editors and journalists of national repute. Despite these protests the trial has been continued.

It is not surprising, therefore, that the Government of Bangladesh has decided to promote Norplant through the country's Population Control Programme. At an inter-

ministerial meeting on 19 April 1989, the Executive Committee of the National Population Control Council decided to introduce Norplant in 32 clinics in an introductory phase of operation.

This development to promote Norplant on a large scale is alarming indeed. Since its inception in 1984, UBINIG has been raising ethical issues in biomedical research conducted on the population of Bangladesh. Our point of reference is the concept of informed consent and the Declaration of Helsinki of 1964, and we have observed previously, that in Bangladesh biomedical research ethics are being violated consistently (see Akhter, 1988). In the Norplant trial, which is only one of the examples of such violations, poor women, because of their vulnerable conditions, became the innocent victims of unethical research practices. They were — and are — victimised on two accounts: (a) as guinea pigs for (international) contraceptive research; and (b) as the receivers of an unsafe contraceptive method as a means of population control.

We find this an untenable situation, especially when neither the government nor the research organisation is prepared even to discuss vital issues of research ethics and methods and importantly take seriously the many health problems the women we interviewed experienced. This, to us, indicates a gross violation of human rights and we are very concerned about the consequences of the introduction of Norplant for women in Bangladesh.

ENDNOTES

1. *Kabiraj* is the name for a practitioner of Ayurvedic medicine. The tradition of Ayurvedic medicine still exists in some limited form and *Kabiraj* stands for rural practitioner.

2. A quack is an unqualified allopath medical practitioner in the village.

3. Norplant was called *the needle* because of the silastic rod. Most of the women we interviewed were unaware of the brand name of the method.

4. Among the national dailies that covered the press conference on November 7, 1986, were *The Daily Inqilab, Daily Sangbal, Dainik Nobo Abhijan, Daily Khabar*, and *Dainik Azad.* Almost all the papers covered the violation of biomedical research ethics on their front page.

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