

Norplant - A Long Acting Contraceptive Implant: A Critical Review

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Stree Shakti Sanghatana (Hyderabad) Saheli (Delhi), Chingari (Ahmedabad) and several women, were co-petitioners in a case in the Supreme Court in 1986 which demanded a court ruling on introduction of contraceptive NET-EN. The petition demanded that the contraceptive should be introduced in Indian family planning program only after it was adequately tested in the country for short and long-term risks. It also demanded that there is an assurance that the women were given adequate and accurate information so that abuse in a target oriented program would be prevented. Conditions for adequate medical screening and follow-up were, demanded to be assured at peripheral health centers before potentially dangerous contraceptives' were introduced in the Indian family planning program.

An additional affidavit was filed in December 1990, bringing other hazardous contraceptives, such as sub-dermal implants, vagina rings, anti-fertility vaccines, nasal sprays etc, into the ambit of the earlier case.

On- 6-7 December 1990, Indian Council of Medical Research (ICMR) had a close door meeting with 'Health Advocates' to discuss introduction of NORPLANT and other spacing methods, into the national family planning program. NORPLANT was presented as an ideal contraceptive, 100% safe, 100% effective and 100% return of fertility on discontinuation of its use. This was being presented even when the mandatory Phase III trials and post introduction trials were not undertaken.

Trials were conducted with NORPLANT2, and on ICMR's admission 10% of the women were lost to follow-up. Council also admitted that it has not followed any of the women who were given NORPLANT2 and their number may be around 1500. Council explained that because of the financial constraints, the follow-up could not be taken.

ICMR wanted the Health Advocate to spread a message around about NORPLANT6, newer version of NORPLANT, and to actively associate with the forthcoming trial of the implant by the Council. The Council explained the need to promote spacing methods since the terminal methods, which were currently being used, were having very little impact on the birth rate. In the opinion of the

Council it was therefore necessary to get younger women with fewer children to accept contraceptives.

Phase IV trials with NET-EN had shown 41.21% women experienced menstrual abnormalities, pregnancy rate was 2.1%, ICMR had therefore recommended to the Drug Controller that NET-EN may be made available at the urban health centers where comprehensive medical care could be available, and a doctor present. Council had also recommended that targets for achievements should not be fixed for NET-EN.

At the meeting the Council also reported that 1466 women were given NORPLANT2 during January 1986 and September 1991. Discontinuation after 36 months was 36 to 40%. The Council said that the method was safe and did not affect return of fertility. The trials of NORPLANT2 were discontinued because the Council could not get supplies since the production was stopped. It was found that the silicon content of the rods stopped. It was found that the Silicon Content of the rods was carcinogenic and terratogenic.

The Council reported that in the new project, staff of 17 to 20 medical college hospitals in the country would implant about 200 women each with, NORPLANT. In the next 6 months another 50 medical college hospitals in India will recruit additional women. In total 100 college hospitals will introduce 20,000 implants.

As per the instructions that the Council will give, contra- indications for recruiting the cases for NORPLANT will include, first 6 months of lactation, irregular menstrual cycles, genital and breast pathology, hypertension, and diabetes. A review of the cases will be undertaken after 2 years.

The questions that need answers for the women's groups include the fact that in view of the pending case against introduction of implants and other contraceptives in the national family planning program, can ICMR introduce NORPLANT?

Women also believe that all the women who were included in the trials of NORPLANT2 should be treated as the women who had accepted Dalkon Shield i.e. in view of the fact that the implant is known to cause serious side-effects the women who were implanted, must be located, necessary medical help provided and financially compensated.

In view of the interest of the Council to implant a large number of women with NORPLANT, it is important that the legal position in the Experimentation on Human Beings is known. In this context P. M. Baxi, an eminent expert says,

"Interference with human body is illegal and in certain circumstances criminal, unless consented. Even if the consent is obtained without provision of essential facts, legal liability arises. He also adds that, even with consent, reasonable care at medical procedures is binding on the medical person.

Somnath Roy, a medical person involved with medical research for the official agencies, while discussing about the introduction of contraceptives in the national family programs - especially injectables and implants, says that expectance gained from clinic based trials does not provide adequate guidelines and preparations for the program operations. He emphasized that this is particularly true with injectables and implants.

In the light of the fact that Indians have experienced a highly coercive, government during Emergency and government promoted family planning program even the experience of the day to day functioning of the program shows that there is emphasis on increasing the number of acceptors and a review of some of the printed material is adequate to convince that the coercion continues and women are the major targets of the program. Such a review was undertaken and was published. (Karkal Malini 1991, Compulsion - Political Will and Family Planning) It is therefore necessary that the women's organizations equip themselves with all the information available on NORPLANT. Fortunately such information is available from several countries. An attempt is made here to present it.

As will be seen from the experience with NORPLANT in other countries, as well as whatever is experimented in India, also the side effects that are listed by the Population Council and WHO, the health condition of Indian women and the facilities available to them, must be borne in mind. Among the side effects major one and suffered by a large proportion off the users, is menstrual irregularity and which includes, heavy and prolonged bleeding. It is known that anemia is widely prevalent in Indian women. Question therefore arises is can these women bear additional blood Loss?

Other side effects include medical problems. Currently 70% of rural and 30% of urban women are delivered by untrained persons. And this is when the trained persons include trained Dais. What facilities will be available for this highly medicalized method?

Experience from other country shows that careful training, to medically qualified persons is needed for implantation of the method. What plans has ICMR made for the selection and training?

More important is the training for removal of the implants. It is known that the removal is more difficult than the implantation. Also the women, who are implanted, are likely to migrate to areas away from the place where they got the implant. It is obvious therefore that there is a need for a wide network of trained medical persons for removal of the implants. What is being done to meet this need?

NORPLANT is known to cause several side-effects such as headache dizziness, nervousness, weight gain, breast tenderness, excessive facial hair growth and ovarian cysts. What is being done to tackle problems arising out of these possible changes? Are there provisions for training suitable staff to tackle problems among women who are already socially oppressed under prevailing conditions?

Review of the Available Literature

NORPLANT was developed at the Population Council (PC), New York. It is manufactured by Leiras Pharmaceuticals, which is required to provide it at a low price to developing country governments and family planning organisations.

NORPLANT, is a package of six matchstick size hormonal contraceptive capsules, that is claimed to be effective for five years and reversible. The capsules are made of silicone, are non-biodegradable tubes and are filled with synthetic hormone - progestin. It is implanted, by surgery, under the skin of a woman's upper or lower arm. Each 34mm by 2.4mm tube contains 36mg of levonorgestrel, a synthetic progestin, used in combined oral contraceptive pill. The hormone was selected after conducting researches with levonorgestrel, norgestrienone and megestrol acetate implants. Though levonorgestrel showed higher bleeding disturbances, it was chosen because it was long acting, it was used in oral pills and was approved by FDA (Food and Drug Administration) of USA, and as an implant, removal rates within first three years were believed to be lower.

The hormone is gradually released through the walls of the capsules in a continuous low dose. Exact working mechanism of the method is not known but it is believed that it inhibits ovulation in 50% of the menstrual cycles and thickens cervical mucus, making it difficult for sperm to fertilize the egg. The contraceptive effect of the capsules starts within hours of the insertion. The contraceptive effect of NORPLANT was initially based on the principle that microdose of progestins suppresses fertility, but does not suppress ovulation. The Population Council (PC) researchers expected less side effects than with the contraceptive pill due to continuous release of low doses of progestin.

Betsy Hartman says that NORPLANT must be removed after 5 years. Its presence in the arm past that period may increase the risk of life-threatening ectopic (outside the uterus) pregnancy.

If a woman wants to continue using the method for a period longer than five years, she will have to get the earlier implanted rods removed by surgery and get new ones implanted.

The research that led to the development of NORPLANT was initiated by the PC in 1967 and NORPLANT was researched from 1970 to 1975, to find the most effective combinations of capsules and hormones. The system was developed in 1974. The trials in Chile, Brazil and India had showed increased numbers of ectopic (outside the uterus) pregnancies among the failures and swelling in the ovaries. In 1975 therefore PC increased the dose of progestin thus reducing the chances of pregnancy as well as the risk of ectopic pregnancy. This dose however, is lower than that in the pill.

In 1985 WHO gave its report declaring NORPLANT as an "effective and reversible method of fertility regulation particularly advantageous to women who wish an extended period of contraceptive protection" and is considered "suitable for use in family planning programmes along with other methods of fertility regulation."

WHO had simulatenously reccommended:

1. A training and supervision of medical personnel, especially bearing in mind the side-effects listed below, the client selection needs a careful examination.
2. More research on long-term side effects.
3. Research into the use of implants during lactation.
4. Post-marketing surveillance studies and continuation of studies on the acceptibility of the method.

The PC established training centres in Dominican Republic, Indonesia and Egypt. Leiras, a pharmaceutical company, trained a number of clinicians in Finland. For training of physicians, nurses and counsellors, the PC prepared a five day NORPLANT curriculum, in collaboration with Family Health International (FHI), Association for Voluntary Surgical Contraception (AVSC), and Programme for Appropriate Technology in Health (PATH)

For knowing about long-term side-effects, FHI, with assistance from WHO and the PC, has initiated a post marketing surveillance in the developing countries. The collaborative study will follow 7500 to 8000 NORPLANT users and the same number of controls, for five years. The study began in pilot projects in June 1987 in Chile, Sri Lanka and Thailand and in full surveillance projects in autumn of 1988 in Bangladesh, Chile, China, Egypt, Indonesia, Sri Lanka and Thailand. The findings were expected to point out rare and long-term side-effects.

The PC, based on these researches, recommends that, steroids are not considered the contraceptives of first choice for breastfeeding women, though in the opinion of the PC, on significant effects, on infants, were noticed for mothers who used the method six weeks after the birth.

User and programme studies are under way in, Bangladesh, Brazil, Colombia, Dominican Republic, Egypt, Ghana, Haiti, Kenya, Indonesia, Mexico, Nepal, Nigeria, Philippines, Senegal, Singapore, Thailand, United States and Zambia.

On the failure or the pregnancy rate among the users, it is reported that the rate is 0.2% for the first year, 1.2, 1.6 and 0.4% for the subsequent three years. Cumulative pregnancy rate for 5 years is 3.9%. Correlation was observed between effectiveness and woman's weight. After the second year, heavier women, particularly those with weight 70kg, have proportionately higher probability of becoming pregnant than the lighter women. For women with weight 70kg the cumulative pregnancy rate, among the users, was 8.5%.

Contra-indications for the acceptance of NORPLANT, according to the PC and WHO, are: pregnancy, presence of cardio-vascular disorders, women with undiagnosed abnormal vaginal bleeding, women with benign or malignant liver tumors, women with known or suspected breast cancer. In addition, women suffering from anaemia, diabetes, and high blood pressure are advised regular check-up. NORPLANT is not to be a method of first choice for lactating women and it is not to be used before 6 weeks of a birth. Clinicians are also asked to look into women who smoke or are on any medication.

In addition to irregularities in menstruation, heavy and irregular bleeding as well as amenorrhea, the PC and WHO list following method related side-effects: headaches nervousness vomiting dizziness inflammation of the skin acne change of appetite weight gain breast tenderness excessive facial hair growth or hair loss infection, pain or itching at the implant site and functional ovarian cyst

Though WHO had advised careful study of 7500 to 800 women before approving use on large scale, according to the Population Council, more than 55,000 women in 46 countries have been involved in the clinical or pre-

introductory trials, and more than 500,000 women worldwide have used the method. In reply to the complaint by UBINIG in Bangladesh, against NORPLANT, USAID said the users to be nearly three-quarters of a million, around the world.

Among the 17 countries that have approved marketing of NORPLANT are China, Finland, Indonesia, Nepal, Sri Lanka, Sweden, Thailand and Tunisia and the U.S. In Latin America and the Caribbean, NORPLANT has been approved in Chile, Colombia, the Dominican Republic, Ecuador, Haiti, Peru and Venezuela.

It is important to note that the PC acknowledges most of the issues that women activists are raising. However it is observed that government family planning programmes in many Third World countries are in favour of rapid expansion of NORPLANT delivery services, without fully acknowledging the possible constraints. In reply to protest from UBINIG, regarding promotion of NORPLANT in Bangladesh, USAID insisted that the method was proved to be safe and effective. And this is said inspite of evidence to the contrary. USAID further added that the women in the developing countries have too few choices and NORPLANT offers women an additional contraceptive option that is safe, effective and long-acting. It offers women the freedom to control their own reproduction and fertility.

In a letter, dated August 21, 1991 to the Medical Director of IPPF, in response to guidelines developed for medical and service delivery by the IPPF, USAID says, "..we are very concerned that the manual may unintentionally set up medical barriers to access to care for other potential recipients."

"All too often, in our view, family planning programmes impose numerous medical barriers to service which we are convinced hinder program effectiveness and impact, especially for hormonal contraception. Common examples of what we mean by medical barriers include:

1. Unncessary laboratory tests;
2. Excessive physical exams (e.g. pelvic and breast)
3. Holding the oral contraceptive "hostage" to other reproductive medical care (e.g. pap smear and STD tests)
4. Restrictions on the number of OC cycles dispensed (e.g. providing only on cycle for a new client and only if menstruating, or only three cycles on subsequent visits.)

5. Excessive follow-up schedules (e.g. every three months, including counselling, weight, blood pressure, breast check etc.)
6. Conservation medical thinking (e.g. taking women off the pill for a while if she develops a headache just to play it "safe" or denying a postpartum woman with an enlarged thyroid the pill until the gland becomes smaller)
7. Excessive counselling and history taking in such a way as to include a lot of irrelevant information rather than the important things, the net effect being to increase waiting time and see few clients.
8. Categorical exclusion of clients (arbitrary age and parity criteria)
9. Categorical exclusion of methods (not providing IUDs because the STD rate is too high in the population) and
10. Categorical exclusion of who can provide methods (only OB/GYNs or only physicians) are allowed to perform surgical contraception, provide OCs etc."

The letter further says, "With respect to contraindications, in our view, we prefer not to even use the term. It is a term which may have very negative connotations and major inhibitory effect, especially when transmitted downward through the system. A low level health worker needs a lot of confidence to go against even a 'relative contraindication'"

"Although the fact that the risk from pregnancy is relatively greater compared to risks from using methods even when contraindicated is mentioned, this point could be emphasized more. In addition, the benefits of contraception could be more fully explored and stressed, such as benefits of pills."

On the one hand these population controller agencies have no hesitation in introducing methods that are known to have side-effects in significantly larger numbers of users, they advocate introducing these methods without any restrictions, on the grounds that they see population control as the most important agenda, even when it means sacrificing the health and well being of women.

UBINIG, and NGO, working for women in Bangladesh reports that NORPLANT was introduced in that country, by a voluntary agency funded by international monies, Bangladesh Fertility Research Programme (BFRP), even when the Technical Advisory Committee had not approved the method.

The method was advertised, in 1981, through newspapers as a "wonderful innovation of modern science." These claims were however challenged by 151 doctors and pharmacists and BFRP stalled its trials. They however were undertaken from February 1985, with the financial assistance from PC and the Family Health International, both based in the USA.

An argument supporting the introduction of NORPLANT was that, "contraceptive pills containing progestin and more commonly used other reversible methods necessitate continuous motivational involvement by 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". This is another way of emphasising effectivity and superiority of the method in use for population control. It says nothing about the safety and women's ability to control their own fertility. It in reality points the ability of the family planning workers i.e. population controllers, to control the use of the method. BFRP, in keeping with the population control objective, started promoting NORPLANT, before the results of the trial were available. It is important to note that the above mentioned claims about the safety and effectivity were made inspite of findings from the research undertaken by WHO.

It is also observed that as the programme expanded rapidly, training became more informal and theoretical aspects, were dropped. Betsy Hartman reviewed the PC report on the experience with NORPLANT in Indonesia. She says in that country as many as half a million women have had NORPLANT and the method is on the list of the national family programme. The training in that country does not include training for removal. Experience shows that as the programme expanded, women were not told about removal and they are informed that the method is effective for five years. If women ask for earlier removal they are reminded that they had asked for the implantation. It was observed that 30% women wanted removal but they did not dare to approach the clinic for fear of refusal. Women are also unaware as to what is involved. NORPLANT, the cost of which is high, is given free, in contrast to the other methods which are charged a fee. This has helped in increasing the acceptance of NORPLANT.

The family planning programme in Indonesia is target oriented and emphasises increase in contraceptive prevalence, including emphasis on long-acting contraceptives such as IUD, NORPLANT and sterilisation. Zimmerman reports that in Dominican Republic, Egypt, Indonesia, women are not given removals if they asked for them. If they reported irregular menstruation, they were advised to 'wait and see'. Soon the women in these countries learnt to give false reasons

that the clinicians would accept e.g. spouse desiring to have a baby. Women were not told that NORPLANT had to be removed after 5 years. It is therefore not known as to how many women still carry them.

In Indonesia NORPLANT programme is sponsored by the UNFPA and the Asian Development Bank and it is promoted by powerful social groups, including government, religious groups and military. The situation in the country is generally such that the pressures from such groups are generally effective in getting acceptance. In addition the method is given to the women who visit clinic and without any information about other methods. Information given about the NORPLANT is very limited. There is no surely about the woman being pregnant at the time of insertion. Generally the insertion is done within seven days of starting the menstruation and experience shows that 20% of the users had accepted NORPLANT during menstruation and 21% post-pregnancy or abortion.

The managers of the programme indicate that NORPLANT should be used in strongly fundamentalist Muslim areas where IUD is not acceptable. The PC report from the evaluating team of the Indonesian programme says that the field workers uses techniques of "persuasion" or "motivation" to assist the client in coming to a decision and these techniques are described as similar to pressurising or even coercing clients to accept the particular method.

There are some problems about the technical aspects such as shortage of trocars, the instruments for the insertion of the capsules. It was observed that sterilisation standards were not met. There was 1 trocar for 25 insertions whereas the actual need is of atleast 3 for 25 insertions. In addition there is a need of staff that will wash and sterilise the instruments.

WHO research had concluded that its findings were based on insufficient animal experiments, lack of knowledge regarding comparability of the findings on animals and human, insufficient clinical research, absence of research on effects on women with frequently found health conditions, and on the whole the claims of suitability for most women were made without support from facts, and the findings from experiances in the field were therefore very important.

UBINIG's enquiry revealed that poor, illiterate, pregnant women who went for help were asked to give their written consent to MR(menstrual regualtion) without reading out to them the contents which stated, "I know about the problems such as infection, bleeding and perforation of uterus, and yet I request for the MR." After MR the women were implanted with NORPLANT without any information on the method, excepting that it was a simple and safe method that prevented pregnancy for five years. Information provided to other non-

pregnant women was the same. There were other details in the information provided to the women that were not supported by the facts available from WHO and other sources. Bangladesh Fertility Research Programme (BFRP) reported that continuation among the 600 women after 14 months of use was 31%.

In Brazil, clinical trials were authorised by the Ministry of Health in 1984, but were suspended after two years. In Bangladesh official received long-acting NORPLANT with enthusiasm. A government report noted "With largely illiterate and conservative population, together with poor communication facilities, is unsuitable for short-term contraceptive techniques which demand continuous motivation on the part of the client and a continuous supply of material on the part of programme managers. NORPLANT, was therefore viewed not as a reversible contraceptive but as a drug with the potential for becoming nearly as effective as sterilization. Activists from UBINIG, a women's health network protested to the US FDA that, their research "uncovered gross violations of ethics and an inadequate research practice." UBINIG also pointed out that most of the developing countries do not have physical infrastructure and manpower to effectively manage the technology and ensure follow-up care. "Within the population control context, the 'provider' is often a repressive government and 'acceptor' are poor and malnourished women. This technology is open to widespread abuse."

Soledad Diaz from Chile, participated from 1973, in the initial research for development of NORPLANT. About 4000 to 5000 women are currently using the method. Diaz says that about half the women continue using the method for 5 years and about 25% ask reinsertion. She mentions that close rapport between service provider and the clients as an essential component for these results.

Among the criticisms of the feminists, of NORPLANT, is the fact that the method is provider controlled. Insertion as well as removal requires trained persons, direct medical supervision and highly sterile conditions. Experience so far shows that the method is promoted by the population controllers and their main interest is increasing the number of users. It shows lack of training in identifying the cases with contra-indications and generally lack of enthusiasm among the service-staff to reject cases. In such situations women with definite contra-indications are likely to be implanted with NORPLANT.

The experience also shows that there is unwillingness in removal of NORPLANT even if the women so desire. This is sure to result in larger numbers of women experiencing problems because of the implantation.

Wemos/HAI - international groups of women and pharmaceuticals, say that the side-effects noted by the PC/WHO, require high level training to ensure appropriate client selection. Also, the insertion and removal require hygienic conditions and the side-effects an appropriate referral system, including specialised gynaecological care.

Currently the NORPLANT delivery programmes are expanding too far and too soon. It must be remembered that WHO had advised close follow up of 7500 to 8000 cases. However according to the PC, more than 55,000 women in 46 countries have been involved in the clinical or pre-introductory trials, and more than 500,000 women worldwide have used the method. In reply to the complaint by UBINIG in Bangladesh, against NORPLANT, USAID said the users to be nearly three-quarters of a million, around the world.

Among the 17 countries that have approved marketing of NORPLANT are China, Finland, Indonesia, Nepal, Sri Lanka, Sweden, Thailand and Tunisia and the US. IN Latin America and the Caribbean, NORPLANT has been approved in Chile, Colombia, the Dominican Republic, Ecuador, Haiti, Peru and Venezuela. The attitude of pushing the programme so fast, also generates doubts whether the conditions for safe use of NORPLANT will be ever met.

In India, about 80% of the rural and 30% urban deliveries are conducted by untrained persons. Availability of trained services under these conditions, becomes suspect. Also women are expected to face problems in finding a trained person, if they wish the implant to be removed.

Both, for implantation as well as for the removal, the user is dependent on the provider. This can create problems in countries that have strong anti-natalist policies. Experience, reported from Bangladesh, and Indonesia shows that the women who experienced problems with the method, and who went back to the clinics, were either not able to go for removals because of the attitude of the providers or were refused the removals, even if they picked up the courage to go and ask for removals.

Among the studies that are reported, from Indonesia, even in the closely controlled study, 238 (29%) women of the total 813 under study, were lost to follow up. Reports from other studies are no different. This raises doubts about the reliability of the findings of the studies and the possibility of undetected long-term effects on the health of the women.

Coercion in family planning, and especially of women (and the poor), is widely experienced in countries with anti-natalist policies. Experience about NORPLANT, not only in Bangladesh, Brazil, Ecuador, Indonesia and Thailand

but even in a developed country such as USA, shows that the method is used to oppress women. The reports from USA show that NORPLANT has become a method of choice for prosecutors, probation officers, a raft of law makers and policy makers and as indicated by recent opinion polls, a majority of the general public.

Time magazine reported that "real progress was brought" when the FDA approved NORPLANT. It claimed that the method was as reliable as sterilisation, "and unlike sterilisation it is totally reversible. Reclaiming one's fertility was as simple as having the device removed".

"It is what many women were waiting for." According to Time, "the most common complaint was the NORPLANT disrupts menstruation. Four out of five users reported menstrual disruption. Though only a third of those who experienced changes were bothered about them." Time also forecasted that if the family planning advocates would subsidise the price of NORPLANT and it would be available cheaper. "women's lives will never be the same".

From the available information, it seems that the method is not used by the White American women but the others are persuaded to use it. This is happening mainly in States Louisiana, Kansas and California. Women on welfare are offered \$500 to have NORPLANT inserted and \$50 each year it remained in place. The women will however have to return the money received and pay \$300 if for any reason they wish to remove the implant before 5 years. Thus even if the women has side effects, she has very little choice.

Two weeks after NORPLANT received approval from FDA (Food and Drug Administration) in USA it was proposed that insertion of NORPLANT be made an acceptable condition of probation for women convicted of drug offences. In California Judge Broadman ordered thus, a woman on probation. Darlene Johnson, a 28 year old unwed mother on welfare was ordered to be implanted with NORPLANT or face four years in State prison. Darlene was pregnant at the time of the order. It is not known as to what was to happen to her pregnancy, since the hormonal implant would certainly interfere with it. Judge Broadman says that his order is fair and constitutionally supportable since the State has compelling interest in protecting future children of the women involved.

US columnist, Ellen Goodman, commented, "it took 24 years to develop, test and approve an implantable device that can prevent pregnancy for as long as five years. (But) It took less than two weeks for NORPLANT to be billed as a new method of coercion."

There are already provision in 42 States in USA that have agreed to pay for NORPLANT under their Medicaid programmes. Many of the doctors and nurses who care for problem babies are pushing for the legislation. A physician even suggested that pimps be paid \$100 for every prostitute implanted with NORPLANT.

A poll conducted by Los Angeles Times found that 46% of the respondents strongly approved of making NORPLANT mandatory for drug-abusing women and another 15% said that they approved "somewhat", 67% approved of giving teen-agers access to NORPLANT. Glamour magazine reader poll indicated 60% approval of forced NORPLANT for female child abusers.

Studies in Family Planning (Vol.21, No.3, May/June 1990) a publication of Population Council, an agency responsible for the development of NORPLANT, reports about the use of the method in San Francisco, in USA. It was found that 95% of the users (250 women) reported side-effects with 82% reporting changes in menstruation. In the interviews it was found that 57 (23%) of the women discontinued using the method and their average use was 10 months. Enquiry by the end of three years and four months, found that another 110 (44%) women had discontinued. Finally only 95 (38%) women continued with the method. Interestingly, the authors conclude, "Most of the women were pleased with the NORPLANT--- For the women enrolled in this clinical trial, NORPLANT appeared to be highly acceptable method of contraception, despite the frequent occurrence of bothersome side effects." Another aspect of the study that would be interesting to the readers is the distribution of the NORPLANT users by their ethnicity. Hispanic (44%) Caucasian (37%), Black (13%), Others (either Asians or American Indian) 6%.

It is clear that the heart of the matter is that who should control women's reproduction has clear racist, sexist bias. Aid to families with dependent children is 34.6% and is highly disproportionate to their representation of 6.35% in the population. There is no proposal to bribe men convicted for child abuse, with use birth control or agree to vasectomy.

Experience with the method shows that women who use it suffer from side effects such as, menstrual irregularities such as amenorrhoea and excessive and prolonged bleeding, dizziness, headaches, burning sensation, nervousness, tiredness, weight gain and ovarian cysts. Dr. Philip Darney, an Obstetrician-Gynaecologist from California, who reported from the follow up of 400 NORPLANT users, adds to the above side-effects, that the capsules can be seen on slender arms. He also reported that 40 to 60% women requested removal before five years. Long-term side effects on women as well as on fetuses of women who were pregnant at the time of insertion or after the implant is

removed, are not known but the above mentioned side effects are reported even by WHO and it therefore stresses the importance of the service delivery setting in the contraceptive's service record.

Since NORPLANT does not contain estrogen, it is claimed that it does not carry the risk of heart attack, breast cancer or other problems that are known to be associated with pills. However this conclusion needs to be tested.

Wemos/HAI the above mentioned International Groups on Women and Pharmaceuticals says, that though WHO had suggested a trial on about 7500 to 8000 women before introducing the method for large scale use, the studies so far offer information on the duration for which the women are willing to tolerate side-effects. There is no information from the "user-perspective" of safety and efficacy of NORPLANT. Though headache, dizziness and nervousness are described as minor, they can affect women's lives considerably, and more so when they do not know that the cause is NORPLANT. In the absence of such knowledge there is likely to be further medication through the use of pain-killers and anti-depressants.

Also it is important to know how menstrual irregularities are perceived. Amenorrhea with vomiting and other symptoms may be interpreted as the symptoms of pregnancy. Use of traditional methods of abortion are not unlikely or it may be interpreted as infertility and may cause strained family relations. Removal is difficult if implant is deep and forms scar tissues around the rods. Cases where the implants were lost are also reported.

Bibliography

1. A Birth-Control Breakthrough - The FDA finally approves a long-awaited implant, (1990) Time, December 24, p.68.
2. Alvarez-Sanchez Francisco Vivian Brache and Anibal Faundes (1988) The Clinical Performance of NORPLANT Implants Over Time: A Comparison of Two Cohorts, Studies in Family Planning, Volume 19 Number 2, pp. 118-121.
3. Basanayake Sriani, Shyam Thapa and Sander A Baalogh (1988) Evaluation of Safety, Efficacy and Acceptability of NORPLANT Implants in Sri Lanka, Studies in Family Planning, Volume 19, Number 1, pp. 39-47.
4. Baxi P.M. (1992) The Experimentation on Human Beings: The Law, Lawyer's Collective, pp. 13-14.

5. Concern Over Safety, Coercion Greet US Approval of NORPLANT in Women's Health Journal, ISIS, Jan-Feb-Mar 1991, pp. 46-47.
6. Contraception Volume 38, Number 6, pp.650-673 (report on the NORPLANT 2 trials in India)
7. Diaz Solledad (1991) NORPLANT in Chile, ISIS, Jan-Feb-Mar, p.48
8. Hardon Anita and Lenny Achtuoven (1991) NORPLANT : A Critical Review. Women's Global Network for Reproductive Rights Newsletter 34, January-March pp. 17-21.
9. Hartman Betsy (1991) Population Council Report on NORPLANT in Indonesia. Women's Global Network on Reproductive Rights Newsletter 34, pp 21-24.
10. Karkal Malini 1991, Compulsion-Politica Will and Family Planning. (available from the author)
11. Roy Somnath (1983) Introduction of Contraceptives in the National Programme-Injectables and Implants, Health and Population - Perspectives and Issues, Volume 6, Number 1, pp. 5-24.
12. Satyapan Suvane, Kanchanasinith and Somasak Varakamin (1983) Perceptions and Acceptability of NORPLANT Implants in Thailand, Studies in Family Planning Volume 14, Numbers 6-7, pp. 81-94.
13. Sivin I, Diaz Soledad, Pentti Holma Francisco, Alvarez-Sanchez and Dale Robertson (1983) A Four Year Clinical Study of NORPLANT Implants, Studies in Family Planning, Volume 14, Numbers 6-7, pp.184-191.
14. UBINIG (1988) NORPLANT: The Five Year Needle, An Investigation of the Trial on NORPLANT from the User's Perspective pp.50.
15. The Population Council (1990) Approvals Rise to 15 Countries, NORPLANT Worldwide, May, p.14.
16. The Resistance Network Against Abuse of Contraception on Women's Bodies, Newsletter Research Centre Women's Studies, Summer Issue, Volume 12, Number 1, pp.9-10.
17. Segal S.J. (1983) The Development of NORPLANT implants, Studies in Family Planning, Volume 14, Numbers 6-7, pp.159-163.

18. WHO (1985) Facts About an Implantable Contraceptive, WHO Bulletin Volume 33, Number 3, pp. 485-494.
19. Zimmerman Margot. et al (1990) Assesing the Acceptability of NORPLANT Implants in Four Countries: Findings from Focus Group Research, Studies in Family Planning, Volume 21, Number 2, pp.92-103.
20. (Unnamed) (1991) Implanted Birth Control Devid Renews Debate Over Forced Contraception, WGNRR Newsletter 34, pp 24-25