Current Abstracts
focus on contraceptive research

UNFPA
PATH

Volume 4, Number 1/January 1991

Sterilization

Akhter, H.H. et al. The need for prophylactic antibiotics after female sterilization: tetracycline in Bangladesh. Contraception, Vol. 42, No. 3, September 1990, pp. 297-308.

A study of 1,350 women from rural and urban Bangladesh who were treated with one of two antibiotics or placebo following minilaparotomy sterilization found that infection rates seven days after surgery were significantly lower with tetracycline (6%) than with placebo (10%). Infection rates did not differ significantly between the ampicillin and placebo groups or between the tetracycline and ampicillin groups. Treatment was for five days, four times each day, with 250 mg tetracycline (453 women), 250 mg ampicillin (449 women), or placebo (448 women): treatment type was unknown to patients and providers. The authors concluded that although their findings could be used to justify the current practice in Bangladesh of providing all female sterilization patients with a 5-day course of tetracycline, a cost analysis of this practice was needed. They recommended that programs focus on identifying causes of infection and reducing infection rates without the use of antibiotics.

MacLennon, A.H. et al. Post-operative discomfort after ring or clip tubal ligation — is there any difference and do indomethacin suppositories help? Contraception, Vol. 42, No. 3, September 1990, pp. 309-313.

This randomized study of 95 Australian women whose laparoscopic tubal sterilization involved either a Falope ring (42 women) or clip (53 women) found no difference between occlusion devices in immediate postoperative discomfort. Furthermore, there was no difference in postoperative side effects or analgesic requirement between women who, one hour prior to surgery, were given either a rectal suppository containing 100 mg of the anti-prostaglandin indomethacin (47 women) or placebo (48 women). The type of suppository administered was unknown to patients and practitioners. There was no statistically significant difference between the device groups in analgesic requirements, side effects, or need for overnight hospital stays. Although a narcotic analgesic was required by more women who were pretreated with placebo than with indomethacin, there was no statistically significant difference between treatment groups in overall analgesic requirements. The authors concluded that (1) immediate postoperative discomfort rates are the same for the two devices and (2) their results do not substantiate those of a small, case-control study that showed preoperative use of indomethacin rectal suppositories reduced postoperative pain in Falope ring sterilization patients.

Yan, J.S. et al. Comparative study of Filshie clip and Pomeroy method for postpartum sterilization. International Journal of Gynecology and Obstetrics, Vol. 33, No. 3, November 1990, pp. 263-267.

This prospective comparison of the Filshie clip and the Pomeroy method of sterilization among 200 postpartum women in Taiwan found no difference between groups in perioperative complications or long-term sequelae up to two years after surgery. Women were randomly assigned to receive tubal occlusion by Filshie clip (100 women) or the Pomeroy method (100 women). All procedures were performed by the same physician. The women were evaluated in the postoperative period by a second physician who did not know which method had been used. One-month follow-up data were obtained for 85% of women in the Filshie clip group and 86% of women in the Pomeroy method group. There was no difference between groups in postoperative pain or complications, which were

mild and infrequent. Some 96% of women in the Filshie clip group and 97% of women in the Pomeroy method group completed at least one follow-up visit 6-24 months after surgery. There was no statistically significant difference between the groups for any of three possible long-term side effects, including duration of menstrual flow, amount of menstrual flow, or dysmenorrhea. No complications or complaints related to the procedure were reported by members of either group at long-term follow-up. The authors concluded that both methods are effective among postpartum women and have a similar, low complication rate.

Intrauterine Devices

Sivin, I. et al. A randomized trial of the Gyne T380 and Gyne T380 Slimline intrauterine devices. Contraception, Vol. 42, No. 4, October 1990, pp. 379-389.

This one-year prospective study of 966 women from 5 international centers found no statistically significant difference in the performance of the Copper T 380A and the Copper T 380A Slimline, a modified version of the Copper T 380A designed to make loading the device into the inserter tube easier and to facilitate insertion. Women were randomly assigned to use the Slimline (698 women) or the standard model (298 women) but were not told which device they had received. At one year, pregnancy rates were extremely low for both devices: 0.3% for the Slimline and 0.4% for the standard model. One-year continuation rates also were very similar: 79% for the Slimline and 80% for the standard model. The difference in termination rates for bleeding and/or pain was not statistically significant: 7.2% for the Slimline and 9.5% for the standard model. The rate of expulsion was higher in the Slimline group (5.6%) than in the standard model group (2.6%), but the difference was not statistically significant. Reports of pain at insertion were the same: approximately 37% of women from each group reported pain with insertion. There was no statistically significant difference between devices as reported by providers in ease of loading the device into the inserter tube.

Male Hormonal Methods

World Health Organization Task Force on Methods for the Regulation of Male Fertility. The Lancet, Vol. 336, No. 8721, October 20, 1990, pp. 955-959.

A World Health Organization study of 271 healthy men from 10 centers in 7 countries found that in a majority of men, weekly injections of 200 mg testosterone enanthate caused azoospermia (absence of sperm in semen) within 6 months. Among men who achieved azoospermia, weekly injections for up to 12 months provided safe, effective, and reversible contraception. The study included men age 21-45 with normal sperm analysis and no history of infertility and whose stable partner had no history of infertility. At six months, the cumulative lifetable rate of azoospermia was 65%. The mean time to attain azoospermia was 120 days. After achieving azoospermia, some 157 men entered a 12-month efficacy phase, during which weekly injections were the only contraceptive used. Only one pregnancy occurred during the efficacy phase (0.8 pregnancies per 100 person-years). Cumulative annual discontinuation rates were highest for unachieved azoospermia within 6 months (23%); personal reasons (13%); medical reasons (12%), primarily acne; and difficulties with the injections (8%), such as objection to their frequency. Once injections ceased, the mean time to recovery (sperm concentration of at least 20 million/ml) was 3.7 months. The authors noted that the major limitations of the regimen were the frequency of injections and inability of the treatment to uniformly produce azoospermia. A second stage of the study will assess whether treatment with testosterone enanthate that significantly reduces sperm but does not cause azoospermia can effectively prevent pregnancy.

General

Eslami, S.S. et al. The reliability of menses to indicate the return of ovulation in breastfeeding women in Manila, The Philippines. Studies in Family Planning, Vol. 21, No. 5, September/ October 1990, pp. 243-250.

This prospective study of 40 breastfeeding women in the Philippines showed that for women who menstruate during the first six months postpartum, first menses was not a good indicator of resumed ovulation. For these women, about two-thirds (67%) of the menses were anovular and the mean time from first menses to ovulation was almost 16 weeks. Six months after delivery, however, less than one-fourth (22%) of the first menses were anovular and the mean time from anovular first menses to ovulation was a little more than 7 weeks. Menstrual status was determined by weekly interview and ovulation was detected by hormone assays of daily urine samples. The authors concluded that in breastfeeding women, the resumption of menses is an inaccurate marker for returned fertility during the first six months postpartum but is a reliable indicator after six months.

Franks, A.L. et al. Contraception and ectopic pregnancy risk. American Journal of Obstetrics and Gynecology, Vol. 163, No. 4, Part I, October 1990, pp. 1120-1123.

In this article, investigators calculated incidence rates for ectopic pregnancy associated with various methods and concluded that incidence rates may be a more accurate reflection of actual risk than relative risk estimates. Typically, method-related ectopic pregnancy risks are expressed as relative risk estimates and often are conflicting, due to control group selection bias common to case-control studies. To calculate incidence rates the authors multiplied the pregnancy rate with each method (based on perfect use by 1,000 women in the first year of use) by the proportion of ectopic pregnancies observed with that method in the United States. For the tubal sterilization calculation, the proportion of pregnancies that are ectopic was derived from literature reviews; for the IUD calculation, this proportion was derived from two large IUD cohort studies. For combined oral contraceptives (OCs), barrier methods, and vasectomy it was assumed that the method did not affect the site of implantation and that ectopic implantation was the same as the overall proportion among reported pregnancies in the United States. The resulting estimated ectopic pregnancy incidence rates per 1,000 woman-years varied more than 500-fold: OCs, 0.005; vasectomy, 0.005; condoms, 0.100; diaphragm, 0.150; tubal sterilization, 0.318; IUD, 1.020; no method, 2.600. The authors noted that because most of the IUD cohort data pertained to the use of non-medicated IUDs (which are less effective than currently widely-used copper IUDs), the incidence rate for IUD users may be overestimated. The authors also estimated incidence rates with typical use: vasectomy, 0.0075; OCs, 0.15; condoms, 0.60; tubal sterilization, 0.64; diaphragm, 0.90; no method, 2.60; IUD, 3.06. Again it should be noted that the IUD pregnancy rate used for this calculation is higher than the rate associated with copper IUDs in wide use today: actual ectopic incidence rates associated with no method and with IUD use are believed to be very similar.

Gajanayake, I. and J. Caldwell. Fertility and its control: the puzzle of Sri Lanka. International Family Planning Perspectives, Vol. 16, No. 3, September 1990, pp. 97-102.

The authors of this article argue that contraceptive prevalence survey data from Sri Lanka support the theory that discrepancies between fertility and contraceptive use seen in some countries are due to substantial underreporting of the use of traditional methods, such as rhythm, withdrawal, and abstinence. Three surveys (1975, 1982, and 1987) showed increasing contraceptive prevalence but little change in fertility. In all three surveys, fertility levels predicted on the basis of reported

contraceptive use were higher than actual rates. The authors concluded from vital registration, census, and survey data that former unreported users of traditional methods who later accepted and reported using sterilization accounted for much of the increase in prevalence between surveys. The authors note that their findings should remind researchers of the need to carefully tailor survey instruments to local conditions. The findings also underscore the need to consider that traditional method use may be underreported in contraceptive prevalence data.

Mosher, W. Contraceptive practice in the United States. Family Planning Perspectives, Vol. 22, No. 5, September/October 1990, pp. 198-205.

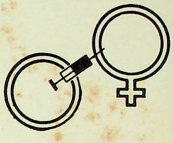
This article describes trends in contraceptive use between 1982 and 1988 among U.S. women overall and by age, race, ethnic origin, marital status, education, income, and fertility intention. Data were drawn from the last three cycles of the National Survey of Family Growth (1973, 1982, and 1988) and focused on 1988 data. For each cycle, data were gathered using personal interviews with a representative sample of about 8,000 women age 15-44. Overall, in 1988 approximately 60% of 57.9 million reproductive-age women were currently practicing contraception. Of the 40% not using contraceptives, some 7% were at risk of pregnancy but not trying to become pregnant. Between 1982 and 1988 the distribution of contraceptive users changed in several statistically significant ways: IUD use fell from 7% in 1982 to 2% in 1988; use of female sterilization rose from 23% in 1982 to 28% in 1988; diaphragm use dropped from 8% in 1982 to 6% in 1988; and condom use rose from 12% in 1982 to nearly 15% in 1988. In 1988, female sterilization was the most prevalent method among ever-married women. Increases in the use of female sterilization were greatest among the formerly married, the less educated, those with lower incomes, Hispanic, and black women. Overall, diaphragm use declined and condom use increased most among younger women, never-married women, and those who intended to have more children. Several possible explanations for the trends were proposed, including the withdrawal of all but one IUD from the U.S. market in the mid-1980s and a rising concern about sexually transmitted diseases, including AIDS.

Current Abstracts ISSN: 1012-2680

Current Abstracts is published quarterly. It features abstracts of recent articles on contraceptive methods and products selected from a large number of publications. Its objective is to keep United Nations Population Fund (UNFPA) Country Directors and family planning decision makers up-to-date on current contraceptive research findings and reports. The abstracts reflect the content of the selected articles and do not constitute endorsement by PATH of the conclusions or methodology. *Current Abstracts* is funded by UNFPA.

Program for Appropriate Technology in Health (PATH) and Program for the Introduction and Adaptation of Contraceptive Technology (PIACT) are nonprofit, international organizations dedicated to improving health, especially the health of women and children in developing countries. PATH will provide a full copy of any article abstracted in *Current Abstracts* to readers on request. Send requests to *Current Abstracts*, PATH, 4 Nickerson Street, Seattle, Washington 98109-1699, U.S.A.

injectables : immaculate contraception ?



COUNTERFACT NO. 3 A CED HEALTH CELL FEATURE MARCH 1983

"Look after the people and the population will take care of itself" was the slogan adopted at the Bucharest conference in 1974, the World Population Year---a slogan which tacitly admitted that the "population explosion" was **not** the cause of poverty but a symptom of it. Without a back-up system of improved socio-economic conditions, it was recognised that the mere availability of contraceptive facilities could make a small family **possible** but not necessarily **desirable.**

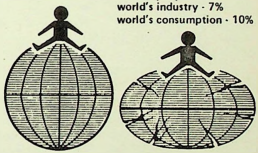
Seminars and slogans notwithstandings. well-entrenched myths still flourish and influence national and international attitudes, policies and measures adopted to tackle the population problem. In recent years, however, the subject of population control and the use and abuse of contraceptives has generated increasing popular attention and controversy, raising a host of relevant questions and focussing on a number of vital inter-related issues.

These include the intrinsically unequal First World — Third World dynamic, the enormous amounts of aid funnelled from developed countries to developing countries through international agencies, and the Western attitude towards what is considered a "Third World problem" rather than a consequence of the international economic order. Also, attention has been focussed on the dumping of unsafe contraceptives by the West on the Third World, and the use of Third World women as guinea pigs to test new and untried contraceptives. Finally, with rapid technological advances, the contraceptives coming into vogue today reveal the growing lack of control women, the world over, possess over their bodies.

In the Industrialised World

THE CONSUMPTION EXPLOSION

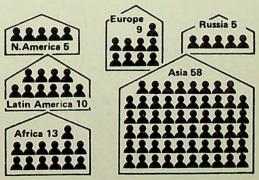
THIRD WORLD HAS .. world's people - 70%
world's industry - 7%
world's consumption - 10%



Each child born in industrialised world consumes 20 to 40 times as much as child born in developing world. So small population increase in rich world puts 8 times as much pressure on world resources as large population increase in poor world.

... and

IN THE GLOBAL VILLAGE 2000AD



If the world in the year 2000 is imagined as a global village of 100 people, then 58 of these people will be Asian, 13 will be African, 10 Latin American, 9 European, 5 North American and 5 Russian.

In this context it is important to differentiate between birth control and population control. The former is "about people deciding to exercise control over their own fertility. Population control means that fertility is controlled by the decisions of outsiders, national govts, religious bodies, international agencies and, on a limited scale, doctors and social workers..." (1)

The latest "miracle contraceptives" being touted as the best are the injectable contraceptives (ICs) better known by their brand names Depo Provera and Norigest. Like all miracles these too need to be examined more carefully.

In January of this year, Dr. Badri Nath Saxena, deputy director general of the Indian Council for Medical Research (ICMR) announced in press releases in several national dailies, that a new IC had been successfully tested on 2,600 women in 14 centres around the country.(2) The IC tested was norethisterone enanthate or NET-EN which is marketed mainly by the German multinational Schering and costs between Rs. 27 and Rs. 45 per injection (according to a report in the Feb. 15 issue of India Today, the ICMR has been told by the government "that prices can be reduced substantially once the drug is mass-marketed"). The Institute for Research in Reproduction (IRR) in Bombay, affiliated to the ICMR, is also conducting further trials of NET-EN. Unfortunately, even preliminary results are not available to the public. (3)

In the absence of sufficient information on NET-EN and its research in India, this issue will discuss ICs in general. It will focus primarily on DP, as this is the most well-documented IC today. DP has not been officially sanctioned by the Indian government, but has been used sporadically by private family planning workers in various parts of the country. The example of DP, as we shall see later, does raise questions about the use of ICs in general and will be particularly relevant, once ICs receive the green signal from the Indian government.

What Are Injectable Contraceptives?

Injectable contraceptives are progestogens -- synthetic compounds with the effects of the natural female hormone progesterone (it prepares the uterus for the fertilised ovum and maintains pregnancy). Developed in the early '50s, the first progestogens metabolised quickly, and were effective only when given in small, frequent doses. Thus in the early '50s when Dr. George Pincus, an American scientist, and his colleagues experimented with using these progestogens for fertility control, they concentrated on developing oral contraceptives.

In 1953, Dr. Karl Junkman discovered that certain progestogens have long-lasting effects when injected. His research group synthesized norethisterone enanthate (NET-EN), which is produced by Schering AG a West German pharmaceutical company. It is marketed under the brand name Norigest and will be available for family planning agencies under the brand name Noristerat.

Schering AG began testing Norigest in 1957. Major field trials were conducted in Peru, but other studies were conducted in Egypt, Europe and elsewhere. Norigest was first marketed in Peru in 1967 but was withdrawn four years later because of toxicologic findings in rats. (Since then some researchers have maintained that the results of trials on rats were not necessarily applicable to humans). (4)

At the same time as Schering was experimenting with Norigest, the Upjohn company in the USA developed Depo Medroxyprogesterone Acetate (DMPA), which is marketed under the brand name Depo Provera (DP). Upjohn began clinical trials of DP in 1963 and by the late sixties had begun marketing it in several countries.

How Do They Work?

Injectable progestogens like Depo Provera and Norigest prevent pregnancy in four ways :

a) by inhibiting ovulation;

b) by changing the texture of the cervical mucus and making it thicker, thus forming a barrier to sperm;

c) by making the lining of the uterus (endometrium) less suitable for the implantation of fertilized ovum (because the natural hormonal balance is altered); and

d) by decreasing the rate of transport of the ovum through the fallopian tubes to the uterus.

Depo Provera depends largely on its ability to prevent ovulation; while Norigest works by thickening cervial mucus, not necessarily by preventing ovulation. This is probably because the two injectables are derived from different sources: Depo Provera is derived from a compound structurally similar to progesterone while Norigest is structurally similar to testosterone (a hormone secreted by the testes.)

THE CASE OF DEPO PROVERA

Depo Provera is the more widely used of the two injectable contraceptives (ICs) currently available. A report in the World Health Organization's (WHO). World Health estimates that it accounts for about 98% of the ICs used in the world. (5) DP is used in more than 80 countries including France, Sweden, West Germany and Norway, some of which are countries usually credited with being particularly vigilant about the safety of drugs. Within the Third World, DP has been used extensively in Asia, especially in Thailand and Bangladesh. It has also been an essential component of family planning programmes in Africa and Latin America.

In recent years, the use of DP has become highly controversial and campaigns to restrict and even ban it have sprung up in several countries. The central issue at stake is the balance between the safety of DP and its benefits.

The Benefits

For a start, injectable contraceptives like DP are highly effective. In Population Reports, a bulletin of the George Washington University Medical Centre, the authors of "Injectable and Implants" claim that IC's are as effective in preventing pregnancy as the Pill, and slightly more effective than progestogen-only "mini pills" and markedly more effective than Intra-Uterine Devices (IUDs). When pregnancies do occur, they do so shortly after the first injection, when the ICs have not yet taken full effect or just before the end of the effective period of 3 months.(6)

DP is also easy and quick to administer. All it takes is an injection every 3 months. Besides, in most of the Third World, including India, injections are considered the best form of medicine. Thus women are by no means averse to the idea of an I.C. In fact, they even welcome it. Population control agencies have heavily endorsed the use of DP and other ICs. The International Planned Parenthood Federation (IPPF) describe ICs as the "most dependable and useful method of family planning".(7) But what are the medical side-effects?

Side-Effects

The whole issue of DP's side-effects continues to be hotly debated. Two distinct "camps" have developed. One **for** and the other **against.** Those in favour of DP comprise the drug corporations like Upjohn, population control agencies like the IPPF, the medical advisory panel of the U.S. Agency for International Development (USAID), the WHO, the American College of Obstetrics and Gynaecology and doctors who for years have been using DP in their family planning programmes. Those against DP include the Washington based Health Research Group (affiliated to Ralph Nader), the National Women's Health Network and other health activists and feminist groups.

The main problem, as far as the debate is concerned, is that there have been very few studies on the long-term effects of DP. In the words of Robert N. Hoover, Deputy Chief, environmental epidemiology, American National Cancer Research Institute, "There is essentially no good epidemiological study of Depo Provera to date".(8) Most of the limited research on DP has been conducted by the "camp" **for** DP, and its opponents claim that as a result, the studies have been biased in favour of the drug.(9) Furthermore, DP's opponents allege that access to research reports on DP and its side-effects is controlled by DP supporters.(10) This only makes any assessment of DP's side-effects more difficult.

The following are some of the side-effects, unearthed by various studies.

1. MENSTRUAL CHAOS : DP disrupts menstrual patterns of most users.

Bleeding problems of varying degrees, from light spotting to heavy bleeding and even complete absence of bleeding (amenorrhoea), have been reported. Nash has reported that "as many as 11 to 30 days with bleeding are seen in a month in 10 to 35 percent of patients in the first months of use."(11) Apart from the inconvenience, increased bleeding can result in or even exacerbate anaemia in women. (This would be particularly dangerous for Indian women as most of them are anaemic.) Also, in many countries where menstruation is considered unclean, there are all kinds of taboos and practices that separate women from the family during their periods. Thus constant bleeding becomes a tricky socio-cultural problem.

After about a year of using DP, amenorrhoea becomes a problem. According to one estimate, amenorrhoea appears in upto 60% of users.(12)Family planning workers explain that amenorrhoea is not a harmful side-effect :

> "We explain that these side-effects are not harmful. Sometimes they believe us and sometimes they do not listen. The women are always worried about amenorrhoea and menstrual disorders. They say that they really have a problem to go on with their activities."(13)

While amenorrhoea is not considered harmful, there is very little in the medical literature regarding the effects of long-term DP-induced amenorrhoea. As Toppozada points out :

> "Very little is known about the possible risks induced by cycle alterations caused by DP...The impact of prolonged amenorrhoea upon the health of users is poorly understood. What would the cycle alterations impose upon the state of health among women with endemic diseases or with metabolic disorders is another unresolved question.... There is a paucity of information regarding any metabolic disturbances or hormonal changes related to prolonged amenorrhoea".(14)

Disruption in the menstrual cycle often necessitates the administration of additional drugs to combat side-effects. Frequently, estrogen is given to women in order to control the bleeding. Some doctors even use it routinely with every shot of DP. In her article "Depo-Provera : the extent of the problems", Jill Rakusen has noted that "whatever the regimes given the use of DP becomes increasingly questionable when another potent drug with its own potential side-effects is used to combat those of the first drug, particularly when : (a) the women concerned had no need of drug treatment in the first place; and (b) the promoters of the first drug - DP - argue that it is valuable precisely because it is not considered to be implicated with the same risks as oral contraceptives containing oestrogen".(15)

2. INFERTILITY : While the long term effects of DP on fertility have not been adequately researched, several health workers and researchers have reported a delayed return to fertility through use of DP. A study quoted in Population Reports of 144 women who discontinued DP in order to get pregnant, revealed that the "median time to conception was 13 months from the assumed end of contraceptive protection". By comparison, the median time of conception after discontinuing the use of the IUD or diaphragm is 2 months.(16)

Fertility studies from Chieng Mai, Thailand, the centre of one of the biggest

DP projects, have shown that "while there is a delay in the return of fertility among women discontinuing Depo use compared to IUD users, by 24 months after discontinuation there is no significant difference between the two groups in the proportion of women who have become pregnant. Unpublished data from the study suggest that the same is true when Depo users are compared to pill users".(17)

As there is not enough research and documentation on the effects of DP on fertility, several countries and organisations that have endorsed DP have placed restrictions on its use. For example, the WHO and the IPPF have advised that women who have not yet completed their families should not be given DP. (18)

3. CANCER :

a) Breast Cancer : A seven year beagle study sponsored by the Upjohn company itself first raised alarms about potential breast cancer risk. It was found that beagles given a high dose of DP developed breast tumours. Subsequently these results were dismissed by DP's promoters who argued that (1) The beagle studies were of no relevance to humans because the dogs were given high doses of DP not comparable to those given to women and (2) beagles are an inappropriate species for comparison with humans, because they are known to be susceptible to certain progestogens and to mammary tumours.

It is true that beagles are especially susceptible to mammary tumours.(19) But, as the Health Research Group has pointed out, "if no problems were shown up in these beagle studies, few would be arguing that the animals used were inappropriate".(20)Based on the beagle studies, the American Federal Drug Administration (FDA) withdrew its approval in 1970 of "Provest", a contraceptive pill marketed by Upjohn containing the same hormone, DMPA, as DP. Yet curiously the drug in its injectable form was not banned in the U.S. till 1978.(21)

Much of the research on breast cancer and DP is not freely available. However, even Upjohn concluded in 1973 that more research was necessary before ruling out the risk of breast cancer.(22) The beagle study has been repeated by Upjohn and its results have probably been released to the FDA, which is currently reviewing its ban on DP in the U.S.(23)

b) Cervical cancer : There is some evidence that DP users face a higher risk of cervical cancer than non-users.

Upjohn conducted a study on the incidence of cervical cancer among DP-users. When this was compared to the findings of the American Third National Cancer Survey, it was found that the cervical cancer rate among DP-users was three to nine times higher than that of the general population recorded in the National Cancer Survey. DP supporters criticized the above finding, arguing that the incidence of cervical cancer in the general population is often under-reported, because unlike DP-users, they do not undergo regular cervical smear tests to check for cancer (DP-users are generally advised to check regularly for cervical cancer by taking smear tests).

However, Anita Johnson of the Health Research Group claims that Powell, a scientist who conducted the original Upjohn studies on cervical cancer, compared the incidence of cervical cancer in DP-users and the "general population" in his hospital and although he had screened the letter for cancer, he still found a higher incidence among DP-users. (24)

c) Endometrial Cancer (cancer of the lining of the uterus) : In 1978, Upjohn released a 10-year study on 52 rhesus monkeys that had been divided into four treatment groups :

i) 16 monkeys given DP doses 50 times the amount given to humans
ii) 16 monkeys given DP doses 10 times that given to humans
iii) 4 monkeys given the same doses as that given to humans
iv) 16 monkeys given no DP at all - the control group.

After 10 years, 2 of the monkeys in group (i) had endometrical cancer. However the authors of a booklet that campaigns for a ban on DP have written:

> "A less widely circulated critique of the monkey studies has revealed that two years after the project began, the animals in the group receiving mid and high doses of the drug had abnormally protruding clitorises. Three out of the sixteen monkeys in the high dose group were dead (N.B. not from cancer), compared to one which died in the control group. These 3 monkeys in the high dose group **were replaced with fresh monkeys** more than a year and a half after the start of the experiment". (25)

As in the case of the beagle studies, there has been much dispute on the question of using monkeys to assess cancer risk in humans. Upjohn (as also the WHO) has criticized its own monkey studies asserting that monkeys' reaction to progestogens differs from women's reactions.

4. FOETAL ABNORMALITY : Certain progestogens when given in large doses causes masculinisation of external genetalia of female foetuses. No such effect has been reported in humans with doses of DP as high as 400 mg or with Norigest, although large doses of DP has caused masculinsation in rat and rabbit foetuses.(26)

In their article in the May 1982 issue of WHO's magazine World Health, Hall and Holck have written that "it appears that physical growth and development (of children of DP-users) proceed normally at least upto 13 years of age". They have also noted that "a limited amount of information suggests that there is no increase in the incidence of congenital abnormalities among children exposed in utero to contraceptive doses of Depo or NET-EN".(27) At the same time, Hall and Holck have stressed the need for more long term research.

5. EFFECT ON LACTATION : There is apparently no effect on children exposed to DP or NET-EN via breast milk, although the drugs and their bi-products can be found in breast milk. (28)

6. OTHER SIDE EFFECTS : These include headache, backache, abdominal

discomfort, nervousness, dizziness, depression, decreased libido, weight gain, nausea, fatigue and diarrhoea.

What emerges from this brief discussion of DP's side-effects is that there is considerable uncertainty and dispute about the safety of the drug. In the cases of cancer and infertility, in particular, no definitive claims can be made either for or against DP. Perhaps the current information regarding the safety of DP is best summed up in the WHO's report on the drug:

"...Studies thus far have not shown any serious short or long-term effects of DMPA or NET-EN. However, both DMPA and NET-EN have been used for a relatively short period of time, and the potential long-term effects (more than 15 years) are not known. With regard to metabolic effects the areas in which research should continue are on the effects and physiological consequences of long-term use of DMPA and NET-EN on carbohydrate and lipid metabolism. In addition further research is needed regarding the risk of neoplasia among women using DMPA or NET-EN. Finally, the effects on the later development of infants who are exposed to DMPA or NET-EN in utero or through breast milk are not known. Research should continue in these areas..."(29) (N.B : lipids are fats and fat-like substances in the body; neoplasia are any tumours).

However, the same report concludes that DMPA or NET-EN "appear to be acceptable methods of fertility regulation. Clinical evidence from more than 15 years of use as contraceptive agents shows no additional and possible fewer adverse effects than those found with other hormonal methods of contraception..."(30) It also adds that the high effectivity and the reversibility of the two injectables makes them particularly advantageous for fertility regulation.

This view is held by countless others also who argue that virtually all contraceptives have side-effects and that ICs are "the best of the bad lot". Many also assert that in nations where thousands of women die every year at childbirth or because of unwanted pregnancies, it is absurd to condemn ICs like DP on the grounds of an unproven cancer risk that at most will affect a handful of women.

These and other arguments advanced for the use of ICs will be discussed in the final section of this issue. But first, let us take a look at what is perhaps the most dangerous "side-effect" of ICs like DP - their misuse, by those who are in a hurry to achieve their population control "targets".

Injectable Contraceptives & Social Control.

The problems connected with ICs go far deeper than an awareness of their medical side-effects. As we shall see in this section, the potential for abuse of ICs is a particularly nasty "side-effect" and one that has already surfaced in countries where DP has been used.

In her article in Women, Health and Reproduction, Helen Roberts has noted

that there are several interest groups in the birth control empire, the least powerful of which are the women using contraceptives.(31)A major disadvantage of ICs is that they take fertility control out of women's hands and into the hands of the medical profession, social workers and population control agencies. The participation of women in regulating their own fertility is limited to being passive recipients of an injection.

This is particularly dangerous, because in most of the Third World, including India, injections are considered to be the best form of medicine. Injections are increasingly seen as the panacea for all ills. Thus there will be little difficulty in promoting the belief that because contraceptives like DP and Norigest are injectable, they must be good.

Considering these facts, it is not surprising that population control proponents have been most enthusiastic about ICs. The IPPF, a major distributor of DP, has been one of the most vocal promoters of the drug.(32)

Besides, injectables are good business. According to market analyst Arnold Snider of Kidder Peabody and Co. in New York, the value of DP sales has already reached about $25 million. He has said that "oral and injectable methods have an incredible profit margin" and that they are "among the most profitable of all pharmaceuticals". (33) Without question, the biggest market potential for contraceptives is in the Third World. There is already evidence that drug corporations like Upjohn have been aggressively marketing ICs abroad. Rakusen writes :

> "In a deposition unearthed by Minken (1979), the manufacturers of DP admitted paying $ 2,710,000 in bribes to employees of foreign governments and to their intermediaries for the purpose of obtaining sales to government agencies. Bribes to hospital employees raised this total to $ 4,098,000, and further $ 147,579 was paid out 'in connection with foreign governmental actions related to the company's business'. Upjohn's deposition specifically notes that the above figures exclude 'small amounts which were paid to minor government employees to expedite governmental services'. (34)

Supporters of DP often claim that it is very easily accepted by women who want contraception. They argue that women eagerly choose DP. But as we have seen above, there are several powerful interests actively and aggressively promoting DP and this must be remembered when discussing "free choice" and DP's high acceptability. Moveover, various studies have shown that women's "choice" of contraceptives is largely determined by those responsible for giving out contraception. In Studies in Family Planning the results of WHO-sponsored research on women's choice of contraceptive methods revealed that "in India and Korea, 68% of women choosing Depo-Provera said that the individual providing the balanced presentation was the most important person influencing their choice."(35)

On the question of choice and informed consent, already several abuses have been reported in countries where DP has been used. Bonnie Mass cites the

case of a Black woman in the U.S. who was threatened with the loss of her social security money if she did not accept the drug. Further, a young girl from Scotland was given DP under the guise of a glucose injection and finally there is the case reported by the campaign against DP of, a young Black girl in London who was given an injection of DP without her knowledge, while she was under a general anaesthetic having an abortion. (36)

Of the women whose consent is obtained, it is doubtful whether they are given the full details of possible side-effects. Again in Britain, there have been several cases of Asian women who were not told about side-effects such as bleeding.

It is certainly not fanciful to suggest that such abuses of ICs might well occur in India. Already there have been instances of abuse of other contraceptives. In a recent conference on sexism in the Indian health care system, several delegates reported that IUDs have been inserted without the consent of women who were undergoing abortions. Then why single out ICs for attack? Obviously the misuse of any method of contraception, and denying women the right to free choice, is totally unacceptable. We should certainly press for a close monitoring of all birth control methods currently in use. But a particularly disconcerting feature of the injectable method is the ease and speed with which it can be administered (this is often cited as a benefit of DP), and thus misused by population control agencies and the state, even if this endangers women's health. All of this indicates that while ICs seem to be the "best of the bad lot" compared to other contraceptives, the potential for misuse is also the greatest.

It may also be true that our maternal mortality rate, outweighs the possible cancer risk due to the use of ICs. But, surely we should be pressing for improvements in our health care system, instead of introducing a drug about which several questions remain.

Another strong case for injectables is that put forth by Dr. Hari John, a well-known figure in the community health field in India :

> "DP is the most popular choice that women in South India make. Women in South India choose DP because they are totally deprived, and have no say in any aspect of their lives ... if they want contraception their husband accuses them of wanting extra-marital sex. Most forms of contraception are very difficult to hide, and DP is the only one their husbands won't know about. Using DP is the only way these women can have control over any aspect of their lives."(37)

Dr. John has pointed out a very real problem faced by millions of Indian women today. No doubt at first glance injectables seem to be the perfect answer -- at least in the short-term. But in the long-term, this solution does nothing to question the real problem underlying the attitudes she discusses : the unequal relationships between women and men in our country. And in fact by failing to challenge these relationships, ICs used under the conditions she describes might even buttress the sexist status quo.

From this discussion, it is clear that ICs are not the "miracle contraceptives" some people would have us believe. And focussing on the medical side-effects, as yet shrouded in controversy, can distract our attention from some important questions that remain unanswered. Should we be developing methods that are easier, faster and more convenient for those whose main interest is to control the swelling numbers of the Third World? Or should we be developing new techniques that are safe and involve women in controlling their own fertility? Why is there so little research on the safer barrier methods of contraception, such as the diaphragm and the cervical cap? And why is all contraceptive research directed at women, though it is men who are more sexually dominant? Are women alone condemned to accepting full responsibility for contraception?

Instead of blithely accepting any new contraceptive method developed in the West, it is time population control proponents stopped to confront some of these issues.

NORIGEST AND DEPO PROVERA

	Norigest	Depo Provera
1.	Derived from compound structurally similar to testosterone	Derived from compound similar to progesterone.
2.	200 mg given at 84-day intervals.	150 mg given at 90-day intervals.
3.	Works largely by altering nature of cervical mucus	Works largely by inhibiting ovulation.
4.	Pregnancy rate higher than DP *	Lower pregnancy rate than Norigest. *
5.	Some evidence that it disturbs menstrual patterns less than DP. *	Causes considerable disruption of menstrual patterns - more than Norigest. *
6.	After discontinuation, return to fertility quicker (3-6 months after discontinuation) than in DP's case. *	After discontinuation, return to fertility slow (13 months after discontinuation) than in Norigest's case. *

* From Population Reports, Series K, Number 1, March 1975.

References

(01) Campaign Against Depo-Provera, "Depo Provera", p. 39.

(02) India Today, Feb. 15 issue, p. 79-81.

(03) When we visited the IRR, we were told that no information on NET-EN could be released.

(04) "Injectables and Implants", Population Reports, Series K, Number 1, March 1975, K-2.

(05) Hall, Peter E. and Holck, Susan E., "Injectable Contraception" in World Health, May 1982, p. 2.

(06) Population Reports, Op. cit., K-3-K-4.

(07) "Factsheets" on Depo Provera, International Planned Parenthood Federation (1978), as quoted by Jill Rakusen, "Depo-Provera : the extent of the problem", in Women's Health & Reproduction (ed) Helen Roberts, Routledge & Kegan Paul, London, 1981.

(08) Sun, Marjorie, "Depo-Provera" Debate Revs Up at FDA" in Science, Vol. 217, 30 July 1982, p. 426.

(09) Rakusen, Jill, "Depo-Provera : the extent of the problem" in Women, Health & Reproduction. (ed) Helen Roberts, Routledge & Kegan Paul, London, 1981, p. 83.

(10) Ibid., p. 94.

(11) Nash, H.A., "Depo-Provera - a Review" in Contraception, Vol. 12, No. 4, p. 377-93.

(12) Benson Gold, Rachel and Willson, Peter D., "Depo-Provera : New Developments in a Decade Old Controversy" in International Family Planning Perspectives, Vo. 6, No. 4, Dec. 1980, p. 158.

(13) Ali, Azam, Hussain, Zahid and Cohen, Nicholas "Results following the uses of Depo-Provera injection in the River Project", Save the Children Fund (UK) in Bangladesh, p. 4.

(14) Toppozada, M, evidence to U.S. Select Committee on population House of Representatives, as quoted in Rakusen, Op. cit., p. 88.

(15) Rakusen, Op. cit. p. 88.

(16) Population Reports, Op. cit., K-8.

(17) Benson Gold, Rachel and Willson, Peters D., Op. cit., p. 157.

(18) Population Reports, Op. cit., K-12 ;
Hadley, Janet, "The contraceptive injection some things you should know about it", leaflet issued by the Campaign Against Depo-Provera, p. 8.

(19) Rakusen, Op. cit., p. 93.

(20) Ibid.

(21) Campaign against Depo-Provera, Op. cit., p. 8.

(22) Rakusen, Op. cit., p. 94.

(23) Newsweek, January, 24th 1983, p. 44.

(24) Campaign Against Depo-Provera, Op. cit., p. 9.

(25) Campaign Against Depo-Provera, Op. cit., p. 10.

(26) Population Reports, Op. cit., p. K-9.

(27) Hall and Holck, Op. cit., p. 3-4; My brackets.

(28) Ibid; Population Reports, Op. cit., p. K-12.

(29) Hall and Holck, Op. cit., p. 4.

(30) Ibid., p. 4.

(31) Roberts, Helen, "Male hegemony in family planning" in Women, Health & Reproduction, (ed) Helen Roberts, Routledge & Kegan Paul, London, 1981.

(32) See note (7)

(33) Sun, Op. cit., p. 428.

(34) Rakusen, Op. cit., p. 78.

(35) "User Preferences for Contraceptive Methods in India, Korea, the Philippines, and Turkey" in Studies in Family Planning, Vol. 11., No. 9/10, September/October 1980, p. 271.

(36) Rakusen, Op. cit., p. 80-84.

(37) Smith, Carol, "Depo-Provera, control of fertility - two feminist views." in Spare Rib, No. 116, March 1982, p. 51.

ABOUT CED

The Centre for Education & Documentation (CED) is an independant non-profit organisation involved in research-cum-action oriented programmes, catering to the need of scholars, professionals, students, development workers and other concerned individuals.

Established in 1978, and registered under the Societies and Public Trusts Acts, the CED collects, collates researches and disseminates information on a wide range of subjects of social importance.

Besides conducting and initiating independent studies, the CED organises seminars and workshops on related topics and houses a library of books and a collection of clippings from a wide spectrum of newspapers, magazines, journals, both from India and abroad.

Above all, the CED provides a focal point for like-minded individuals and groups to interact with one another in order to relate theory to experience and action, in their respective areas of involvement.

THE CED HEALTH CELL specialises in documentation and dissemination of information concerned with health issues. It is in touch with other similar groups in various parts of the country.

Our address : Centre for Education & Documentation,
3, Suleman Chambers,
4 Battery Street,
Behind Regal Cinema, Tel : 220019
Bombay 400 039.

(Open 11.00 a.m. to 7.00 p.m. on weekdays. Fridays 11.00 a.m. to 2.00 p.m.)

Courtesy

NEW INTERNATIONALIST
62a High Street
Wallingford
Oxon OX10 0EE

WH 3.48

NEW INJECTABLE CONTRACEPTIVES -

INDIAN WOMEN DESERVE A BETTER DEAL

A campaign group has been formed in Bombay to protest against the Drug-controller of India approving NET-EN as a contraceptive. Two companies - UNICHEM and GERMAN REMEDIES - have been given licences to manufacture this drug.

Today's protest demonstration in front of Oberoi Towers, where the Family Planning Association is holding a closed door conference of 'experts' on NET-EN. We plan to continue with the campaign and expand it to include all long-acting contraceptives.

What are Injectable Contraceptives? Injectable Contraceptives (I C) prevent pregnancy more or less in the same way as oral contraceptives. But they are administered by injection and are long-acting. The best-known ones are Depo-provera and NET-EN. Depo needs only one injection every 3 months and NET-EN one every 2 months.

Population control enthusiasts consider injectables the ideal form of contraception for women in the third-world because of the ease with which they can be administered on a mass-scale and the low failure rate. To those who look at women in the third world as nothing but faceless factors to be considered in any strategy of population control they cook up, the benefits seem overwhelming and the 'risks' in terms of women's health negligible. There has been a concerted campaign lately to 'sell' the idea of I Cs through the media and elsewhere. The conference organised by the Family Planning Association on 28th and 29th December 1984 at Oberoi, is part of this 'marketing strategy'.

Depo-provera and NET-EN -the controversial contraceptives...

Depo-provera has been the centre of a fight between Health groups and women's groups on the one side and Pharmaceutical companies on the other since the sixties, when the Upjohn Co. of U S A sought approval for it in the sixties. Upjohn has fought a hard and long battle in the U S unsuccessfully. They desparately wanted approval before their exclusive rights on the drug expired. The campaign in the U S and elsewhere brought Depo-provera a 'bad name'. Approval for its manufacture has not been given by the Drug-controller of India. But neither has any explanation been given to the public or to interested groups about why it has not been approved. Meanwhile, NET-EN another I C about which not much is known has been approved in India and licence to manufacture it has been granted to two companies - Unichem and German Remedies.

Both Depo-provera and NET-EN have been used in India for several years now for research purposes. This research has been carried out maily on poor women by voluntary agencies who conduct community health programmes, under the supervision of the Indian Council of Medical Research. The reports of the studies have not been published till today

and ICMR has refused to make it available to anyone. All interested parties are supposed to take their word for it that while Depo is not so good, NET-EN is just fine. Past experience with contraceptives and other drugs does not inspire in us any such trust or confidence. We believe that we have a right to know the details of the research studies, to make our own investigations and to come to our own conclusions. We do not consider the masses of women mere pawns in population control strategies to whom contraceptives are 'sold' on the basis of incentives without prior information.

What we do know about ICs is quite disturbing. Upjohn Co., conducted two animal safety studies in the sixties - a seven year one on beagle dogs and a ten year one on monkeys. Within three and a half years of the dog study, all dogs on high doses and half on low doses were dead due to inflamation of uterine lining. (The two on low doses who survived had their uteruses removed.) All control dogs and survived except one which died of bite wounds and four which were sacrificed by the researchers. The dogs also developed cancer of the breasts, drug-induced diabetes and various other problems. At this point, Upjohn declared that beagle dogs were not the ideal animals to judge risks to human females. Later even the monkey studies in which cancer of the uterus occured were said to be 'irrelevant to human experience'. The history of this controversy has been marked with disinformation and a desparate desire on the part of the company to maximise profits without making sure first that the drug is safe.

Breast cancer, two types of uterine cancer, serious menstrual disturbances and masculinisation of female foetuses are some of the serious effects of Depo-provera. Others are depression, decreased libido, nausea, dizziness,(weight gain without any increase in nutrition)etc.

The W H O report on I Cs (1982) says that the majority of women on I Cs have their menstrual cycle disrupted. The extent of disruption is stunning. "Less than one third of women on Depo report having any normal menstrual cycle during the first year of usage' and 'approximately half the users (of NET-EN) reported at least one normal menstrual cycle during the first year'. Both the above quotes from the W H O report are examples of the concerted attempt to underplay the dangers of I Cs. In fact a significant number of women stop having their periods only to have severe bleeding after injections are withdrawn while others bleed every day of the month while on the drug. But everyone concerned seems to feel that it is a minor side-effect. For Indian women who hold the world record for anemia, it is a very very significant side effect.

There is far less information available about NET-EN on human metabolism, on infants exposed to them through breast-milk or about their carcinogenic properties. No one seems to know why the majority of women on these drugs suffer from menstrual chaos. No do they know why these women put on weight without more nutrition or why they are depressed.

Yet the advocates of I Cs, including the W H O, consider them an ideal form of contraception. Their favourite phrase is risk-benefit ratio. According to them if the benefit outweighs risk, the drug should be used.

But the risks are taken only by women. The benefits are mainly for the pharmaceutical companies, the population control experts and the Governments of third world countries.

There is a lot that is wrong with our family planning policies. Its always our families and their plans. A beginning must be made somewhere to correct them. Lets start with the newest strategy which is about to be imposed on the masses of Indian women. Lets struggle against the inundation of this country with I C S.

OUR DEMANDS: 1) Ban all long-acting contraceptives and withdraw approval for NET-EN.

2) Make public all studies in India on Depo and NET-EN. immediately.

3) Stop exporimonting on third world women with hazardous drugs and contraceptives.

4) Institute a public enquiry on the controversial injectable and implanted contraceptives.

JOIN US IN OUR STRUGGLE FOR A BETTER DEAL FOR OUR WOMEN.

Campaign group against long-acting contraceptives.

1. Forum Against Oppression Of Women.
2) Women's Centre, Bombay.
3) Medico-friends' Circle.
4) Stree Mukti Sanghatna
5) Sangharsh Vahini.

Current Abstracts
focus on contraceptive research

UNFPA PATH

Volume 3, Number 2/April 1990

Oral Contraceptives

Vessey, M.P. et al. Mortality among oral contraceptive users: 20 year follow-up of women in a cohort study. British Medical Journal, Vol. 299, No. 6714, December 16, 1989, pp. 1487-1491.

This British cohort study involving 17,032 women who were followed up annually for an average of almost 16 years found no overall effect of oral contraceptive (OC) use on mortality. Women entered the study from 1968-1974 when they were age 25-39 and using either OCs, a diaphragm, or an IUD. The overall relative risk of death among OC users compared with diaphragm/IUD users was 0.9. Although the number of deaths in specific disease categories was small, trends were generally consistent with other reports, with relative risks for OC users compared with diaphragm/IUD users as follows: cervical cancer, 4.9; ischemic heart disease, 3.3; ovarian cancer, 0.4; breast cancer, 0.9. The value for breast cancer may have been affected by the fact that few women in this study began using OCs before age 20. The relative risk of circulatory disease among OC users was 1.5, while the corresponding relative risk from a large 1981 British cohort study of long-term OC use was 4.2. While these results support the view that the risk reported in 1981 may have been overestimated, women in this study showed a low overall mortality and thus may not represent the general population.

Wolner-Hanssen, P. et al. Decreased risk of symptomatic chlamydial pelvic inflammatory disease associated with oral contraceptive use. Journal of the American Medical Association, Vol. 263, No. 1, January 5, 1990, pp. 54-59.

This U.S. case-control study investigated the relationship between OC use and pelvic inflammatory disease (PID) and found that, among women already infected with *C. trachomatis*, OC users were at decreased risk of symptomatic PID compared with non-users. Study cases were 141 women with verified PID and controls were 739 randomly selected, sexually active women with no clinical evidence of PID. Overall, cases were significantly less likely to have used OCs than controls (odds ratio, 0.50). The negative association between OC use and PID was stronger when women infected with only *C. trachomatis* were considered separately. Among these women, the odds ratio between OC use and PID when compared with non-use of OCs was 0.22 and when compared with use of no contraceptive method was 0.17. In general, these associations remained the same when analyses were adjusted for potentially confounding variables including age, race, etc. In contrast to two earlier studies, no association was found between use of OCs and PID among women infected with only *N. gonorrhoeae*.

Sterilization

Koetsawang, S. et al. Long-term follow-up of laparoscopic sterilizations by electrocoagulation, the Hulka clip, and the tubal ring. Contraception, Vol. 41, No. 1, January 1990, pp. 9-18.

This study examining the long-term effects of female voluntary surgical contraception (VSC) found a cumulative eight-year pregnancy rate of 1.5%, with pregnancies occurring as late as seven years after the procedure; 75% of the pregnancies were ectopic. The study also found that the need for hysterectomy among VSC acceptors was unrelated to VSC or to tubal occlusion technique. Some 70% of women who had VSC at least 42 days after delivery at a Bangkok hospital from 1973-1976 returned for follow-up 4-12 years after the procedure. Of these 499 women, 42% had had electrocoagulation,

37% had used a Hulka clip, and 21% had used a tubal ring. Four pregnancies were confirmed, all occurring between two and seven years following VSC: three ectopic pregnancies in the electrocoagulation group and one uterine pregnancy in the Hulka clip group (no pregnancies occurred in the tubal ring group). Because pregnancies occurred as late as seven years following VSC, the authors concluded that short-term failure rates for female VSC probably do not represent actual failure rates. Other conditions often thought to be sequelae of VSC, including adnexal masses, pelvic infection, and various conditions requiring hysterectomy, could not be linked to VSC or to the use of a specific occlusion technique.

Long-acting Progestins

Klavon, S.L. and G.S. Grubb. Insertion site complications during the first year of NORPLANT® use. Contraception, Vol. 41, No. 1, January 1990, pp. 27-37.

First-year clinical trial data on insertion site complications among 2,674 NORPLANT® acceptors in seven countries showed that infection and expulsion rates were low, but that a substantial proportion of insertion-related complications occurred after the first two months of use. Complication rates varied widely among countries and between clinics within a country. At one year, complication rates were: insertion site infection, 0.8%; expulsion, 0.4%; local reaction, 4.7%. While most complications occurred within 60 days of insertion, some 35% of insertion site infections and 64% of expulsions occurred after 60 days; about two-thirds of these infections and expulsions were among women without insertion site complications during the first 60 days. Possible causes of later infection were (1) trauma to the insertion site causing it to open or (2) change in the immunologic environment of the implants. The authors recommended that implants be removed when infection occurs: of 16 women with infections who did not have the implants removed immediately, half eventually had them removed.

Paul, C. et al. Depot medroxyprogesterone (Depo-Provera) and risk of breast cancer. British Medical Journal, Vol. 299, September 23, 1989, pp. 759-762.

This New Zealand population-based case-control study found no overall increase in risk of breast cancer with use of the three-month injectable contraceptive Depo-Provera (DMPA), but found increased risks in users who: (1) were diagnosed with breast cancer before age 35, (2) had used DMPA for at least two years before age 25, and (3) had used it recently. Cases consisted of 891 women age 25-54 with recently diagnosed breast cancer selected from the National Cancer Registry; controls consisted of 1,864 women randomly selected from electoral rolls and matched to cases by age. DMPA had been used by 12.3% of cases and 13.5% of controls. The relative risk of breast cancer (adjusted for confounding variables) with any duration of use was 1.0. In women age 25-34, the relative risk was 2.0. For women who first used DMPA before age 25, the relative risk was 1.5. In both groups, risk was higher in those who used DMPA for six years or longer. The relative risk for women who last used DMPA within five years was 1.6; the highest relative risk in these women was associated with the shortest duration of use. For all categories of duration of use, risk declined with increasing time since last use. The authors determined that a possible explanation for this finding is that DMPA increases the risk of breast cancer only during the first few years after exposure, suggesting that it may act as a promoter during late stages of carcinogenesis. The authors commented that these results could be interpreted to mean that DMPA has an initial harmful effect, followed by a protective effect, and noted the need for additional research to clarify the findings.

World Health Organization (WHO) Task Force on Long-Acting Systemic Agents for Fertility Regulation. Microdose intravaginal levonorgestrel contraception: a multicentre clinical trial: I. Contraceptive efficacy and side effects; II. Expulsions and removals; III. The relationship between pregnancy rate and body weight; IV. Bleeding patterns. Contraception, Vol. 41, No. 2, February 1990, pp. 105-167.

The results of a large WHO multicenter clinical trial of the levonorgestrel-releasing vaginal ring showed that: (1) the ring, which releases 20 mcg levonorgestrel per day and is used for 90 days, was an effective and safe contraceptive for at least one year; (2) expulsions occurred frequently but did not necessarily lead to discontinuation; (3) pregnancy rates increased with increasing body weight; and (4) ring use disrupted menstrual bleeding patterns in about half of all users. The study, conducted from 1980-1986, involved 1,005 women at 19 centers in 13 countries, including 9 developing countries. The one-year life-table pregnancy rate with the ring in place was 3.7%. The 12-month discontinuation rate for all reasons was 50%; principal reasons for discontinuation were bleeding disturbances (17%), expulsions (7%), and vaginal symptoms (6%) (including discharge, irritation, or infection). The 12-month first expulsion rate was 29%; some 57% of first expulsions occurred with defecation. Weight was positively correlated with risk of pregnancy, with pregnancy rates ranging from 1.7% for 40 kg women to 9.8% for 80 kg women. Daily menstrual diaries kept by 70% of the women showed that approximately half experienced bleeding irregularities; of these, 25% experienced irregular bleeding, 10% had prolonged cycles, 10% had shortened cycles, and only a few experienced amenorrhea or continuous prolonged bleeding.

Intrauterine Devices

Sivin, I. IUDs are contraceptives, not abortifacients: a comment on research and belief. Studies in Family Planning, Vol. 20, No. 6, November/December 1989, pp. 355-359.

The author argues that studies on the mechanisms by which IUDs prevent pregnancy clearly demonstrate that IUDs are contraceptives and not abortifacients: IUDs appear to act primarily by interfering with fertilization. Sensitive assays to detect human chorionic gonadotropin, an early indicator of pregnancy, have been used to look for signs of early abortion among IUD users and have shown that IUD users experience the same or lower rates of embryonic loss as non-contraceptors. Microscopic searches for eggs in the Fallopian tubes and uteri of IUD users have shown that fertilization is rare with IUD use. In one case-control study, uterine searches found fertilized eggs in only 1.5% of attempts in IUD users, compared with 22% of attempts in non-users. Several studies have shown that IUD use reduces both the number of sperm that reach the oviduct and their fertilization capacity. Two large studies found a significantly lower incidence of ectopic pregnancy among IUD users than among non-contraceptors—further evidence that IUDs exert a contraceptive effect outside the uterus.

Pregnancy Termination

Harris, B.M.L. et al. Risk of cancer of the breast after legal abortion during first trimester: a Swedish register study. British Medical Journal, Vol. 299, No. 3, December 1989, pp. 1430-1432.

In contrast to most previous reports, this prospective Swedish study found no overall increase in risk of breast cancer in young women after a first trimester induced abortion. The study cohort

consisted of 49,000 Swedish women who underwent legal first trimester abortion before age 30 from 1966-1974. The women were followed using the Swedish cancer register to identify cases of breast cancer diagnosed more than five years after abortion. A comparison of observed cases of breast cancer (65) with expected cases of breast cancer (84.5) yielded a relative risk of 0.77. Women who were parous at the time of abortion had a significantly lower relative risk (0.58) than women who were nulliparous at the time of abortion (1.09). Whether this difference was due to the postponement of a first birth among the nulliparous women or to a differing effect of early pregnancy termination could not be determined from the data. The authors noted that confounding factors such as smoking and family history of cancer were not considered in this or previously reported studies.

Silvestre, L. et al. Voluntary interruption of pregnancy with mifepristone (RU 486) and a prostaglandin analogue: a large-scale French experience. The New England Journal of Medicine, Vol. 322, No. 10, March 8, 1990, pp. 645-648.

This study of 2,115 French women who terminated pregnancies using mifepristone (RU 486) plus a prostaglandin analogue found that the drug combination, as administered in France, is safe and effective for terminating early pregnancy. Only pregnancies of 49 days amenorrhea or less were included in the analysis. The drug regimen involved administration of a 600 mg oral dose of mifepristone followed 36-48 hours later by vaginal or intramuscular administration of a prostaglandin analogue. The overall effectiveness rate was 96%; pregnancies continued in 1.0% of the women and incomplete abortions occurred in 2.1%. In the remaining 0.9% of treatment failures, a vacuum aspiration or dilation and curettage procedure was used to complete pregnancy termination because of excessive uterine bleeding: one of these women required a blood transfusion. A vacuum aspiration or dilation and curettage procedure also was used to complete pregnancy termination in the other cases of treatment failure. Side effects, primarily abdominal pain and gastrointestinal complaints, were generally mild and concentrated in the 24-hour period following prostaglandin administration (when fetal expulsion was most likely to occur). The effectiveness rate was slightly higher (98.7%) and the time to fetal expulsion shorter among women given the highest recommended dose of prostaglandin (0.5 mg sulprostone). Higher prostaglandin doses were associated with more pain and longer duration of bleeding, however. The authors concluded that more research is required to optimize the prostaglandin dose and to establish criteria for selecting between pharmaceutical and surgical abortion methods.

Current Abstracts ISSN: 1012-2680

Current Abstracts is published quarterly. It features abstracts of recent articles on contraceptive methods and products selected from a large number of publications. Its objective is to keep United Nations Population Fund (UNFPA) Country Directors and family planning decision makers up-to-date on current contraceptive research findings and reports. The abstracts reflect the content of the selected articles and do not constitute endorsement by PATH of the conclusions or methodology. *Current Abstracts* is funded by UNFPA.

Program for Appropriate Technology in Health (PATH) and Program for the Introduction and Adaptation of Contraceptive Technology (PIACT) are nonprofit, international organizations dedicated to improving the availability, acceptance, safety, and continued use of health and contraceptive products in developing countries. PATH will provide a full copy of any article abstracted in *Current Abstracts* to readers on request. Send requests to *Current Abstracts*, PATH, 4 Nickerson Street, Seattle, Washington 98109-1699, U.S.A.

Current Abstracts
focus on contraceptive research

UNFPA PATH

Volume 3, Number 4/October 1989

Oral Contraceptives

Schlesselman, J.J. Cancer of the breast and reproductive tract in relation to use of oral contraceptives. Contraception, **Vol. 40, No. 1, July 1989, pp. 1-38.**

The author reviewed the results of studies published since 1980 investigating possible associations between use of oral contraceptives (OCs) and cancers of the breast and reproductive tract. He concluded that the data suggest no relationship between OC use and risk of breast cancer through age 59. For women under age 45, however, data from several studies raise questions about a possible increased risk linked to OC use before a first full-term pregnancy. OC use is associated with a duration-related protective effect against endometrial cancer: the risk is reduced by about 60% with four years or more of use. OC use also is associated with a duration-related protective effect against ovarian cancer: the risk is reduced by about 50% with four years of use and by 60%-80% with seven years or more of use. Evidence suggests that OC use is linked to a slightly increased risk of cervical dysplasia, carcinoma *in situ*, and invasive cancer. Studies of cervical cancer are difficult to interpret, however, due to their failure to control for factors that could distort findings, such as number of sexual partners.

World Health Organization Task Force on Oral Contraceptives. The WHO multicentre trial of the vasopressor effects of combined oral contraceptives: 2. Lack of effect of estrogen. Contraception, **Vol. 40, No. 2, August 1989, pp. 147-156.**

This double-blind study of 680 women age 18-34 in six countries (developed and developing) found no significant difference in the effect on blood pressure after one year of use of combined OC formulations containing either 50 mcg or 30 mcg estrogen. Results were the same for standard statistical analysis and life-table analysis. The investigators argued that their findings provided some evidence against the hypothesis that it is either the estrogen alone or the estrogen-to-progestin ratio in combined OCs that produces hypertension in some OC users. They noted that the results should be interpreted cautiously due to the relatively small sample size of the study, however. They advocated additional, larger studies to rule out minimal effects of estrogen and to investigate the relative effects of various progestins.

Of special interest A recently distributed issue of Population Reports (Series A, Number 7) provides a comprehensive report on lower-dose OCs (defined as those containing less than 50 mcg estrogen), including their effectiveness, use, benefits, and risks. A copy of the report can be obtained by contacting the Population Information Program, The Johns Hopkins University, 527 St. Paul Place, Baltimore, MD 21202, U.S.A. Single copies are provided free of charge.

Sterilization

Hapugalle, D. et al. Sterilization regret in Sri Lanka: a retrospective study. International Family Planning Perspectives, **Vol. 15, No. 1, March 1989, pp. 22-28.**

This study of 817 women from urban and rural areas in Sri Lanka who accepted sterilization between 1980 and 1983 and who received payment for undergoing the procedure found that 14%

subsequently regretted undergoing the procedure. No association was found between regret and the amount of payment received for accepting sterilization. Regret was defined as wanting to have another child or wishing sterilization had occurred later or not at all. The most important factors associated with regret were: not having one child of each sex, being under age 25, being married fewer than five years, having two children or fewer, having a husband who opposed sterilization or with whom it was not discussed, not having control over the sterilization decision, and having a child die subsequent to the procedure. The authors noted that counseling, especially for individuals with risk factors for regret, is a cost-effective means of reducing regret.

Rivera, R. et al. Menstrual patterns and progesterone circulating levels following different procedures of tubal occlusion. Contraception, Vol. 40, No. 2, August 1989, pp. 157-169.

This prospective study of 65 Mexican women whose surgical sterilization involved one of three tubal occlusion techniques found statistically significant differences in menstrual bleeding patterns associated with minilaparotomy/Yoon ring placement compared to other techniques and no sterilization. The investigators considered the differences medically and clinically unimportant, however. One year after the procedure, women whose sterilization involved minilaparotomy and Yoon ring placement (19 women) tended to have menstrual cycles lasting about 2 days longer and bleeding-free intervals lasting about 10 days longer than women sterilized by laparoscopy and Yoon ring placement (24 women), women sterilized by minilaparotomy and the Pomeroy technique (22 women), and nonsterilized women (26 women). No differences were observed between any of the groups for other bleeding characteristics, such as total days of bleeding, or for frequency of ovulation.

Rulin, M.C. et al. Changes in menstrual symptoms among sterilized and comparison women: a prospective study. Obstetrics & Gynecology, Vol. 74, No. 2, August 1989, pp. 149-154.

This U.S.-based prospective study found that tubal sterilization did not change the frequency or duration of menstrual cycles or the occurrence of between-cycle bleeding but increased the frequency with which dysmenorrhea (cramping with menses) was reported by sterilization acceptors. Perceptions of menstrual parameters were assessed before sterilization and about 10 months later for a cohort of 657 women. Perceptions of the same menstrual characteristics also were obtained twice for 956 nonsterilized women of similar age and parity. The only significant difference between the groups related to dysmenorrhea: during the second interview the sterilization group reported a net increase of almost 11%, compared to a net increase of 2% reported by the nonsterilized group. When the analysis controlled for contraceptive use that could affect bleeding events (such as IUD or OC use), differences were more pronounced. Sterilization techniques included the Pomeroy technique (used postpartum), the Falope ring, and bipolar electrocautery.

Long-acting Progestins

Thomas, D.B. et al. Monthly injectable steroid contraceptives and cervical carcinoma. American Journal of Epidemiology, Vol. 130, No. 2, August 1989, pp. 237-247.

A recent analysis of hospital-based case-control data from Chile and Mexico found little or no elevation in risk of cervical cancer among ever-users of certain monthly injectables marketed in the

two countries. The analysis was part of the World Health Organization Collaborative Study of Neoplasia and Steroid Contraceptives and was prompted by an earlier analysis of Chilean data in which a strong association (ninefold increase in relative risk) between use of these monthly injectables and cervical cancer risk was observed. The monthly injectables contained the long-acting progestin dihydroxyprogesterone acetofenide plus a shorter-acting estrogen (usually estradiol enanthate). The adjusted relative risks among women who had ever used the monthly injectables were as follows: for invasive cervical cancer, 1.31 (data from Chile) and 0.65 (data from Mexico); and for carcinoma *in situ*, 0.81 (data from Chile). The analysis included a total of 342 cases and 1,672 controls. The investigators concluded that the earlier finding likely was due to chance but that a causal relationship could not be ruled out. They recommended that monthly injectables continue to be monitored for their possible carcinogenic effects.

Fertility Awareness

Sheon, A.R. and C. Stanton. Use of periodic abstinence and knowledge of the fertile period in 12 developing countries. International Family Planning Perspectives, Vol. 15, No. 1, March 1989, pp. 29-34.

An analysis of data from the Demographic and Health Surveys carried out between 1986 and 1987 in 12 African, Asian, and Latin American countries found that in 10 countries fewer than 22% of women had ever practiced periodic abstinence and fewer than 7% currently practice the method. Current use was highest in Peru (18%) and Sri Lanka (15%). At least half of all current users in 7 of 11 countries (Brazil, Colombia, Ecuador, Morocco, Peru, Sri Lanka, and Trinidad/Tobago) were able to correctly identify the fertile period. The vast majority of users relied on the calendar rhythm method. Between one-fourth and slightly more than one-half of current users in seven countries used an additional method (usually condom or withdrawal) sometime during the month. The authors noted that if use of periodic abstinence is to increase, programs promoting the method must help women, especially less-educated women, learn to identify the fertile period correctly.

General

Alauddin, M. and M. VanLandingham. Young, low-parity women: critical target group for family planning in Bangladesh. Asia-Pacific Population Journal, Vol. 4, No. 1, March 1989, pp. 49-58.

Based on a review of Bangladesh contraceptive prevalence surveys from 1979 to 1985, the authors advocated targeting young, low-parity couples for family planning services in Bangladesh. Prevalence data showed that the increase in contraceptive use observed since 1979 was primarily among older couples with three or more children, while use among low-parity women age 15-24 remained quite low. The authors argued that young, low-parity women should be targeted because: 1) they make up an increasingly high proportion (44% in 1987) of all women of reproductive age, 2) early adoption of contraception for child-spacing may result in continued child-spacing throughout a woman's reproductive life, 3) there is evidence of high demand for contraceptives among women age 15-24, and 4) this age group has the highest fertility rate. The authors recommended several field-level interventions (including training fieldworkers to effectively reach young couples) and national-level interventions (such as emphasizing temporary child-spacing methods and directing some messages to community and religious leaders and men in general).

Coeytaux, F. et al. An evaluation of the cost-effectiveness of mobile family planning services in Tunisia. Studies in Family Planning, Vol. 20, No. 3, May/June 1989, pp. 158-169.

This report on the cost-effectiveness of 63 mobile family planning service delivery units serving 868 rural sites in Tunisia concluded that use of mobile units was appropriate for extending services to remote rural areas. The study estimated that for mobile unit services provided in 1985, the median cost per visit was US$4.93 and the median cost per couple-year of contraceptive protection (including tubal ligation) was US$18.66. Average costs per visit varied among mobile units, ranging from less than US$1.00 to greater than US$27.00. The investigators estimated that mobile units provided one-third of all national program services while accounting for one-fourth of national program costs. To increase mobile unit cost-effectiveness, the investigators recommended improving vehicle reliability, giving more attention to OC promotion, and reducing constraints to IUD provision.

Fakeye, O. and O. Babaniyi. Reasons for non-use of family planning methods at Ilorin, Nigeria: male opposition and fear of methods. Tropical Doctor, Vol. 19, No. 3, July 1989, pp. 114-117.

A 1986 survey in Ilorin, Nigeria, of 646 sexually active women who were not using contraceptives revealed that almost one third (31.4%) did not use contraceptives because their husbands objected to family planning. Other frequently cited reasons for non-use included not wanting to use contraception until the desired number of children were born (13.6%), fear of contraceptives (13.3%), and previous negative experience using a method (11.3%). The survey also revealed that fewer than half (45.7%) of the women could accurately identify the nearest source of contraceptives and only 37% said they knew how to use a contraceptive method. The researchers recommended short- and long-term information, education, and communication strategies to increase contraceptive use: short-term strategies to teach women about family planning, overcome fears, and dispel negative rumors about various methods and long-term strategies to change men's perceptions of family planning. The researchers also recommended ways to improve access to contraceptive supplies.

Current Abstracts ISSN: 1012-2680

Current Abstracts is published quarterly. It features abstracts of recent articles on contraceptive methods and products selected from a large number of publications. Its objective is to keep United Nations Population Fund (UNFPA) Country Directors and family planning decision makers up-to-date on current contraceptive research findings and reports. The abstracts reflect the content of the selected articles and do not constitute endorsement by PATH of the conclusions or methodology. *Current Abstracts* is funded by UNFPA.

Program for Appropriate Technology in Health (PATH) and Program for the Introduction and Adaptation of Contraceptive Technology (PIACT) are nonprofit, international organizations dedicated to improving the availability, acceptance, safety, and continued use of health and contraceptive products in developing countries. PATH will provide a full copy of any article abstracted in *Current Abstracts* to readers on request. Send requests to *Current Abstracts*, PATH, 4 Nickerson Street, Seattle, Washington 98109-1699, U.S.A.

"Injectible Contraceptives - a Threat to Women's Health"

This was the subject of a well-attended meeting organised by the Joint Women's Programme.

Dr Marie Mascarenhas, Director CREST, outlined the dangers of a long-acting contraceptives injected into women. Depo-Provera and NET-EN were potent and powerful forms of hormones given by injection for birth control protection upto 3 months. These drugs are banned in USA because of the harmful effects with fatal results when researched upon. The research on Depo-Provera showed that within 3 years on all the dogs on high dosage were dead and half of those on low dosage. Breast cancer, uterine cancer, serious menstrual disturbances, masculinisation of female foetus and other side effects like depression etc, were found. The WHO report on these drugs showed that the majority of women suffered from severe menstrual disturbances.

In India some research has been done by the ICMR. The reports of these studies have not been published till today. Meanwhile the Family Planning Association of India is planning to use them on a mass scale. Hormonal implants lasting for 5 years are also sought to be introduced.

Women's organisations in Bombay have already voiced their protest against the introduction of injectible contraceptives.

The Joint Women's Programme sees this as a matter of human concern and requests all health bodies, women's organisations and the Indian Medical Association to join in making the following demands.

1. Ban all long-acting contraceptives, in particular NET-EN
2. Withdraw manufacturing licences to German Remedies and Unichem and any other companies, for long-acting contraceptives.
3. Make public immediately all studies on NET-EN and DEPO-PROVERA.

This experimental immunocontraception approaches are directed at inactivation of either one or more hormones, gametes or early embryo antigens. The reproductive system is exquisitely sensitive to hormones and several are involved in a chain like manner in the process of gametogenesis, in accessory reproductive organ function in preparation of the reproductive tract for implantation and in sustenance of pregnancy. The gonadotropin releasing hormone (GnRH) a decapeptide synthesized and secreted by the hypothalmus stimulates the secretion of follicular stimulating hormone (FSH) and Luteinizing hormone (LH). GnRH, FSH and LH are made by both male anf female and inactivation of the bioactivity can influence male as well as female fertility. The gonadotropins act on the male gonads to generate sperms and testosterone in the female gonadotropins are involved in follicular development ovulation and production of female sex hormones, estradiol (E_2) and progesterone (P). In the first half of the cycle E_2 dominates. The cervical mucus during this phase and in particular around the day of ovulation is permissive of the ready passages of sperms. In the post ovulation phase, dominated by P the cervical mucosal glycoproteins have altered confirmation, hindering the passage of sperms. Progesterone is important for uterine receptivity, for implantation of the embryos and for the continuity of pregnancy. Compounds or antibodies inteffering in the production or action of this hormone during early pregnancy causes abortion.

GnRH - As far as immunological approaches against GnRH are concerned bioeffective immune responses could be elicited in monkeys and baboons employing GnRH linked to TT administered with alum or other permissible adjuvants. High antibody titers were induced ~~in these primates by boosters in~~

in these primates by booster injection after 4 to 5 months of primary immunization and the antibody response was of long duration. But this approach may not be readily acceptable for contraception as coincident with the blockage of fertility in the reduction of sex steroids. But immunisation against GnRH may be useful for control of precocious puberty as well as in patients of sex hormone dependent cancers such as carcinoma of the prostate and breast cancer.

On the FSH Vaccine & LHRH - (A contraceptive vaccine for use by the Human Male) Results of a feasibility study carried out in Adult Male Bonnet Monkeys - N R Moudgal, G S Murthy, N Ravindranath, A J Rao, M R N Prasad.

Among the various methods being evaluated for contraceptive use in the human males - the development of an effective contraceptive vaccine appears attractive & currently three possible immunogens are considered - Two are polypeptide hormones (Luteinizing hormone - releasing hormone (LHRH) and follicle - stimulating Hormone (FSH) and third is a sperm specific protein (Lactic dehydrogenese X (LDH-X).

LHRH - The Luteinizing hormone releasing hormone (LHRH) analogues in combination with androgen substitution are either more active than the native decapeptide and are known as agonists or they block the function of LHRH and thereby act as antagonists. But the ultimate effects of both analogues are identical i.e. suppression of pituitary gonadotropin secretion. During the last ten years a number of LHRH agonists became available for clinical use in the treatment of prostatic carcinoma. Some of these agonists have been used in clinical trials for male fertility regulation. Similarly studies are being carried out determine the contraceptive efficiency of these antegonists.

Another approach to anti-LHRH is immunization against LHRH. According to the Annual Report of National Institute of Immunology LHRH vaccine in male rats demonstrated production of consistently high antibody titre accompanied by a decline in testosterone levels. The vaccine was found to be safe by toxicological studies in monkeys and there was no chromosomal abnormalities in rats.

The only difficulty with this method is that since blockade of LH secretion leads to cessation of testosterone production and consequently loss of libido immunisation with LHRH would require continuous testosterone supplementation with exogenous testosterone. The long term effects of continuous testosterone supplementation remains to be investigated.

FSH Vaccine - A male contraception vaccine might soon be developed if the findings of recent research on rats and monkeys on the regulatory role of one of the two hormones secreted by the pitutory gland. Follicle stimulating Hormone (FSH) holds true.

According to Professor Moudgal of the Department of Reproductive Biology at the Indian Institute of Sciences, Bangalore, neutralisation of FSH which is required for initiating sperm production - can be brought about by introducing an FSH antigen which produces an antibody that blocks the action of FSH leading to a drop in sperm count besides reduction in the mortality of sperms to the fallopian tube (where fertilisation takes place) thereby resulting in impotency.

The hormone OFSH isolated in the laboratory from frozen sheep pituitaries ..... has been used as the immunogen. It s efficacy has been tested thus far in more than 30 monkeys. In addition to our own tests, the efficacy of the vaccine was tested in two collaborating laboratories, one situated in New Orleans and the other in New Delhi. All these laboratories used the same protocol and adjuvant ..... The protocol itself consisted of three to four primary immunisations given ten days apart and boosters given at intervals of 100 days. All the immunized monkeys responded positively by producing high antibodies capable of neutralizing hFSH .....

Sperm counts in ejaculater obtained periodically by electro-ejaculator start showing a sharp reduction by 150 days of immunization. This reduction ranges between acute oligospermia to azoospermia..... During this entire period of immunization which has thus for covered 380 to 550 days no significant change in serum testosterone has been observed. This is particularly advantageous as no testosterone supplementation was required to maintain

Ten of the immunized monkeys have been mated . .... with a total of 50 proven fertile females.....None of the male were able to impregnate the females thereby demonstrating that FSH immunization had rendered them infertile. What is of interest is that infertility could be achieved without compromising or resorting to testosterone supplementation.

But one of the major consideration in the development of FSH vaccine is the long term effect active immunization may have on a) sperm production, particularly with respect to the quality and number of sperms produced b) recovery of testicular function following cessation of immunization and c) clinical well being which includes absence of diseases due to immune complexes.

But according to the scientists (mentioned above) the immunization has not resulted in deleterious effection the health status of the monkeys (For more than nine years in bonnet monkeys or for 4½ years in rhesus monkeys) Immune complexes were not detected in circulation nor were precipitated immune complexes found in any of the organs/tissues.

No doubt such immunological approach is fraught with risks. No one really knows the long term impact of playing with the body's natural defence system and the health hazard it poses.

1) Cycloprovera, a combination of 25 Mg DMPA and 5 Mg Oestradiol Cypionate and (ii) HRP 102, a combination of 50 Mg Norethindrone enanthate (NET-EN) and 5 Mg Oestradiol Valerate.

Preliminary results in a study of 2,400 women in three countries showed both formulations are highly effective, both preparation induced bleeding patterns like the normal menstrual/cycles and side effects have been minor.

Norethindrone containing Microspheres tested in about 200 women with different formulations of 3 month infections have prevented pregnancy and caused very few side effects other than menstrual irregularities. The 3 month injections containing 75 Mg of norethandrone release on an average 0.48 mg norethandrone per day as compared to 0.5 to 1 mg in combined oral contraceptives. Irregular menstrual bleeding is the only common side effect and only a few complained of mild headaches or nausea. No changes have been observed in blood pressure, hesmoglobin, serum lipoproteins, etc. The reversibility is rapid.

A one month infection with 15 or 30 mg NET has been tested in 30 women in Mexico. The implant favoured by the Population Council named Norplant contains levonorgestrel and proved to be highly effective, safe and liked by its users.

Biodegradable Implants

The problem associated with the removed of Norplant implants led to the development of biodegradable implants.

Those undergoing clinical trial at present include capronor and Norethandrone Pellets. Capronor contains progestin Levonorgestrel. Norethindrone pellets are made of 15 % pure cholesterol and 85 % Norethindrone (NET). Current trial involve implant that are less than 0.24 cm in diameter and either 2.5 cm (16 mg) and 4 cm long (26 mg levonorgestrel). The polymer carrier remains largely intact for 18 to 24 months. The phase II clinical trials comparing the 2.5 and 4 cm capsules began in early 1987 and are being conducted by the US National Institute of Child Health and Human Development (NICHHD) the W.H.O. and the Indian Council of Medical Research (ICMR). Norethindrone Pellets. Each of these Pellets contain 30 mg NET which is released as the pellets gradually biodegrade. Preliminary trials have been conducted with two, three and four pellets in over 100 women in four countries. Both according to 1 Characteristic and status of Biodegradable Implant as of March 1987 was estimated to be available by Mid 1990's.

Given all the imported contraceptives and research underway in Indian laboratories - to provide a wider range of birth control methods - will India soon experience a "Second birth control revolution".

The research on contraceptives received a fresh impetus when a National Programme on Research on Human Reproduction was launched in 1980. The work on contraceptives began to be coordinated and 26 research institutes were set up to evaluate the effect of the drugs being developed. What is the importance of this contraceptives research ?

Clear indications are that the ~~exciting~~ existing methods of contraception have not gained the mass acceptance needed to make the family planning programme a success. While the use of Mirodh has shown a marked increase it is still not the best bet. IUD's are slowly increasing in popularity but are not good enough. The oral pill is yet to catch on. And sterilisation is only popular among those who already have an average of four children.

Justification for ~~or~~ going in for bio medical research in Family Planning i.e. if it is successful it looked or to be for must be technology

But more & more contraceptives are being recommended only for clinical use - so how are they going to create mass acceptance and actually performance on a mass scale ?

Even this international data on Norplant raises many issues:

1. The ethics of "pre-introductory studies done in developing countries designed to give physicians experience with the system prior to approval". On this plea 14,000 women from developing countries were subjected to the trial.

On the basis of the data procured from the developing countries it was recommended by a panel member of the FDA Committee/USA (Raul Manganiello, MD Dartmouth University Medical School) that "we feel that it is a safe and effective means of contraception from the information derived from the Third World countries..... " and hence "..... it would also be a safe and effective means of contraception in the United States".

The population council you must note has data from studies on 55,000 women in 44 countries including about 10,000 from China, approximately 1,000 women from India, 1,000 from Egypt and 800 from Sri Lanka.

Trials of Norplant capsules or Norplant - 2 rods

Country	No. of women
Bangladesh	600
Brazil	3600
Chile	900
Egypt	2600
Haiti	300
India	3500
Jamaica	100
Kenya	200
Korea	200
Mexico	300
Nepal	500
Nigeria	300

Country	No. of Women
Philippines	300
Senegal	100
Singapore	300
Taiwan	100
United States	1100
Zambia	200
Total	15200 out of 55,000

Estimated No. of Norplant & Norplant-2 acceptors by country as of September 1987.

Country	No. of Acceptors
Norplant Capsules approved for General use.	
China	12,000
Colombia	2,000
Dominican Republic	2,000
Ecuador	2,000
Finland	10,000
Indonesia	1,50,000
Peru	1,000
Sri Lanka	800
Sweden	10,000
Thailand	20,000
Venezula	1,000

on its Efficacy -

Paul Bardin (Norplant Expert) admitted that a further clinical trial is being conducted on 8,000 women "and they will be followed for over five years whether they continue or not" to ascertain and

"look for adverse events (rates) that we were not able to detect in phase-III clinical trials". This indicates that its safety is still an unresolved issue. Some of the issues raised by the Committee members were -

(a) Whether the capsules would migrate over time?

(b) If irregular bleeding could mask underlying endometrial cancer?

(c) If HDL levels could go in the wrong direction?

(d) If the drug would have an adverse effect on cardiovascular function?

(e) If the female children would experience masculinisation abnormalities if the implant remains in the mother during pregnancy?

Apart from these doubts the FDA reviewer Ridgely Bennett noted several disadvantages of these products

1) Need to insert and remove by a health professional

2) Implants may be visible

3) Approximately 25% of the women who discontinued use of the implant over five years did so because of disturbances in bleeding patterns.

4) Pain and unnecessary surgery may result from enlarged ovarian follicles among others.

Beside these issues- The clinical trial on the developed and developing countries (which is attached) reveals the presence of many serious medical problems like Hypertension, ovarian cyst, cervical cancer, gall bladder problems, anaemia, ectopic pregnancy. In one instance a birth defect was also reported. Out of 101 accidental pregnancies - 27 with unknown outcome. In Canine

cardiovascular and circulatory problem played a major role for Norplants termination. Hypertension - heart rate problems and few cases of myocarditis manifested itself. Again although Hematologic (blood related) events were uncommon yet the few cases that occurred were so dramatic that in the case of Californian woman due to severe anemia (due to excessive bleeding) she had to not only discontinue Norplant but also take recourse to blood transfusion.

As far as the problem of ovarian cysts associated with implant use is concerned it may pose a serious problems -

(a) It may grow to 5-7 cm.

(b) May persist for a number of weeks.

(c) Will regress on its own.

(d) No intervention is recommended.

While all this is happening-growth and regression of the cyst - the woman is bound to experience terrible pain and discomfort.

Again ectopic prognancies rate is not insignificant. The ectopic pregnancy rate was 0.16 per 1,000 woman years. Given this possibility of ectopic pregnancy it was stressed that "surveillance should provide reasonably precise information with respect to short and middle term health effects particularly rates of ectopic pregnancy". But even this kind of surveillance cannot address very long term questions such as the relative risks of gynaecological cancers or "atherogenic" cumulative circulatory and cardiovascular diseases.

ICMR Task Force on Hormonal Contraception:-

Comparative Evaluation of contraceptive efficacy of norethisterone Oenanthate (200 mg) injectable contraception given every two or three months. National Programme of Research in Human Reproduction Division of Reproductive Biology & Fertility Control. ICMR - Ansari Nagar New Delhi, India.

Institutions that participated:- R G Kar Medical College, Calcutta; M L N Medical College, Allahabad; Baroda Medical College, Baroda; Institute for Research in Reproduction, Bombay; K E M Hospital Pune; K G Medical College, Lucknow; Medical College, Gauhati; A I I M S, New Delhi; Medical College, Jammu; Kasturba Hospital, Delhi, K E M Hospital, Bombay; S P Medical College, Bikaner; Institute of Obstetrics & Gynaecology, Madras; Medical College, Allepey; R M S P Hospital, Calcutta; J J Hospital, Bombay; I C M R New Delhi.

The National Family Welfare Programme of India is being supported and strengthened through research and development in contraceptive technology by the Indian Council of Medical Research (ICMR) "Newer and better methods of fertility control are being evaluated by ICMR through its network of Human Reproduction Research centres located in different parts or the country, prior to their inclusion in the National Family Welfare Programme.

The ICMR through its network of HRRC's initiated a randomized Phase-II clinical trial, in March 1981 to evaluate the contraceptive efficacy and safety of injectable Net OEN (200 mg) given in two different treatment schedules of 60 + 5 days and 90 + 5 days.

After exclusions - 2388 subjects, 1181 for 60 + 5 day schedule and 1207 for 90 + 5 day schedule were considered for analysis

constituting 28, 513 woman months of use.

A total of 41 involuntary pregnancies were reported out of which 21 pregnancies occurred within the first six months when all the subjects received injectable NET OEN (200 mg) at an interval of 60 + 5 days. The method failure rate at six months was 1.2 per 100 users for the 60 + 5 day schedule and 0.7 per 100 users for the 90 + 5 day schedule. The remaining 20 method failures occurred after 6 months of treatment. Of these only one was reported in the 60 + 5 day schedule whereas alarmingly high method failures were seen with the 90 + 5 day treatment schedule.

In the case of the 19 failures occurred in the 90 + 5 day schedule it was observed that the majority of these (13) had occurred during the 3rd month following the injection. These observations clearly indicate that 90 + 5 day treatment has lower efficacy because the contraceptive effect of the drug does not last beyond 65 days.

Moreover keeping in view the fact that the average body weight of Indian woman is lower than their counterparts in Western countries it is likely that the body weight may be an important ~~factor~~ Causative factor responsible for higher method failures and more failures were reported amongst women with a body weight of 40 kg and below.

The effect of the body weight on the hormone metabolism is incompletely understood. However in a small study no effect of the body weight was seen in Thai women either on the metabolism of NET OEN or the return of ovulation. The available evidence in the literature also suggests that women in different population groups may metabolize the injectable progestational steroids at different rates. Whereas the Indian women ovulated within 10 weeks after an injection of 150 mg DMPA, the Swedish women did

not ovulate for at least 20 weeks. In contrast after an injection of 200 mg NET OEN Indian and Thai women took twice as long as Brazilian women to resume ovulation.

Surprisingly the method failures within the first six months where all the study subjects received 200 mg NET OEN at 60 + 5 day intervals were higher in the present trial as compared to the WHO study certain difficulties in administering the drug such as the leakage of NET OEN solution from the syringes was reported in general and specifically from the centres where maximum pregnancies were reported. It was suggested that to prevent it would be useful to pre-pack the drug in sterilized disposable syringes.

Discontinuation rates per 100 women by Reasons for Discontinuation:

Reasons	Treatment Schedule	Rates + SE			
		6 months	12 months	18 months	24 months
Pregnancy 60+5	I	1.2+0.3	1.2+0.3	1.4+0.4	1.4+0.4
90+5	II	0.7+0.3	1.8+0.4	2.8+0.6	6.6+1.2
Menstrual	I	3.5+0.6	7.5+0.9	11.1+1.1	15.6+1.5
disturbances	II	8.8+0.9	19.5+1.3	31.2+1.6	42.2+1.9
Heavy & prolo-	I	3.5+0.6	7.5+0.9	11.1+1.1	15.6+1.5
nged bleeding	II	3.2+0.5	6.5+0.8	10.6+1.1	13.5+1.3
Irregular	I	2.5+0.5	7.8+0.9	10.6+1.1	12.1+1.2
bleeding	II	4.0+0.6	7.5+0.9	11.8+1.2	16.4+1.5
Amenorrhoea	I	1.6+0.4	7.6+0.9	13.2+1.3	23.8+1.9
	II	1.8+0.4	6.9+0.8	12.7+1.2	20.1+1.7
Other medical	I	0.9+0.3	1.5+0.4	2.7+0.6	3.2+0.7
reasons	II	1.2+0.3	2.3+0.5	3.7+0.7	4.4+0.8
Personal	I	5.1+0.7	11.6+1.1	22.0+1.5	29.7+1.9
	II	3.5+0.6	9.2+0.9	16.9+1.4	23.1+1.7
Late for	I	1.7+0.4	3.3+0.6	4.9+0.8	4.9+0.8
followup	II	2.3+0.5	4.7+0.7	5.9+0.8	5.9+0.8
Loss to	I	7.6+0.9	10.3+0.9	11.2+1.0	11.7+1.0
followup	II	7.3+0.8	10.0+0.9	11.0+0.9	11.5+1.0
Total dis-	I	21.8+1.2	41.5+1.4	56.9+1.5	68.6+1.5
continuation rate	II	22.0+1.2	40.2+1.4	55.5+1.5	67.4+1.5
Continuation	I	78.2	58.5	43.1	31.4
rate	II	78.0	59.8	44.9	32.6
No of Acceptorse	I	1181	921	644	281
at the beginning of interval	II	1207	959	678	296

It is clear that discontinuations due to menstrual disturbances which was 7.4 per 100 users for 60 + 5 day schedule and 8.8 per 100 users for the 90 + 5 day schedule at 6 months of contraceptive treatment rose in geometrical progression and reached a 43.5 per 100 users and 42.2 per 100 users at the 24 month of NET OEN use.

Discontinuation due to other medical reasons which amounted to 3.2 and 4.4 per 100 users for 60 + 5 days and 90 + 5 days treatment schedule were not only considered to be small in proportion but also unrelated with the use of the drug. They ranged from deseases like jaundice/infective hapatitis which occurred in 10 cases to a host of other ailments like hypertension (1) palpitation (3) pain in chest (3) allergy (4) T B (2) fever (3) psychiatric problem (2) weight gain (3) prolapse uterus (1) ovarian cyst (1) breast tenderness (1) weakness/ headache (10).

What is important to note is that the continuation rates were marginally lower than those observed under similar conditions for intrauterine devices in our country. Moreover the continuation rate drastically declined during the second year due to personal reasons and amenorrhoea. In fact the project itself stipulated discontinuation of women having amenorrhoea of more then one year.

File no. 7

WH 3

Comparative Risks and Costs of Male and Female Sterilization

Gregory L. Smith, MD, MPH, George P. Taylor, MD, MPH, and Kevin F. Smith, MD

Abstract: Couples who are considering elective sterilization should compare the risks and costs of male and female sterilization procedures as part of the decision process. Morbidity, mortality, failure rates, and short-term costs associated with male and female sterilization procedures were estimated from data available in previous case series. Male sterilization procedures were found to have zero attributable deaths and significantly less major complications when compared to female sterilization procedures. No more than 14 deaths a year can be attributed to female sterilization procedures in the US. Male and female sterilization procedures have efficacy rates that are not significantly different from each other. The short-term costs of female sterilization are 3.0 to 4.1 times those of vasectomy. (*Am J Public Health* 1985; 75:370–374.)

Introduction

There are over 15 million surgically sterilized adults in the United States, 19 per cent of US couples with a wife 15–44 years of age.[1,2] Each year close to one million surgical sterilizations are performed, the number of vasectomies being almost equal to the more popular tubal ligation.[1,2] Sterilization is now the most common method of fertility control among married couples over age 30.[3] When socioeconomic, family, and marital factors are looked at, those couples whose wives are undergoing tubal ligation are not significantly different from those couples whose husbands are undergoing vasectomy.[4]

The goal of this analysis is to estimate comparable efficacy, complication, and mortality rates and short-term costs associated with male and female sterilization procedures.

Previous publications[2,5–8] have shown that sterilization is safer than using temporary contraception or no contraception.

Generally, sterilization is requested after procreation for the sexual couple or single person is deemed to be complete,[2,3,8,9] a very different situation than that of couples or single persons choosing temporary contraception. The costs, efficacy, and risks associated with temporary versus permanent sterilization are used for a different set of decisions by different groups of individuals. The person who elects to be sterilized expects that for a given level of efficacy and cost that he or she will have the lowest rate of complications and mortality possible.

The psychological and social aspects of choosing male versus female sterilization by members of a sexual couple are not discussed in this analysis. However, we recognize that the risks, efficacy, and costs associated with the different sterilization procedures are only part of the information necessary for informed decision making by the consumer and the health care provider.

While the reversibility of the sterilization procedure is not a conceptual issue, it may be an empirical issue in the decision process. Clinical success of both male and female sterilization reversal is reported to range from 10–50 per cent[2] and is dependent on the type of sterilization procedure and the skill of the surgeon. The re-anastomosis in the male would be associated with significantly less costs and risks and complications than the comparable female procedure.

Methods

A literature search was done to capture all case series publications presenting data on deaths, complications, and failures of tubal ligation and vasectomy procedures in the US. Because of the changing nature of sterilization, including a multiplicity of techniques the increasing skill of the surgeons, and an increasing awareness of the associated risks, only case series published after 1970 were reviewed. Each case series was reviewed for consistency of the definition of attributable mortality, morbidity failure, and a minimum follow-up interval of three years. Over 50 case series were reviewed, including a variety of retrospective and prospective study designs. The numerator and denominator data from the case series were combined and averaged to produce estimates for the morbidity, failure, and mortality rates for tubal ligation and vasectomy. A Poisson distribution was assumed in calculating the 95 per cent confidence intervals of each estimated rate.

Because the case series varied in informational detail, it was not possible to calculate the rates by age, race, or socioeconomic status. Thus the estimates are for all US males and females undergoing sterilization. There is evidence in studies from lesser developed countries to suggest that for any age, race, or socioeconomic status the risk ratio among the various sterilization methods will be relatively constant even though the absolute rates will differ.[10]

Forty-eight per cent of tubal ligations are done within one month of an abortion or parturition, but this does not affect complication rates.[9] Only complications and fatalities directly attributed by each author to the tubal ligation procedure are included in the risk estimates.

Procedure Costs

The procedure costs estimates are intended only to reflect the short-term costs. Costs associated with failure, complications, recuperation time, or death are not included.

Because cost information was complete and easily available for Boston and Dallas, these data were used to estimate procedure costs. It is recognized that these estimates may not be appropriate for less urbanized areas, or statistical metropolitan areas with a lower cost-of-living index.

The procedure costs include the surgeon's fee, anesthesia fee, and the facility costs for the operation and preoperative care. The maximum allowable insurance pay-

Address reprint requests to Gregory L. Smith, MD, MPH, Captain, US Army Medical Corps, Division of Preventive Medicine, Walter Reed Army Institute of Research, Washington, DC 20307-5100. Dr. Taylor is with the General Program, Harvard School of Public Health; Dr. Smith is with the Department of Pediatrics, Lincoln Medical Center, New York City. This paper, submitted to the Journal July 16, 1984, was revised and accepted for publication October 5, 1984.

ments* to the surgeon and anesthesiologist for tubal ligation and vasectomy were used to reflect the physician costs. The federal regional diagnosis-related group (DRG) payments for uncomplicated laparoscopy and laparotomy tubal ligation and vasectomy, for Dallas and Boston, were used to reflect all inpatient costs, excluding physician fees. An average outpatient post-operative facility fee for Dallas and Boston** for $200 is used in the cost estimates for that proportion of tubal ligations and vasectomies done as outpatient procedures.

Only very rarely is a vasectomy done as an inpatient procedure. It may be included occasionally as an inpatient procedure when the patient was hospitalized for another indication, or when the patient is at high risk for complications.

Data are not available on the number of person admitted to the hospital for the purpose of undergoing vasectomy.*** However, so as not to underestimate the costs associated with these inpatient procedures, 5 per cent of vasectomies will be included as inpatient procedures in this cost estimation.

Data are not available on the proportion of vasectomy patients who stay in outpatient post-operative facilities.*** However, a random telephone survey of Dallas and Boston primary care physicians who regularly perform vasectomy showed outpatient post-operative facilities to be used in most instances. In order not to underestimate the costs of vasectomy, all outpatient vasectomies will be included as using post-operative facilities.

Nationally, about 25 per cent of laparoscopy tubal ligations and 2.5 per cent of laparotomy tubal ligations are done as outpatient procedures.[11] Those procedures done as outpatient procedures will be included as using post-operative facilities.

Table 1 shows the estimated procedure costs for inpatient and outpatient vasectomy, laparoscopy, and laparotomy tubal ligation.

Vasectomy Risks

Mortality Rate

No deaths were reported in any of the case series, and a recent review found no reported deaths in the US attributable to vasectomy.[1,2] Potts, *et al.*,[16] in reviewing relative risks of sterilization in lesser developed countries quote a rate of 0.1/100,000 procedures in India, with most of the deaths attributable to tetnus or sepsis. This is the only value that exceeds zero in the available literature. A theoretical argument for a dose-related risk of death from anaphylaxis to the 3–5cc subcutaneous injection of anaesthetic has been made[12] but no estimate is available.

A mortality rate of zero will be used for later calculations.

Cumulative Failure Rate

In the case series, failure was defined as continued presence of motile sperm in the semen three months after the procedure. Close comparison with tubal sterilization failure, the occurrence of pregnancy in a previously sterilized women is not possible.[3] In this analysis, the cumulative failure rate for vasectomy will be compared with that for tubal ligation, with the understanding that the vasectomy failure rate may be an overestimate of the actual number of failed vasectomies that result in pregnancy of the spouse.

Eight US studies from 1971–74 from a review by Hatcher,[2] where the current standard procedure was performed, found nine failures in 5,638 vasectomies. This gives a rate of 0.16/100 procedures (95 per cent confidence limits 0.07–0.28).

Long-Term Mortality Rate

The long-term mortality rate is related to sterilization failure which leads to pregnancy and its associated maternal mortality risks. The number of pregnancies which are assumed to occur from each failure is multiplied by the maternal mortality rate for US women 15–44 years of age (9.2/100,000 pregnancies). On the one hand, this overestimates mortality because not all failed vasectomies would lead to pregnancy; on the other hand, it underestimates the true mortality because the average age of wives of vasectomized men is older than that of all US pregnant women.[7]

In calculating estimates for male and female sterilization, the assumption is made that there are no elective abortions.

Complication Rate

Major complications are those associated with significant morbidity and/or large additional costs; all complications requiring intravenous antibiotics, hemorrhage requiring transfusion, operative complications or trauma requiring further repair or extended hospitalization.

Minor complications include fever or localized infection treated with oral antibiotics not requiring hospitalization, superficial hematoma, localized pain or complaints not requiring hospitalization or surgical repair.

Only those case series reporting complications that can be categorized into minor or major were used for the parameter estimation.

*Personal Communication, representative from Health Insurance Institute of America.

**Phone survey of area hospitals, outpatient facilities, and physicians.

***Personal communication, Dr. William Pratt, National Survey of Family Growth, National Center for Health Statistics.

TABLE 1—Estimated Short-term Sterilization Procedure Costs

Procedure Type	Anesthesia & Physician Fee	Outpatient Facilty	Inpatient (DRG rate)	Total
Outpatient Vasectomy	$251	$200	$ 0	$ 451
Inpatient Vasectomy	$251	$ 0	$ 900	$1151
Outpatient Laparoscopy	$673	$200	$ 0	$ 873
Inpatient Laparoscopy	$673	$ 0	$ 952	$1625
Outpatient Laparotomy	$710	$200	$ 0	$ 910
Inpatient Laparotomy	$710	$ 0	$1303	$2013

SOURCE: Health Insurance Institute of America, Blue Shield Health Insurance, *Federal Register* DRG payment schedule for Dallas and Boston, 1983–1984.

Fifteen studies in a review by Hatcher[2] found seven major complications out of 16,319 vasectomies, 0.43/1,000 procedures (95% confidence limits 0.17–0.81).

We have not used the minor complication rate, however, because of the considerable underreporting particularly in the case of tubal ligation, which would be expected to have a minor complication rate approaching 100 per cent if the definition were applied literally.

Sexual Dysfunction—No significant difference has been found in the rate of sexual dysfunction between couples with male and female sterilization.[3]

Alder, *et al*,[13] prospectively studied 90 matched couples undergoing surgical sterilization. He found that in the couples where the husband had undergone vasectomy there was a higher frequency of intercourse, fewer sexual problems, and more satisfactory marriage than couples where the wife had undergone tubal ligation.[13] These differences were not felt to be secondary to the procedure but related to underlying differences in the couples.

Arteriosclerotic Cardiovascular Disease and Vasectomy—On the basis of animal studies, it has been postulated that damage to the arterial walls by deposits of circulating immune complexes may have followed vasectomy.[3,14,15,16] Two recent reviews[14,17] of 13 large US epidemiologic studies to evaluate this hypothesis found no increase in ASCVD in vasectomized men.

Sperm Antibodies—Thirty to 50 per cent of men who have undergone vasectomy develop antibodies to sperm.[3,14,17] This has raised concern about the development of immunological disease in vasectomized men. Two recent reviews of a number of large US epidemiologic studies on the subject[14,17] found that sperm antibodies had a negative effect on fertility in males who had undergone vas reanastomosis procedures. No other immunological health effects were identified.

In summary, the available evidence does not support sexual dysfunction, arteriosclerotic cardiovascular disease, or immunological disease as complications of vasectomy. Therefore, they will not be included in the major complication category of this analysis.

Tubal Ligation Risks

Mortality Rate

Several reviews of tubal ligation or complications of tubal ligation present mortality rates from 2.5–10.0/100,000.[9,11,18–24] The most common causes of death were complications of general anaesthesia (38.0 per cent), operative trauma (27.5 per cent), sepsis (24.0 per cent), and myocardial infarction (10.3 per cent).[9] No deaths have been reported due to complications of local anaesthesia with tubal ligation procedures in the US,[9] but tubal ligation performed under local anaesthesia would still retain the mortality risk from operative trauma, sepsis, and myocardial infarction.

Mortality rates are calculated for laparoscopy and laparotomy tubal ligation procedures, using two large US case series.[9,21] For laparoscopy tubal ligation, there were 21 deaths attributable to 444,565 procedures, a rate of 4.72/100,000 (95 per cent confidence limits 2.70–6.74). For laparotomy, there were 13 deaths attributable to 567,000 procedures, a rate of 2.29/100,000 (95 per cent confidence limits 1.22–3.71).

Cumulative Failure Rate

The cumulative failure rate for laparoscopy tubal ligation was calculated from 21 case series, most of which were reviewed in a paper by McCausland.[25] There were 15 failures among 55,877 sterilized women, a rate of 0.28/100 (95 per cent confidence limits 0.23–0.32). Five case series were used to estimate the failure rate for laparotomy tubal ligation.[22,25–27] There were 17 failures among 5,213 sterilized women, a rate of 0.33/100 (95 per cent confidence limits 0.18–0.48).

Long-Term Mortality Rate

Unlike vasectomy, there is an increased rate of ectopic gestation with an associated increased maternal mortality among women with failed tubal ligation.[28–31] The proportion of such women with tubal gestation ranges from 16–50 per cent, depending on the type of procedure.[28–30] The largest series by McCausland[25] is the only study with detailed information of ectopic pregnancy rates by type of procedure. McCausland found 49 ectopic pregnancies out of 160 failed laparoscopy tubal ligations, an ectopic pregnancy rate of 31 per cent. He also reported 13 ectopic pregnancies out of 106 failed non-laparoscopy tubal ligations, ectopic pregnancy rate of 12.3 per cent.

Rubin, *et al*,[29] estimated, for all women in the US in 1978, 37 deaths attributable to 42,400 ectopic pregnancies, an estimated ectopic pregnancy mortality rate of 87/100,000 ectopic pregnancies.

To estimate the long-term mortality rate, the expected number of ectopic pregnancies is multiplied by the ectopic pregnancy mortality rate. The estimated number of non-ectopic gestations is multiplied by the non-ectopic maternal mortality rate for the US.[7]

Complication Rate

For laparoscopy tubal ligation, four case series were used.[15,21,26,27] There were 214 major complications among 10,179 women undergoing sterilization, a rate of 2.1/100 (95 per cent confidence limits 1.8–2.4). For laparotomy tubal ligation, three case series were used.[15,24,27] There were 10 major complications among 1,651 undergoing sterilization, a rate of 6.2/100 (95 per cent confidence limits 5.0–7.3).

Post-tubal Syndrome—The question whether tubal ligation predisposes women to menstrual disturbances has been explored in several studies.[15,24,27] It has been concluded that the observed differences in menstrual function after tubal ligation may be attributed to the older average age, and to previous pelvic disease and birth control methods. Therefore, menstrual disturbance is not considered a complication of tubal ligation.

Results

Table 2 shows the costs, mortality, complication, and failure rates for 100,000 sexual couples or single persons undergoing sterilization. Within the confines of the variables of the available case series and the assumptions discussed in the Methods section, these data are comparable.

Table 3 shows the risk ratios (RR) for tubal ligation compared to the reference vasectomy. The attributable mortality RR and the major complication RR for tubal ligation procedures are each approximately two orders of magnitude greater than vasectomy. The short-term costs of tubal ligation are 3.0 to 4.1 times greater than vasectomy.

In Figure 1, the first section shows the estimated rates from Table 2 applied to the actual numbers of sterilizations in 1981—i.e., 400,000 vasectomies, 140,500 laparoscopies and 299,500 laparotomy tubal ligations.

In the second section of Figure 1, the same rates and numbers of procedures are applied in a hypothetical situa-

TABLE 2—Estimated Deaths, Complications, Failures and Costs for Tubal Ligation and Vasectomy (per 100,000 procedures)

Sterilization Procedure	Laparoscopy Tubal Ligation	Laparotomy Tubal Ligation	Vasectomy
Procedure Mortality	4.72	2.29	0
Long-term Mortality	0.09	0.06	0.02
Attributable Mortality*	4.81	2.35	0.02
Major Complications	2100	6170	43
Sterilization Failures	276	326	160
Short-term Costs (Millions $)	143.6	198.5	48.6

*Attributable = Procedure Mortality plus Long-Term Mortality

TABLE 3—Risk Ratios for Mortality, Complications, Failures and Costs for Tubal Ligation and Vasectomy (Vasectomy is reference RR = 1.0)

Sterilization Procedure	Laparoscopy Tubal Ligation	Laparotomy Tubal Ligation	Vasectomy
Long-term Mortality	5.7 *(1.1–18.1)	3.9 (0.7–13.8)	1.0
Attributable Mortality	241 (146.9–393.8)	117.5 (63.4–217.8)	1.0
Major Complications	49.0 (32.0–75.1)	143.0 (104.6–198.2)	1.0
Sterilization Failures	1.7 (0.9–3.4)	2.0 (0.9–4.5)	1.0
Short-term Costs	3.0	4.1	1.0

*95 per cent confidence limits

tion in which all of the tubal ligations are done as outpatient procedures, using only local anaesthesia. This is the "*best case*" situation for tubal ligation.

In the third section of Figure 1, the same rates and numbers of procedures are applied in a hypothetical situation in which all of the sterilization procedures are done as vasectomy. This is the "best case" situation for vasectomy.

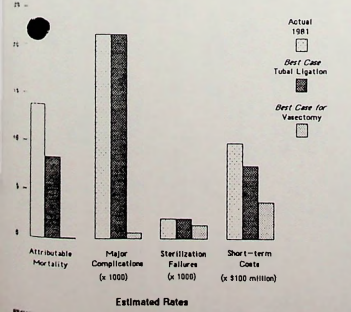


FIGURE 1—Actual and Hypothetical Risks and Costs of Sterilization Procedures (1981 data)

This would lead to an estimated 100 per cent reduction in mortality, 85 per cent reduction in major complications, and 62 per cent decrease in costs with the same efficacy rate as the other alternatives.

Discussion

This method of analysis and rate estimation is flawed by the variability of the case series used including differences in study population, physician experience, and technique. However, by using the raw data from a large number of case series reflecting such a large variety of experience, the estimated rates may be close to the real-life situation. The actual differences among the sterilization procedures will not be adequately known until a large, well-designed prospective study is conducted among sexual couples requesting elective sterilization.

With this limitation in mind, we believe that our data suggest that vasectomy is safer and considerably less expensive than tubal ligation, with efficacy rates not significantly different from tubal ligation.

REFERENCES

1. Reproductive Impairment among Married Couples: United States, 1982. Data from National Survey of Family Growth Data, Series 23, No. 11, National Center for Health Statistics. Washington, DC: Govt Printing Office.
2. Hatcher RA, Guest F, Stewart F, *et al* (eds): Contraceptive Technology 1984–1985. New York: Irvington Publishers, 1984.
3. Vasectomy—safe and simple. Popul Rep 1983; 11:63–94.
4. Markman LM, Frankel HA: The choice of sterilization procedure among married couples. J Fam Pract 1982; 14:27–30.
5. Sachs BP, Layde PM, Rubin GL, *et al*: Reproductive mortality in the United States. JAMA 1982; 247:2789–2792.
6. Keeping JD, Chang A, Morrison J: Sterilization: a comparative review. Aust NZ J Obstet Gynaecol 1979; 19:193–202.

7. Ory HW: Mortality associated with fertility and fertility control: 1983. Fam Plann Perspect 1983; 15:57–63.
8. Rubin GL, Ory HW, Layde PM: The mortality risk of voluntary surgical contraception. Biomed Bull 1982; 3:1–5.
9. Peterson HB, DeStefano F, Rubin GL, *et al:* Deaths attributable to tubal sterilization in the United States, 1977 to 1981. Am J Obstet Gynecol 1983; 143:131–136.
10. Potts M, Speidel JJ, Kessel E: Relative risks of various means of fertility control when used in lesser developed countries. *In:* Sciarra JJ, Zatuchni GI, Speidel JJ (eds): Risks, Benefits, and Controversies in Fertility Control. Hagerstown, MD: Harper And Row, 1977.
11. Peterson HB, Greenspan JR, DeStefano F, *et al:* The impact of laparoscopy on tubal sterilization in United States hospitals, 1970 to 1978. Am J Obstet Gynecol 1981; 140:811–814.
12. Ackman CFD, MacIsaac SG, Schaal R: Vasectomy: benefits and risks. Int J Gynaecol Obstet 1979; 16:493–496.
13. Alder E, Cook A, Gray J, *et al:* The effects of sterilization: a comparison of sterilized women with the wives of vasectomized men. Contraception 1980; 23:45–53.
14. Massey FJ, Bernstein GS, O'Fallon WM, *et al:* Vasectomy and health: results from a large cohort study. JAMA 1984; 252:1023–1029.
15. Lipshultz LI, Benson GS: Vasectomy—1980. Urol Clin North Am 1980; 7:89–105.
16. Advance Report on Final Mortality Statistics, 1980. Monthly Vital Statistics Report 1983; 32:1–40.
17. Perrin EB, Woods JS, Namekata T, *et al:* Long-term effect of vasectomy on coronary heart disease. Am J Public Health 1984; 74:128–132.
18. Peterson HB, Lubell IL (eds): Sterilization: A Worldwide Epidemiologic View. Chicago: Year Book Medical Publishers, 1983.
19. Peterson HB, Greenspan JR, Ory HW, *et al:* Tubal sterilization mortality surveillance, United States, 1978–1979. Adv Planned Parenthood 1981; 16:71–76.
20. Aubert JM, Lubell I, Schima M: Mortality risk associated with [illegible] sterilization. Int J Gynaecol Obstet 1980; 18:406.
21. Phillips JM, Hulka J, Hulka B, *et al:* American Association of Gynecologic Laparoscopists, 1976 membership survey. J Reprod Med 1978; [illegible]
22. Peterson HB, DeStefano F, Greenspan JR, *et al:* Mortality risks [illegible] ed with tubal sterilization in United States hospitals. Am J Obstet Gynecol 1982; 143:125–129.
23. Phillips J, Hulka JH, Keith D, *et al:* Laparoscopic procedures: a survey for 1975. J Reprod Med 1977; 18:219–225.
24. Newton JR, Gillman S: A retrospective survey of female sterilization in the years 1968 to 1973, analysis of morbidity and post-sterilization complications for 5 years. Contraception 1980; 22:295–311.
25. McCausland A: High rate of ectopic pregnancy: incidence and etiology. Am J Obstet Gynecol 1980; 136:97–101.
26. Cunanan RG, Courey NG, Lippes J: Complications of laparoscopic sterilization. Obstet Gynecol 1980; 55:501–506.
27. Brenner WE: Evaluation of contemporary female sterilization methods. Reprod Med 1981; 26:439–453.
28. Peterson HB, Lubell I, DeStefano F, *et al:* The safety and efficacy of tubal sterilization: an international overview. Int J Gynaecol Obstet 1983; 21:139–144.
29. Rubin GL, Peterson HB, Dorfman SF, *et al:* Ectopic pregnancy in the United States: 1970 through 1978. JAMA 1983; 249:1725–1729.
30. Barnes AB, Wennberg CN, Barnes BA: Ectopic pregnancy: [illegible] and review of determinant factors. Obstet Gynecol Surv 1983; 38:349–356.
31. Qvigstad E, Jerve F: Ectopic pregnancy following tubal sterilization. Int J Gynaecol Obstet 1982; 20:279–281.

121 medico friend circle bulletin

OCTOBER 1986

A Feminist Understanding of Contraception

(Manisha Gupte)

Few topics related to the women's health movement are as controversial as is contraception. Liberating heterosexual women at one end by giving them the choice to control their own reproduction, it snatches away the same control when contraceptives, many of them invasive and harmful, come as a package deal with population control programmes that select, motivate and whenever necessary coerce helpless targets. Male hegemony exists in medicine, in policy and decision making and in research. Do women end up having lesser choice and lesser control over their bodies through the usage of existing contraceptives? what designs operate to keep control of women's bodies out of the latter's hands? And is there a solution?

To understand the above, it becomes necessary to clarify our own position regarding contraception. It is particularly important to do so when we are faced with the possibility that injectable contraceptives may be officially introduced into the Indian government's family planning programme. Whereas our fight should be directed against all contraceptives that are invasive, harmful and which have systemic effects, at this moment it is necessary to concentrate our efforts to examine injectable contraceptives vis a vis the personal choice of a woman regarding contraception.

The present paper, based largely on existing information, attempts to bring forward some views regarding contraception, the choice that women are able or unable to exercise when confronted with unsafe contraceptives within a target oriented, coercive population control programme.

Feminism and Contraception :

As regards contraception, one argument put forward is that while it does help a woman to avoid conception the availability of contraceptives has made women 'sexually available' for men. The argument has been especially true in the context of our Western sisters and the recent works of Germaine Greer and Betty Friedan bear testimony to the fact that the sexual revolution of the West, did infact oppress women themselves. The same argument is put forward in India by well meaning persons about the abortion issue. What they want to stress upon and to warn is that once contraceptives are available, men become more irresponsible in their sexual relation with women, since then a woman's sexual availability can be separated from unwanted conception and the accompanying guilt and responsibilities. In the event that conceptions do occur, the woman then is made to go through repeated abortions, much against her will and her physical well being. The position of these protagonists is in principle quite different from that of the moralists who see sexuality without conception as evil, especially if it occurs outside marriage, and who consider accidental pregnancy ensuing out of such a relation as a well deserved punishment.

Let us examine this position and its consequences. In fact, one might raise a counter question in argument. Are we trying to say that if contraceptives were not made available, women too would no longer be 'available' for sexual purposes? In such a situation, what would be our analysis? The fact is that partriarchy is powerful and all pervading. It adapts itself to almost every situation with incredible ease. Infact it has the power to mould situations, even progressive

and radical, for newer forms of oppression. It existed in feudal society, it functions hand in hand with capitalism; what is even more depressing is that it has also not been driven out of post revolutionary societies, nor from left movements. It should not surprise anybody therefore if it exploited the sexual revolution of the West or the availability of contraceptives in general.

Our fight therefore has to be directed against the real enemy. Patriarchy that oppresses us, degrades us to being sexual objects, that refuses to accept responsibility of conception and child rearing and which overtakes any move by us to gain control of our own bodies. Withdrawal of legalised abortion or of contraception would in result be no different from what rightist moralists would desire in complacent glee: a further punishment for women. If we accept the fact that a woman is not free sexually, then to take away her defence mechanisms would amount to victim blaming.

Within marriage, the 'availability' of the wife for sexual gratification in relation to the contraception issue raises delicate questions. Similar to the argument raised earlier, does a wife become a sexual slave only when the couple practices contraception? The reality of the sexual rights of a husband is more deep than is contraception. Restitution of conjugal rights is one such issue that encroaches on to the human rights of the wife. In the Hindu family, the wife cannot raise the issue of rape within marriage, because according to the law she has given her consent once and for all during the marriage ceremony, itself. Legal cases have been filed by husbands when the wife has refused to bear children. Where does contraception figure in these cases?

The woman's choice and control over her own sexuality would more often be much reduced within marriage. Each time she goes through an unwanted sexual experience, she may not be actually 'raped', often, the consequences of not sleeping with her husband may far outweigh the consequences of having slept with him. She may be threatened with insecurity, with the accusation of not fulfilling her conjugal duties, of frigidity and in dire circumstances with desertion. In such a situation, infact contraception comes to the rescue of a woman: she can at least hold on to one end of the rope, however feebly.

One is definitely not making a case that wives and women in general are sexless and that everytime they undergo a heterosexual experience, they are doing it against their own will, only to gratify the man. Of course not. Women can and should express their sexuality in their own right. And yet, they should have the freedom to control their own reproduction, within or without marriage.

From this point, emerges another hotly debated issue; is contraception solely the responsibility of the woman? It is clearly not so. and we have to constantly question as to why there is more research into contraceptives for women as compared to those for men, why women are the more favoured target group in population control programmes and why unsafe and invasive contraceptives are being dumped onto women. Ideally, contraception should be shared equally by the couple and significantly, the natural family planning method which is the safest method of contraception demands such mutual cooperation and understanding. The man respects the women's demand against conception and actively cooperates. Here, however, we are referring to the man who handles an intimate relationship with some amount of responsibility. He may well be exception to the rule. In Bombay city alone the officially registered MTPs in a single year were around 50,000 besides many more that go unregistered. (Karkal, 1985) proving that there were atleast so many unwanted pregnancies in one city in one year.

The point one is trying to make is that while we are aware that contraception is shared responsibility, in the absence of a pro-women milieu. avoiding unwanted conceptions through contraception becomes the woman's last line of defence.

Is there a choice?

If contraception is liberating because it allows a woman to control her own fertility, existing contraceptives tell a sad tale. Contraceptive choice today is not determined so much by the woman in question, but by designs that are beyond her control. These designs work at national and international levels, namely the government's policy regarding population control and the interests of multinational companies. The interests of the latter become clear when one realises the tremendous potential market that they have in healthy women all over the world. Three to five million women in seventy countries were on depo provera alone, in 1978 (Corfman, 1978). According to the 1981 Census of India, 43.4% of all women are in the reproductive age group and of these 80.48% are married. That makes for 11.6 crores of married women in the reproductive age group only on the Indian subcontinent. Since injectables are to be used as a spacing method, all of these women become potential targets at least once in their lifetimes.

It is therefore easy to understand the direct and indirect involvement of drug manufacturers in research

related to long acting contraceptives and the implicit bias underlying all these research studies. Even 'prestigious' international bodies such as the International Planned Parenthood Federation (IPPF) describes all injectable contraceptives as a 'most dependable and useful method of family planning (IPPF, 1978). Contraceptive technology is more under the control of multinationals than it is with women. Delivery of contraceptives may lie with women, as it does in Britain or in India, but this in itself does not mean that decision making or the power to decide on a particular contraceptive on a macro level lies with women. Male hegemony exists and contraception therefore remains an area where all heterosexual women are disadvantaged by a limited choice. (Roberts, 1981). Moreover, the medical establishment is male dominated and much worse, women are made to fit into male defined categories. It is with this preconceived bias that the medical establishment sees our menstrual problems. Since our gynaecological disorders are termed as 'psychosomatic' there is little understanding for menstrual chaos, pain or other psychological disorders that invasive contraceptives induce inside our bodies.

The findings of many of the reasearch studies are questionable. In field trial studies, the necessary physical examination is not always performed on women because it would discourage a woman to continue to participate in the study and would give FP a bad name at the village level (Balasubrahmanyan, 1981). No long term follow up is also conducted. On what basis then are claims of safety made? Hormones can cause long term havoc, therefore women taking hormonal contraceptives have to be monitored for years. Not only they but in the event that they used these drugs in the post partum period, their children too have to be watched until the latter reach puberty. In this context, our fight has also to be directed against the Pill and all contraceptive preparations that cause hormonal and systemic effects. Our concentrated effort against the introduction of injectables, however is more because least control over our own bodies is possible with long acting contraceptives, the dangerous effects of which we cannot remedy by immediate withdrawal and the higher potential of abuse that is related with injectables.

Long acting contraceptives, especially injectables are very important where the question of choice is concerned. The 'value' of injectables, as the proponents of PC see, lies exactly in the fact that it steals choice from women into the hands of male hegemony. A fourteen year old black girl from London was given a shot of DP without her knowledge when she was under general anaesthesia for abortion (Rakasen, 1981). Social workers from Scotland report that a young girl was given a shot of DP, disguised as a glucose injection. In Britain, Asian women in their post partum period are routinely given a DP shot along with the rubella vaccine, without any consideration for the child that would absorb the hormonal drug whilst breastfeeding.

The above examples are only the tip of the iceberg. They are vivid because one can clearly see how choice is snatched from us, throughabuse of the injectable, but the general picture would be more subtle. Throughout the world, especially in the developing countries, injectables would be pushed for the 'sake of convenience'. The question is: whose convenience? When the woman in question cannot decide which contraceptive she must use, 'informed consent' is actually telling half-truths and when she cannot control the long term sequelae of the systemic and hormonal effects on her body, it is inhuman to speak of 'convenience'. Infact, it is the convenience of the drug companies and the dons of population control that is being considered, so that this dangerous hormonal preparation can be administered to 'ignorant and irresponsible' women.

References:

1. Balasubrahmanyan, Vimal, 'After the Pill' Maintream, Vol. XX No. 13, Nov. 1981

2. Corfman, P.A., Evidence to US Select Committee Hearings on Population, US. House of Representative, 1978 (quoted by Jill Rakusen, 1981)

3. International Planned Parenthood Federation 'Factsheets' on Depo-provera.

4. Karkal Malini, Science Age, 1985 (Information Collected through personal communication).

5. Rakusen, Jill, Depo-provera: thee xtent of the problem. A case study in the politics of birth control (in) Women, Health and Reproduction Ed. Helen Roberts, Routledge and Kegan Paul, 1981.

6. Roberts, Helen, Male hegemony in family planning (in above book)

Sexist and Racist Implications of New Reproductive Technologies

(Excerpts from a paper presented at the XI World Congress of Sociology, N. Delhi, August 1986.)

After atomic technology has come under heavy attack, bio-technology, mainly genetic engineering and reproductive technology, are propagated, together with computer technology, as the great hope in the so-called third technological revolution of 'high tech'. In this paper I shall concentrate on the implications of the development of new reproductive technologies. But it should be borne in mind that in practice these technologies do not exist simply side by side but are combined in a number of ways. This is particularly true of the combination of genetic engineering and reproductive technology. It is precisely this possibility of their combination which brings to light their destructive potentialities. The discourse of these technologies is usually following the principle of divide and rule: fundamental research is divided from the application of the research results, genetic engineering is divided from reproductive technology, the application of reproductive technology in industrialized societies is divided from that in the under developed societies. This separation of spheres and contexts which de facto are linked makes a critical assessment of this technological development very difficult if not impossible.

I shall start with a few basic theses:

1. These technologies have not been developed and are not produced on a mass scale to promote human happiness but to overcome the difficulties of the present world system to continue its model of permanent growth of commodities and accumulation. As markets for durable consumer goods are no longer expanding new needs have to be created for the new commodities developed by the scientists and the Industry. The female body with its generative capacities has now been discovered as a new area of "investment" and profit making, for scientists, medical engineers and entrepreneurs, in a situation where other areas of investment are no longer very promising. (1).

2. These technologies are introduced in a situation of social relations between men and women, which are world wide based on exploitation and subordination. It is a historical fact that technological innovations within exploitative and unequal relationships lead to an intensification of the inequality and exploitation of the groups concerned and not to their reduction.

3. These technologies are legitimized by those who want to sell them by humanitarian arguments: to help infertile couples to have a baby out of their own flesh and blood, to help women to avoid handicapped children, to diminish the hazards of pregnancy and child bearing etc. The methodological principle is to high light the plight and unhappiness of a single individual and to appeal to the solidarity of all to help that individual. In this they use all kinds of psychological blackmail. But the individual cases are used to introduce these technologies and to create the necessary acceptance among *all women*. The aim is—total control of women's reproductive capacity. In this woman as a person with human dignity is disregarded.

4. It is often argued that these technologies as such are not good or bad, and that in a better society these technologies could be of great use to mankind. This argument is based on the widespread belief that science and technology are neutral and separated from social relations. A closer analysis carried out by feminists in recent years has however revealed that the dominant social relations are also part and parcel of technology itself. This means, we can no longer say that reproductive technology or genetic technology as such are good, only their application is bad. The very methods and basic principles of this technology have to be criticized (1). They are based on exploitation and subordination of nature, on exploitation and subordination of women, on exploitation and subordination of other peoples, i.e. colonies. It is in this context that one can speak of an inherent *sexist, racist and ulimately fascist bias of the new reproductive technologies.*

Gena Corea in her book 'The Mother Machine' gives ample evidence of the ideological continuity between the eugenics movement and today's genetic engineering and reproduction technology. She quotes the marxist geneticist Muller, who won a Nobel Prize for his work on the effect of nuclear radiation on genes as having said, that infertility, which seemed to be on the increase, provided an excellent opportunity, for the entering wedge of positive selection, since the couples concerned are nearly always, under such circumstances, open to the suggestion that they turn their exigency to their credit by having as well-endowed children as possible (2).

But what constituted the difference between Muller, who dreamt of breeding more men like Lenin, Newton, Leonardo, Pasteur, Beethoven, Omar Khayyam,

Pushkin, Sun Yet-Sen, Marx (2) was that in the meantime it was no longer necessary to have complete men women and make them copulate or prevent this in order to achieve those superior beings. Genetic research had meanwhile advanced and it was possible to use donor sperm of geniuses to fertilize women with. Of course the women should also possess 'superior' quality eggs. A further step in the perfection of the technological means for the application of the principle of selection and elimination are the various methods of quality control and above all in-vitro fertilization (IVF). It is possible today not only to isolate and select ova and sperm but also to isolate genes, to cut up the DNA to examine which of the chromosomes are defective, to recombine and manipulate pieces of the DNA and thus directly influence the genetic substance. Geneticists are busy everywhere now to map the genetic pool of humans, to discover ever more "genetic defects". I would not be surprised if in the near future we would see a whole range of diseases being declared as genetically caused. The ideology of socio-biology and of eugenics will provide the criteria for what is to be understood as 'valuable' and what as 'defective'. These new "hereditary diseases" will provide an ample market for the application of "gene-therapy", and pre-natal diagnosis, and neo-eugenics. The aim of this whole movement is to *adapt the human being to the destructions of the environment which technological process and the growth model have caused.*

Sexist biases permeate the new reproductive technologies as well as genetic engineering at all levels. In general they imply that motherhood, the capacity to bring forth children, is changed from natural process, in which woman cooperated with her body as a conscious human being, to an industrial production process, in which the woman's body is made totally transparent, the processes of childbearing totally rationalized, planned and controlled by the medical experts, the product, the child, monitored at all stages of its production, the woman herself being more than ever objectified. In patriarchy she has long been an object for male subjects. But what is new with the new reproductive technologies is that she is no longer one whole object, which has to be put under male control, but she can be divided up in a whole series of objects, which can be isolated, examined, re-combined, sold, hired, or simply thrown away, like ova which are not used for experimentation. This means in the last analysis that the integrity of the woman as a human person, an individual, i.e. a person who cannot be divided up is destroyed by these technologies. It is the old ideology of dominance of man over nature, the ideology of scientific rationalism which has led to this stage of destruction of the woman as a human person, and her division into an arsenal of reproductive matter. This rationalization process goes hand in hand with an extension of poverty relations into the female body. Women, who have been fighting for reproductive 'rights' in recent years, have coined the slogan: My belly belongs to me or, I am the master of my belly! Such slogans convey the same logic of private property. With the new reproductive technologies this logic reveals its final destructiveness. A woman who considers her womb, her ova, her embryos, her 'property' can sell them or can buy those of other women. On a more specific level, this sexism manifests itself in various ways: For *women* these new developments mean above all, that their reproductive capacity will be put under rigid quality control. One of the scientists working in this field said that in future no woman would have the right to burden society with a disabled child. The social pressure on pregnant women to bring forth perfect children is already enormous today and will grow further. In the industrialised societies women are already now subjected to a whole series of pregnancy tests. If she is more than thirty, she is counted among the 'risk-pregnancies'. She is more or less put under heavy pressure by her doctor to undergo an amniocentesis. Yet, the risk of hurting the foetus is almost as big as that of having a child with Down-Syndrome. In the western industrial societies amniocentesis is used to detect diseases of the foetus like the Down-syndrome. In countries like India and China the female sex of the foetus is already considered the 'defect', and leads to large scale abortion of female foetuses. Vimal Balasubramanyam has rightly observed, that this genocidal tendency, made possible by modern reproductive technology, was advocated by some of the western propagators as a more effective measure of population control. 'Breeding male' was seen as the remedy against the 'population explosion'. Here we see the close interconnection of racism and sexism (3).

Apart from the total quality control which women will have to undergo, the new reproductive technologies provide the technical tool to rob women of their autonomous reproductive competence and to put it into the hands of medical experts. Following the above mentioned general scientific methodology, women are divided into their relevant reproductive part, as ovas, uteri, and embryos. The female body is treated as an arsenal of reproductive raw material out of which the medical engineer selects those parts which he needs for the industrial production of children. Gena Corea writes that the girls who are born today most probably feel, when they grow up, that

giving birth to a child is a highly complicated affair, for which only the medical experts have the necessary competence. The producer of children will then be those medical experts, not the women (2). This loss of the competence of childbirth can already be observed with many women today.

It seems that the technocrats now want to get control over the life-giving processes after they have been the masters of death so far. All their power was hitherto based on the ultimate power of destruction, whereas they had to depend on women to create life. The new reproductive technologies are an attack on this bastion. We can observe a rapid development of IVF clinics in many countries and research in this field is advancing by leaps and bounds. More and more the 'natural' processes of giving birth is also manipulated.

If we ask how medical experts got such sweeping control over women's reproductive capacities, we have to remember the whole contraceptive movement in the last decades. Before sterility was defined as a disease by the WHO, 'fertility' had been treated as a disease for many years. Not only pharmaceutical firms who wanted to sell their contraceptives, not only the medical establishment had an interest in calling women's fertility a disease, but the women themselves became "sick of their fertility" as one woman from Canada put it at the Emergency Conference on Reproductive Technology in Sweden in 1985. By looking at fertility as a purely biological affair, by treating it as a disease, women handed over the responsibility for their generative powers to medical experts and to scientists. Instead of changing the sexual relations of men and women, women's emancipation was expected as a result of technological innovation and medical treatment. And in fact, in the course of time many women became de facto sick, not by their fertility as such, but by treating it with contraceptives of various sorts.

By treating fertility and sterility as diseases, the possibility of looking at them as socially and historically influenced is barred. They are defined as purely biological categories and hence fall into the responsibility of medical experts. Any movement against the sexism inherent in the new reproductive technologies has to fight against the biological determinism implied in the definition of sterility and fertility as diseases. It is this definition, backed by the WHO, which puts women worldwide at the disposal of powerful interests, mostly in the hands of men.

—Maria Mies

(MFC News contd. from p. 8)

ORGANIZATIONAL MATTERS:

1. There was some misunderstanding regarding the members of the cells formed at Patiala (see MFC Newsletter Feb 1986). The reformulated cells are:

Cell 1. Critical analysis of Government Health Policies and Programmes (Ravi Duggal, Padma Prakash, Abhay Bang)

Cell 2. Alternative strategies in Health Care (Abhay Bang, Narendra Gupta, Ashok Bhargava).

Cell 3. Investigative field research to support health action (Padma Prakash, Sathyamala, Kamala Jayarao, Anil Patel).

Cell 4. Communications/lobbying on specific health issues for policy changes (Marie D'Souza, Ulhas Jajoo, Mira Shiva, Dhruv Mankad, Anil Patel)

2. **Convenor's Experience:** Dhruv Mankad sharing his experience during the past six moths as Convenor, felt that over the years the physical volume of mfc's day to day work has increased. Since the convenor like other members of mfc, is also involved in local work, increasing preoccupation with mfc work encroaches upon the local work, sometimes to such an extent as to eclipse it. This would at some time necessitate either a full time convenor for mfc or at least a much quicker turnover of convenors.

Other administrative matters such as the membership position, finances, publication and distribution of the anthologies etc. were also discussed.

— Dhruv Mankad, Convenor MFC

References:

1. Maria Mies: Why do we need all this?—A call against genetic engineering and reproductive technology: Women's studies International Forum, Vol 8 No. 6, 1985.

2. Gena Corea : The Mother Machine: Reproductive Technologies, From Artificial Insemination to Artificial Wombs, Harper and Row Publishers, New York, 1985.

3. Vimal Balasubramanyam: Medicine and the Male Utopia, EPW, 23 October, 1982.

NH 3

Injecting Ill Health: The Depo Provera Story

Issued in Public Interest by

Public Interest Research Group
142, Maitri Apartments, Plot No. 28, I.P. Extn.
Delhi-110092
Phone-cum-Fax—
91-11-2224233

Price : One Rupee

In the era of Deregulation, Free Trade and Foreign Investment, Indian Government is allowing the entry of many products which are hazardous to both people and environment and are banned in many countries. In fact, India is fast becoming a dumping ground for banned products and wastes. The list includes banned pesticide, Monocrotophos, by Ciba Geigy, Plastic Scrap from Pepsi, Cowdung from Holland and lead wastes from the UK and Germany. The latest entry in these products is a hazardous contraceptive injection, Depo Provera. The Indian Government through the Drugs Controller of India gave permission to manufacture and market this contraceptive in India. This drug will be manufactured by Max Pharma, India, in foreign collaboration with Upjohn Co, a US drug Multinational Corporation. In April 1994, Max Pharma launched this drug with much fanfare in India amidst protests by women's groups. Upjohn Co, with a $4 billion turnover, is the 16th largest health care corporation in the world. Started in 1988, Max India is involved in pharmaceutical, electronics, and packaging business, collaborating with many Multinational Corporations. The Family Planning Association of India (FPAI), an NGO, is to launch Depo through its wide-

network, another step in the State washing its hands off its responsibilities. This hazardous injectable contraceptive which has been the centre of a great deal of controversy, could get approved by the US Food and Drug Administration (FDA) only as late as 1992. However, even before FDA approved its use as a contraceptive in the US, it was already in use in 90 countries (mostly Third world), on millions of women, which, given its dubious safety record, amounts to a massive experiment on women. Depo Provera has an annual sales of Rs 300 crore (US$100 million), and is channelised mostly through the USAID.

How does Depo Provera work ?

Depo Provera is a *progestogen*, an artificial form of *progesterone*, the hormone produced during the second half of the menstrual cycle. Synthetic hormones act by imitating the function of naturally occuring hormones. But by being artificially introduced at wrong times, they disrupt the delicate natural hormone balance.

DMPA acts on the *hypothalamus-pituitary* axis in the brain by introducing *progesterone* into the blood stream at times when its level is supposed to be low i.e. soon after menstruation. DMPA, in addition to inhibiting ovulation, also thickens cervical nucus, and makes the uterus a hostile environment for fertilisation in case ovulation does occur.

Depo Provera in India

Manufacturer	**: Max Pharma, India**
Foreign Collaborator	**: Upjohn Co, USA**
Compound	**: *Medroxyprogesterone Acetate [DMPA]***
Dosage	**: 150 mg. every 3 months**
Proposed Cost	**: Rs 150 per injection.**
Status	**: No mandatory clinical trials**

History of Depo Provera

1960 : Depo Provera (DMPA) approved by the US Food and Drug Administration (FDA) for treatment of miscarriage and endometriosis.

1962 : Studies begin of Depo Provera as a 'birth-control shot'.

1967 : Upjohn Co. first applies for permission to market the drug as a contraceptive. Approval denied.

1971 : Depo Provera banned in Peru because of observation of nodule formation in rats.

1972 : US FDA approves the drug for use in treatment of advanced endometrial and renal cancer.

1974 : US FDA withdraws its approval of 1960 for DMPA, because of possibility of birth defects.

1976 : DMPA introduced in Indonesia.

1977 : DMPA introduced in Sri Lanka.

1978 : US FDA, once again, denies approval of DMPA as a contraceptive. But, all restrictions on sales to third world countries lifted.

1983 : US FDA, yet again, rejects Upjohn application for approval.

1985 : Dept. of Health, UK approves Depo Provera for long term use, but not "first-choice" contraceptive.

1986 : Womens' and Health Groups in India file a case in the Supreme Court asking for a ban on Net-en and other hazardous contraceptives like Depo Provera.

1992 : FDA approves DMPA for contraceptive use in the US.

1993 : Indian government gives approval to Depo Provera.

1994 : Depo Provera launched in India.

Hazards of DMPA Use

The most common adverse effects are—menstrual cycle irregularities (varying from frequent bleeding to complete absence of menstruation), extreme weight gain or loss, headache, nervousness, mood changes, dizziness, fatigue, blood pressure changes, fluid retention, abdominal pain. It is unsuitable as a spacing method (between one child and the next) because return of fertility is not assured. The other adverse effects are—

- DMPA is associated with a decrease in bone density, since it inhibits *estrogen* production. Long term use may contribute to the development of *osteoporosis* (brittleness and thinning of bones, leading to repeated fractures pain and disintegrating vertebrae.
- Data show a link between low birth-weight babies and neonatal mortality and (accidental) use of Depo Provera during pregnancy, masculinization on female fetuses, feminisation of male fetuses, congenital abormalities.
- The link between breast cancer and DMPA has not been ruled out. Some data indicate doubling of the risk of breast cancer for younger women, with use of DMPA for over two years.
- There is increased incidence of cervical cancer in women using DMPA for more than five years.
- DMPA causes changes in lipid metabolism, a risk factor for developing *atherosclercsis* and cardio-vascular disease.
- Effects on breast-feeding infants is unknown. Since DMPA passes into breast milk, giving DMPA to mothers of nursing babies violates the restrictions on use of children in medical experiments, evolved after the Nuremburg trials.

Upjohn has had twenty years to compile data but has failed to do so. There is little or no data about effect of DMPA on developing

fetuses, *osteoporosis*, or the mechanism that causes breast cancer. In fact, whatever little data exist, point to the extremely unsafe and dubious nature of the drug.

Barking up the Wrong Tree : Beagle Dogs and Biased Research

The Depo Provera case amply demonstrates biased research setting out to prove whatever is convenient. For years, positive results of drug trials on animals like monkeys and beagles were the green signal to go ahead with human trials. In recent trials on beagle dogs, tumour formation was noted after introduction of *progestogens* (Depo). Suddenly, beagle dogs were found, even by the WHO, to be "inappropriate to investigate the effects of *progestogens* in humans". Beagle dogs were now found to be so different from humans that negative results would not necessarily be seen in women—for once women undergoing clinical trials were elevated to the status of human beings! To consider the subject rather than the drug unsuitable is highly questionable.

The other fraud is that of statistics. Incidence of *endometrial carcinoma* in monkeys is dismissed as "insignificant". Significance obviously has more to do with political motives than with statistical inferences.

Upjohn also turned a blind eye to the fact that in the seven year beagle studies, 18 of 20 dogs receiving Depo, died, by claiming that beagle dogs are especially prone to breast tumours.

Ethical Questions

Injectable contraceptives, especially DMPA, have a notorious track record as regards ethics. Long before it was approved for contraceptive use, physicians in the US were prescribing DMPA to "promiscuous" teenagers and psychiatric patients deemed incapable of managing their own contraception. It was also used on immigrant women, with whom communication is 'difficult'.

In countries of the North, the use of DMPA on minorities smacks of a racist and capitalist bias. It has been used on Black and Chicano women in the US; Maori, Black and working class women in New Zealand; and West Indian and Asian women in Britain. Quite often, these women have been administered Depo without their knowledge and consent.

The highest use of DMPA in countries reporting a high 'acceptability, (like Jamaica, Indonesia, Tonga, Thailand), is among the least well-selected, least well-informed and least well-monitored population. This despite the fact that its long-term safety record is unestablished.

Contraceptive Research : The onslaught of Population Control

In 1984, both UK and the US received recommendations from panels of experts convened to consider the merits of DMPA as a long term contraceptive. Despite access to the same data, the UK panel recommended marketing approval, but the US Public Board of Inquiry did not. Differing national policies helped shape the interpretation of data, and thus the divergent outcomes. Contraceptive research policy in the US during the last 30 years is changing with the liberalising inroads made by the Clinton administration. For example, the reversal of the "Mexico City Policy" which forbade financial support—domestic or overseas—to institutions that may provide abortions.

Upjohn Co. USA, has worked vigorously to get approval for Depo Provera. Not only does Upjohn manufacture Depo, it also controls most of the information about it. It spends millions of dollars a year on research, ($6 million on one study in New Zealand alone—an amount equivalent to the entire annual budget of the Medical Research Council of New Zealand), and investigates mainly cancers, whose causes are difficult to prove under any circumstances, rather than other more immediate side-effects. Moreover, the hostility of the population control establishment to critics concerned about cancer may prevent abnormal conditions from being looked into. **Thus, how much "objectivity" can be attributed to data related to a drug generated by the very interests that stand to profit from its extensive use?**

The constant pursuit of approval for Depo in US and Canada, is not for the small US or Canadian market. Upjohn intends to capitalise on the high international reputation and influence a US-Canadian license would hold for other countries where Upjohn hopes to license Depo. This also has to be seen in the context of the increasing caution of governments in the Third World about licensing a drug unregistered in the country of origin.

A drug for long-term use as a contraceptive should never be used in a country like India where specific studies on the tolerance of the drug, its side effects and potential dangers have not been carried out in the target population. The desperate hurry to introduce Depo is because an injectable contraceptive is "ideal" in the eyes of the population control lobby, since it is completely out of a woman's control and can be given even without her knowledge. The assurances of Upjohn regarding conducting post-marketing surveillance (PMS) are touching, but lacking any sincerity or basis

Quotable Quotes

"... population explosions, unless stopped would lead to revolutions: population control is required to maintain the normal operation of US commercial interests around the world".
Dr. Ravenholt former Head of the USAID

"Allowing Depo Provera into India is part and parcel of liberalisation of the economy," Dr. P. Dasgupta, Drugs Controller of India.

in reality. In a country like India, a prescription for the most potent drug can be had for a song, and infrastructure for carrying out PMS simply does not exist. Collection and use of reports of adverse reactions which even in rich Northern countries tend to produce fragmentary and often unreliable results are completely impracticable in developing countries. Informed consent is again, a far cry, where women's "choice" of contraceptives is shaped by marketing techniques of MNC-backed drug companies, and the nexus between doctors and pharmaceutical companies precludes any "independent" decision making by women. Noresterat (Net en) another injectable contraceptive, manufactured by Schering A.G., Germany will soon be on the market, another move violative of all ethics, in keeping with 'liberalisation'.

An individualistic perspective of "leave-it-to-the-individual" robs the discussion of the drugs impact on the group as well as socio-political realities. The only hope, when the state is abdicating its responsibilities, is for the Indian people to reject Depo Provera and similar tools of control.

What You Can Do

- Write letters of protest asking for ban of Depo Provera in India to **Drugs Controller of India, Ministry of Health & Family Welfare, Nirman Bhavan, New Delhi -110 001**
- Organise meetings of youth, women, NGOs, student groups at various levels to discuss the implications of Depo Provera.
- Write letters to Max Pharma India to withdraw from this project. *Address:* **12th floor, Devika Tower, 6, Nehru Place, New Delhi**
- Write letters in newspapers, magazines and journals expressing your views on this controversy.
- Contact the following groups working on this issue :
  Saheli, Under Defence Colony Flyover, New Delhi - 110024
  Jagori, C-54, South Extension II, New Delhi -110 049
  Forum for Women's Health : 2, Vishwadeep, 95, Bhau Daji Rd, Matunga, Bombay, 400 019.

WH 3

Tel. (02640) 82340 Mangrol.
(0265) 421246 Baroda.

ARCH
Po. Mangrol
Via. Rajpipla - 393 150
Dist. Bharuch (Gujarat) India

action research in
community health & development

November 28, 1994

To,
Dr. Ravi Narayan - Thelma
CHC
Bangalore

Dear Ravi / Thelma,

Enclosed with this letter is a copy of the paper on our experience and efforts to introduce Copper-T as a spacing method. The paper discusses the problem posed by the community women to accept Copper-T and subsequently their readiness to accept it after health education.

We think it would be useful to share our experience with you and get your critical comments and feedback.

With thanks.

Your's Sincerely,
Daxa Patel.

CN
420
7/12/94

IUD Acceptance – Hurdles and Possible Solutions

Introduction:

India is one of the first third world countries that adopted population control as a national goal more than four decades ago. Initially the policy was focused on child spacing as well as permanent sterilization, but gradually the focus shifted to sterilization almost to the exclusion of spacing methods. One could see some efforts to popularize intra-uterine devices (IUDs), condoms, etc., in the early phase, but these unsteady beginnings were very soon abandoned. The health authorities took non acceptance of IUDs and condoms for granted and assumed that women will not accept IUDs. This almost sole reliance on permanent sterilization has got population control program stuck in the rut. The strategy has failed to make required dent in the demographic profile of the country. Excesses during emergency of 1975-77 made sterilization program extremely unpopular amongst Muslims, Tribals and even Harijans. Meanwhile other third world countries like Bangladesh and Indonesia, that were way behind India as far as fertility statistics were concerned, have made rapid progress in this regard by adopting predominantly child spacing programs.

ARCH (Action Research in Community Health & Development) has been working for last fourteen years in a predominantly tribal area of eastern part of Bharuch District in Gujarat to develop appropriate primary health care programs. For the first 10 years of our work in this area we thought it wise not even to mention birth-control. This would antagonize the rural population. Then women first made their needs known to us through increasing demand for induced abortions. It was soon clear that women, while reluctant to accept permanent sterilization soon after the birth of second or third child, were yearning to get respite from rapid succession of pregnancies and also unwanted pregnancies. They desired small families

through spacing, but not sterilization soon after completing the desired family size. Condoms are still not popular, nor are the oral contraceptive pills. But nothing definitive about them should be said, looking at our experience with IUDs.

Apart from the permanent sterilization, IUD is one spacing method known to a large number of women of all classes. Yet, despite their desire for spacing, most of the women are very reluctant to accept it. As is to be expected, they have many misconceptions about where IUD is placed in the body, what it does and how it works. Many women have revealed to us that they believe that it would go up in the chest or would be lost in the abdomen, it is hot and causes loss of weight and energy. Also both men and women strongly fear that with IUD in place they will both get stuck during sexual intercourse and separation will be impossible unless doctor intervenes. These perceived fears and apprehensions have to be systematically dealt with through sensitive health education program. In this paper we present our experience in this regard.

Method and Material:

Between January 1987 and December 1990, 56 women (Group A) of all castes and economic categories came to Mangrol Dispensary for IUD insertion. During this period we were just beginning to learn about the fears and misconceptions of women regarding IUDs and had not yet developed a need specific health education program to dispel them.

By 1991 our understanding of the reasons behind women's misconceptions and fears had improved and from January 1991 we initiated a process of free and friendly exchange of information to bridge the gap of radically different views of women about anatomy leading to various types of differing perceptions. For the first time they saw through the slides that uterus, vagina, fallopian tubes, etc., are completely separate from the gastrointestinal tract in

the abdominal cavity. We also developed a simple low cost model of thermocol showing uterus, cervix, vagina and fallopian tubes for demonstration. All women who came for IUD insertion were first shown this model and the whole process of IUD insertion was shown to them by actually inserting IUD in the model through cervix into the uterus and left in uterum with small thread freely hanging in vagina. They could see that uterus is a separate organ closed from above and the IUD cannot go up in the chest the fear of getting stuck by IUD was also not real. It was also easier for them to see that with the help of thread hanging freely in the vagina, the IUD can be easily removed any time they wanted. All possible problems of leucorrhoea, bleeding and pain were explained at the time of insertion and the women were asked to visit the dispensary if such problems occurred so that appropriate treatment could be given. 80 women (Group B) accepted IUDs during this period of three years from January 91 to December 93.

There was no change of techniques, IUDs, instruments or sterilization method between the two periods. For each woman a separately autoclaved set of instruments, towels etc., was used. The same doctor introduced IUDs during both periods. IUDs were supplied in standard sterilized packs from the nearby government Primary health center in Lachharas. Detailed records were kept of all subsequent visits and reasons for IUD removal were recorded in all cases. Follow up contacts were made in cases where women did not visit the dispensary on their own.

For the purpose of statistical analysis of difference in the rates of IUD removal / retention we have followed life-table technique ('Statistical Methods in Epidemiology' by Harold Kahn and Christopher Sempos, Oxford University Press, 1989. PP. 168-180). Rates of IUD removals in each 2 month time interval after the date of insertion upto 2 years were worked out for both groups. Those cases where no follow up contacts could be made (2 in Period A and 1 in

Period B) have been considered as withdrawn in the very first time interval. Those cases in group B (period 1991-93) where the women were still continuing with the IUDs on November 1, 1994 (date of analysis) and had not yet completed 2 years since insertion were considered withdrawn in appropriate time interval by taking into account the time they had already retained the IUDs. There were no such cases in group A (period 1987-90) as all women who got IUDs inserted in this period had completed more than 2 years on November 1, 1994.

Results:

Tables 1 shows education of women in groups A and B. As is seen the two groups are not significantly different from each other in this regard (P = 0.60).

Table 1. Education of Women in two Groups:

Education	*Group A*		*Group B*	
Category	*(1987-90)*		*(1991-93)*	
Illiterate (0)	12	21%	20	25%
Primary (1 to 4)	9	16%	9	11%
Secondary (5 to 7)	15	27%	17	21%
Secondary (8 to 10)	14	25%	26	33%
Higher Secondary (10+)	6	11%	8	10%
Total.	56	100%	80	100%

Table 2 shows mean age of women with standard deviation in two groups. They are also not significantly different from each other ($P \geq 0.60$).

Table 2. Mean Age of Women in two Groups:

	Group A		*Group B*	
	(1987-90)		*(1991-93)*	
No. of Women		56		80
Mean age in years		23.9		23.4
Standard deviation		5.6		4.5

Table 3 shows caste breakdown of the women in two groups. As can be seen proportion of tribals had increased sharply in group B.

Table 3. Caste groupings in two Groups:

	Group A		Group B	
Castegroup	(1987-90)		(1991-93)	
Upper castes	34	61%	31	39%
OBCs	6	11%	10	13%
Scheduled castes	2	4%	1	1%
Scheduled tribes	7	13%	33	41%
Muslims	7	13%	5	6%
Total	56		80	

Table 4 shows the number of women who complained of leucorrhoea, excessive menstruation or pain during first six months since IUD insertion in both groups and also the number of women who got their IUDs removed because of them. The proportion of women who complained of these problems is not significantly different in the two groups (P = 0.39). But significantly higher number of women in group A also got their IUDs removed because of these problems in group A (80 % of those who complained against 20% in group B. P = 0.0002).

Table 4. Complaints of Leucorrhoea, Bleeding or Pain in two Groups:

	Group A (1987-90)		Group B (1991-93)	
No. of Women who accepted IUDs	56		80	
Those who complained of Leucorrhoea, bleeding or Pain within six months of IUD insertion	20	36%	23	29%
Those who also got their IUDs removed because of these problems.	16	80%	5	22%

Tables 5 presents life-table analysis for women in groups A and B respectively. As is seen, at the end of six months from insertion 66 % and 89% women had retained IUDs in groups A and B respectively while corresponding figures at the end of one year are 48% and 77% respectively. This differences is highly significant (P = 0.002). The rate of IUD retention for all intervals is also significantly higher in group B (P = 0.025).

Table 5: Life-table analysis for Removal / Retention of IUDs

Time at beginning of interval (months)	*No. at beginning of interval*	*IUDs removed in the interval x to x+2*	*Cases withdrawn in the interval x to x+2*	*Ox adjusted for with-drawals.*	*Probability of*		
					IUD removal during interval	*IUD retention during interval*	*IUD retention from time of insertion up to x+2*
				Ox - 2wx/2	*(2dx/O'x)*	*(1 - P1)*	*(x+2)P0*
x	*Ox*	*2dx*	*2wx*	*O'x*	*2qx*	*2px*	
Group A (Period 1987 - 1990)							
0	56	2	2	55	4%	96%	96%
2	52	8	0	52	16%	84%	81%
4	44	8	0	44	19%	81%	66%
6	36	4	0	36	12%	88%	59%
8	32	4	0	32	13%	87%	52%
10	28	2	0	28	8%	92%	48%
12	26	0	0	26	0%	100%	48%
14	26	2	0	26	8%	92%	45%
16	24	1	0	24	5%	95%	43%
18	23	0	0	23	0%	100%	43%
20	23	3	0	23	14%	86%	37%
22	20	5	0	20	25%	75%	28%
24	15						
Group B (Period 1991-1993)							
0	80	5	1	80	7%	93%	93%
2	74	2	0	74	3%	97%	91%
4	72	2	0	72	3%	97%	89%
6	70	4	0	70	6%	94%	84%
8	66	5	0	66	8%	92%	78%
10	61	1	5	59	2%	98%	77%
12	55	1	1	55	2%	98%	76%
14	53	3	3	52	6%	94%	72%
16	47	5	2	46	11%	89%	65%
18	40	6	7	37	17%	83%	54%
20	27	1	7	24	5%	95%	52%
22	19	2	3	18	12%	88%	46%
24	14						

Table 6 shows reasons for IUD removals in two groups. It is seen that removals due to leucorrhoea, bleeding, pain, etc., have fallen sharply in group B.

Table 6. Reasons for IUD Removals in two Groups

Reasons for IUD Removal	Group A (1987-90)		Group B (1991-93)	
Leucorrhoea & Pain	18	46%	10	27%
Excessive Menstruation	11	28%	7	19%
Desires Child	6	15%	11	30%
Desires Permanent Sterilization	3	8%	3	8%
Spontaneous Expulsion	0	0%	6	16%
Other	1	3%	0	0%
Total	*39*	*100%*	*37*	*100%*

Discussion:

This study could have missed out other influential variables in the two periods, but we do not believe that any positive time trend affecting the outcome is operating in this locality and community to affect the difference in rates of IUD removals. The living conditions and the civic amenities available to these communities remain essentially unchanged. The difference in the rates of IUD retention in two groups could possibly be related to the fact that significantly higher number of tribal women are included in group B who may may have greater capacity to bear with body pain and discomfort. A closer look at the data, however, shows that the drop in rate of IUD removal is steep and across all the caste groups. The tribal women's possible greater pain bearing capacity is not an explanation. Moreover if the higher thresold of physical discomfort in tribals was indeed an explanation, one would have expected much higher proportion of tribal women opting for IUD insertion in group A. In fact our understanding is that the level of apprehension amongst tribals is very high.

The proportion of women who reported leucorrhoea, bleeding or pain in first six months after IUD insertion is essentially same in two groups. But rate of IUD removal due to these

problems is significantly higher in group A, which strongly supports our contention that intensive and specific health information related to woman's reproductive system about which there are widespread misconceptions and apprehensions, has had positive effect on acceptance and continuation of IUDs. The findings are strongly suggestive and need to be followed up in a community setting. We have not been able to do proper bacteriological tests on women who came with specific complaints, but on clinical examination there was no evidence of infection except for one woman in group B in whose case IUD was promptly removed. It should be noted that despite complaints a large majority of women who had been given appropriate health education were reassured and could continue to retain IUDs and on followup showed no adverse effects. This is an important finding at a time when IUD has been discarded by all concerned, including health activists. Given all the limitations of this study it can be said cautiously that IUDs can be a decent choice to women who in large numbers are demanding child spacing in subdued voice rather than permanent sterilization. There is reason to believe that similarly other groups of eligible couples are waiting to be offered condoms and oral contraceptives.

Dr. Daxa Patel & Ambrish Mehta

ARCH, Mangrol

21 November, 1994.

Family Planning Methods

Questions and Answers

FAMILY PLANNING METHODS

Questions and Answers

It is now generally understood that family planning means having children by choice and it is possible not to have children when the parents do not want them. Thus, if the couples desire, they can prevent conception by using any family planning.methods that might be liked and selected by them.

There are several methods of contraception or preventing pregnancy i. e. natural methods, non-terminal artificial methods and terminal methods.Some are to be used by men and some by women. The couples have to select the methods of their choice and liking and use them as and when they want. Non-terminal methods are suitable for spacing the birth of children, but can also be used for limitation. The terminal methods are accepted only when couples decide not to have any more children.

Efforts have been made here to provide information in the form of questions and answers about these methods and also to remove certain common doubts and fears about certain methods.

NATURAL METHODS

(a) COITUS INTERRUPTUS

Q What is Coitus Interruptus ?

A Coitus Interruptus means withdrawal of the penis before ejaculation. This is also known as "Withdrawal' method. This is perhaps the oldest contraceptive procedure known to man.

Q How does Coitus Interruptus avoid conception ?

A Coitus Interruptus avoids the flow of semen into the female genital tract.

Q What are the advantages of Coitus Interruptus ?

A This method requires no supplies and no particular preparations. It costs nothing.

Q What are the disadvantages of Coitus Interruptus ?

A In order to practise it successfully, it is necessary that the man must have sufficient self-control. Some men are physically or emotionally unable to use this method. Unless the woman reaches orgasm prior to the withdrawal, additional manual stimulation may be necessary for sexual satisfaction.

Q Is there any possibility of failure of this method, and if so, how ?

A This method may fail due to escape of semen before ejaculation or delayed withdrawal or deposit of semen in the women's external sexual organs which may result in pregnancy,

Q What are the side-effects of Coitus Interruptus ?

A Although a vide variety of gynaecological, urological. neurological and psychiatric ills have been attributed to this practice, the cause-and-effect relationship has never been established. Many couples continue to use the method for years without apparent ill-effects and with adequate sexual satisfaction for both partners.

(b) RHYTHM METHOD

Q what is Rhythm Method ?

A The Rhythm Method is based on the avoidance of coitus during unsafe period i.e. the days when it

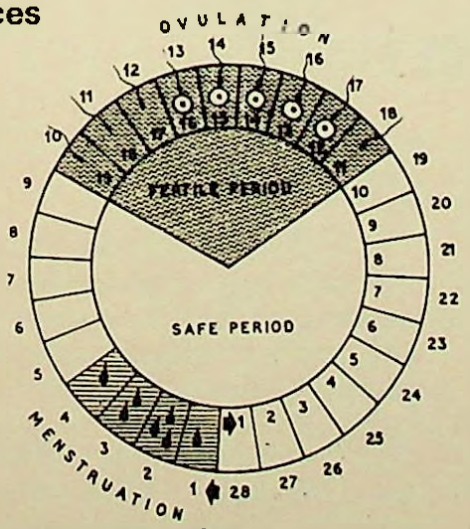
could result in the simultaneous presence of fertilizable ovum and mobile spermatozoa.

Q What is considered safe period and unsafe period according to the Rhythm Method ?

A In every month there is a certain period when intercourse does not lead to pregnancy. This period is called the safe period. This is calculated on the basis of the menstrual cycle of a woman.
In order to find out the exact days of safe period and unsafe period one should count eleven days backward from the expected date of commencement of menstruation. For example, if menses are expected to commence on the 28th of a month, the date backward by eleven days will be the 17th. Now go back by 5 days more and note down the dates. They will be 16th, 15th, 14th, 13th, and 12th. Ovulation from the ovaries of the woman can occur on any of these 5 days. To this we should add 2 days more for the life of the sperm and one day for the life of the ovum. Thus, this middle period of eight days i. e. 16th, 15th, 14th, 13th, 12th, 11th, 10th, and 9th of the month will be full of possibility of pregnancy. This is known as unsafe period. The 8 preceding days, and the following 11 days are regarded as safe period. There will be no ovum to meet the sperm during these days and a coital act performed during this period will not result in pregnancy.

Q What are the disadvantages of Rhythm Method ?

A This method greatly reduces the opportunity for intercourse. However, coital act can be performed during unsafe periods only by using some suitable methods of contraception. Besides it is unsuitable for a women with grossly irregular menstrual cycle. Successful practice of Rhythm Method also requires considerable self-control and an equally strong desire



to control fertility. This method also requires correct calculations and proper understanding.

Q Are there any chances of failure of the Rhythm Method ?

A Apart from taking a chance on the days known as unsafe. the main reasons for the failure of Rhythm Method are errors in recording the menstrual history, errors of calculation, the inherent variability of the menstrual pattern and exceptionally long survival of sperms in the female genital tract.

Q Are there any side-effects of the Rhythm Method ?

A No, there are no side-effects of the Rhythm method,

(c) ABSTINENCE

Q What is abstinence ?

A Abstinence means non-indulgence in sexual intercourse when children are not required,

Q How for is the abstinence practicable ?

A Abstinence requires a high degree of self-control on the part of the men and women. This may not be possible in many cases.

NON-TERMINAL METHODS

(a) NIRODH

Q What is 'Nirodh' or condom ?

A 'Nirodh' or condom is a contraceptive rubber sheath which covers the penis during intercourse and prevents the flow of semen into the vagina. 'Nirodh' is the Indian name of condom.

Q What are the advantages of the use of 'Nirodh' ?

A The 'Nirodh' offers relaible protection not only against pregnancy but also against venereal

infections. If can be used in almost any situation where intercourse is possible.

Q What are the disadvantages of 'Nirodh' ?

A There are no perceptible disadvantages of the use of 'Nirodh'. However, some men and women consider the rubber membranes an obstacle to sexual sensation.

Q Is there any possibility of the failure of 'Nirodh'?

A Pregnancy may result from a break or tear of the rubber sheath or from the escape of semen at the open end of the 'Nirodh', if withdrawal is delayed.

Q What are the side-effects of the use of 'Nirodh' ?

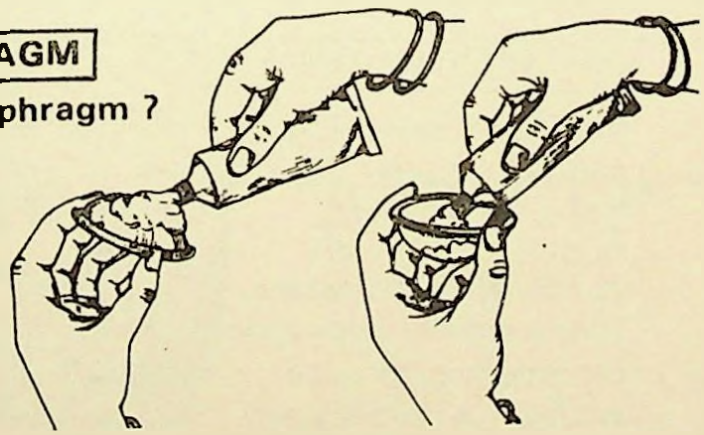
A There are no side-effects of its use. However, an occasional individual may be sensitive to rubber.

Q How popular is the use of 'Nirodh' in India ?

A 'Nirodh' is one of the most popular conventional contraceptive devices used in India-it is freely available from the Family Welfare/Planning Centres, Public Health Centres and Sub-Centers and is widely sold at the rate of 25 paise for three pieces.

(b) DIAPHRAGM

Q What is a Diaphragm ?



A Diaphragm, also known as pessary, is made of soft rubber and has a flexible metal spring around its circumference. It is used by women. It lies diagonally across the vaginal canal. The Diaphragm covers cervix, the upper Part of vaginal opening into the uterus. Diaphragm is always prescribed by doctors and should be used in combination with a vaginal jelly or cream which acts as a spermicide as well as a lubricant for inserting the Diaphragm.

Q What are the difficulties in the use of Diaphragm ?

A The Diaphragm are of different sizes (i. e. from 50mm to 105 mm). It requires a pelvic examination by a physician or a trained health worker to select the Diaphragm of a correct size. In order to be effective it must be fitted properly. The women must also know as to how to insert the Diaphragm and how to remove it.

Q How effective is the use of Diaphragm ?

A If used properly the Diaphragm offers a high level of protection against unwanted pregnancy.

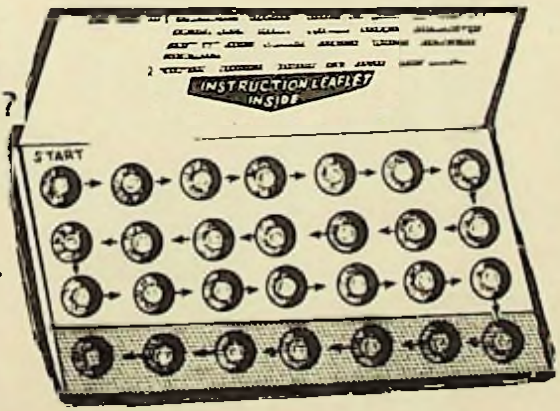
Q In what conditions the use of Diaphragm proves a failure ?

A Even a well-fitted Diaphragm may be incorrectly inserted, so that, it fails to cover cervix, or it may be displaced during the orgastic expansion of the inner two-thirds of the vaginal barrel.

Q Are there any side-effects ?

A Normally there are no side-effects of the use of Diaphragm. However, reactions to rubber or to one of the components of jelly or cream may be reported in rare cases.

(c) SPERMICIDES



Q What is a spermicide ?

A Jellies, creams, foam tablets, etc., contain chemicals which kill the sperms. These spermicides are intended to be used without a diaphragm.

Q How are spermicides used?

A Creams and jellies are applied in the vagina with the help of applicator and foam tablets are inserted with the help of fingers. Foam tablets dissolve in vagina on contact with moisture to release carbon dioxide, producing dense foam.

Q What is the mode of action of spermicides ?

A These materials immobilize sperm on contact with the ejaculate. They destroy the sperms in the

semenal fluid in the vagina and so the woman cannot conceive.

Q What are the advantages of spermicides ?

A They are relatively simple to use and do not require pelvic examination. The foam tablets are inexpensive.

Q What are the disadvantages of the use of spermicides ?

A Many users complain of vaginal leakage (messiness) and excessive lubrication. Foam tablets also require a waiting period of several minutes to allow for melting or disintegration.

Q What is the effectiveness of spermicides?

A Spermicides used alone appear to be less effective than spermicides used in combination with the Diaphragm. However, foam tablets appear to be more effective than other types of spermicides.

Q In what circumstances the spermicides do not prove effective?

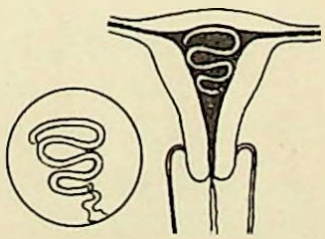
A An inadequate quantity or quality of spermicidal material is the most obvious reason for the failure. Some spermicides dissolve or disintegrate slowly and are inadequately distributed throughout the vagina. Some couples fail to observe the waiting period.

Q What are the side-effects of spermicides?

A In some cases they cause irritation and/or inflamatory changes of the mucous membrane.

(d) INTRAUTERINE DEVICE?

Q What is an Intrauterine Device (I.U.D) ?



A An Intrauterine Device, commonly known as loop/ copper T, is placed by the doctor inside the uterus. Its presence there prevents pregnancy.

Q Does loop interfere with the normal sex life of a woman?

A No, it does not interfere with the normal sex life of a woman.

Q Are there any complications after loop insertions?

A In certain cases excessive bleeding and back-ache is reported after loop insertions. It may continue for

a few days, The first few menstrual period might also be comparatively heavy and may continue for a longer duration. But they become normal within a few months. However, doctor should be consulted for unusual bleeding and pain. The doctor removes the loop if he/she finds that it does not suit a particular woman.

Q Can every woman use loop?

A Experience shows that loop does suit about 25% of women. However, the doctor alone can say after thorough medical examination whether the loop should be inserted or not.

Q Is there any truth in the rumour that loop causes cancer?

A The loop does not cause cancer or any other disease. This has been proved by scientific studies.

Q Does the loop cause sterility ?

A No, actually the best point in favour of the loop is that it is a reversible method. When the woman wants a child, she can get the loop removed.

(e) PILL

Q What is the pill?

A The pill is a contraceptive to be taken by mouth. Starting from the 5th day after menstrual flow begins a woman has to take one pill a day for 21 consecutive days. She can wait for 7 days and start taking the pill all over again. The pill should not be missed even for a day because its stoppage increases chances of pregnancy.

Q Can all women take the pill?

A The pill should be taken only when prescribed by doctor after thorough medical examination.

Q Are there any side-effects of the pill?

A In certain cases tiredness or dizziness, weight gain, nausea, stoppage of the menstrual periods, vomitting, feeling of sickness, tenderness of the breasts, in between period bleeding are reported. Generally they disappear after regular use for three to four months.

Q Should the pill be continued during in-between period bleeding?

A The regularity of taking the pill should be

maintained irrespective of any in-between period bleeding and full course of the pill should invariably be taken.

TERMINAL METHODS

Sterilisation

(i) VASECTOMY

Q What should a couple do when they do not want any more children?

A There are terminal methods both for men and women. Male operation is called vasectomy and the female operation tubectomy. It is not necessary for both husband and wife to undergo these operations. Only one of them may decide to go in for the sterilisation operation and that would provide them a permanent relief from future pregnancy.

Q What is vasectomy ?

A The male sterilisation operation is called vasectomy. This operation is performed practically without any trouble. The male vas is cut and then both the ends are tied. The incision is done at both sides of the scrotum. The whole procedure takes 15 to 20 minutes.

Q How long should a man abstain from coitus after vasectomy?

A Abstinence or use of 'Nirodh' by the male after the vasectomy operation is essential for a period of six to eight weeks. This is because some residual sperms may still be present in the semen after the operation. After the prescribed period the male should get his semen tested. He can stop using contraceptives after the doctor has declared the absence of sperms in his semen.

Q Does vasectomy lead to impotency?

A No, this is a baseless fear. As no sexual glands are removed in this operation, the question of impotency does not arise. However, wherever such complaints are reported, they are generally due to psychological reasons.

Q Are there any side-effects or complications after vasectomy operation?

A There are no side-effects or complications after the operation provided it has been performed by a competent surgeon after full asceptic precaution.

(ii) TUBECTOMY

Q What is tubectomy operation?

A Tubectomy operation is performed on women. This is somewhat different from vasectomy operation and also not as simple as vasectomy. This can be performed at any time but preferably three or four days after delivery. The fallopian tubes of both the sides are cut and tied. After the operation the woman has to lie in bed for about a week.

Q Are there any side-effects of tubectomy operation?

A No, there are no side-effects of tubectomy operation and the woman continues to feel normal.

Q Is it possible to have children after undergoing sterilisation?

A Both male and female sterilisation operations are permanent terminal methods. They are accepted only after it is decided not to have any more children. However, in exceptional cases where the couple might like to have more children later on, the vasectomy or tubectomy operations can be reversed by a competent doctor, but it is a complicated surgery

davp Designed & produced by the Directorate of Advertising & Visual Publicity, Ministry of I. & B., for the Ministry of Health and Family Welfare and printed at Glasgow Printing Co. Private Ltd. Howrah.

2/8/78-PPVI English—80,000 September 1978

Birth control vaccine our idea, says award winner

24/7/91 Times of India

By TABISH KHAIR

The Times of India News Service

NEW DELHI, July 23.

DR G.P. Talwar, the latest recipient of the prestigious Order Of The Legion of Honour, France's highest civilian award, does not conform to the awry-haired, absent-minded image of the quintessential scientist. He is smartly dressed and extremely alert.

The immaculate buildings and grounds of the National Institute of Immunology, which he established almost single-handedly, attest to his organisational capacities. Yet, Dr Talwar is very much a scientist — his heart lies in his laboratory. That is where he rushed the moment he finishes giving an interview to *The Times of India*.

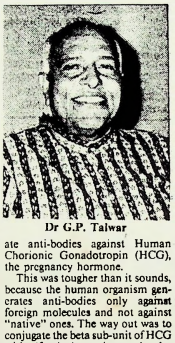
Not only is Dr Talwar the founding director of NII, he can also be credited with laying a strong foundation for immunology in India. The French honour, awarded to an Indian scientist for the first time, is in recognition of his various contributions to this growing and exciting field.

Explains Dr Talwar, "The French award is not for any one contribution. It is for the general body of my works." He goes on to bestow part of the credit on his co-workers, whom he describes as "committed scientists of a high calbire." "I am happy to have created this institute for us to work together," he adds.

However, the field which is almost entirely Dr Talwar's creation, is the idea of a birth control vaccine, now in the second stage of trial. Says the professor, "The idea of a birth control vaccine is ours. This was an entirely new concept. Now it is a reality.

"Normally, vaccines have been used to protect the body and combat some diseases. But the idea that a vaccine can be used to control birth, without effecting other body functions, is a new one."

Not only is the idea a new one, it is brilliant in its theoretical simplicity. As is well known, the average vaccine is used to help the organism generate anti-bodies against foreign elements that may enter it. Dr Talwar's idea was to develop a vaccine which can generate anti-bodies against Human Chorionic Gonadotropin (HCG), the pregnancy hormone.



Dr G.P. Talwar

This was tougher than it sounds, because the human organism generates anti-bodies only against foreign molecules and not against "native" ones. The way out was to conjugate the beta sub-unit of HCG with (foreign) carrier molecules like tetanus toxoid or diphtheria toxoid. This ensured that anti-bodies were created to attack the HCG and render it "infertile."

This birth control vaccine has the advantage of being reversible. It's effect will last for approximately a year (though the exact time-span is still to be determined) and can be indefinitely prolonged by taking booster injections. The method is also said to be safe and without any deletrious side-effect.

An added benefit is that the vaccine will afford protection from some other diseases by way of the carrier molecule used. In effect, if the diphtheria toxoid is the carrier molecule attached to HCG, the body will also be vaccinated againsst an attack of diphtheria. And so on.

What are some of his other contributions? Replies Dr Talwar, "Another vaccine is an anti-leprosy one. It is currently on trial in two major hospitals of Delhi as well as in Kanpur Dehat, which has a community of 3,62,000 people. This vaccine can upgrade immunological responses of the patient and accelerate recovery from the disease."

A special feature of this vaccine is that it can be used to cure patients who are resistant to drugs. The success rate is said to be much higher than that of traditional therapy.

Dr Talwar adds, "One of the injectibles developed by me has already completed the stage of testing. It has been cleared by the drug controller and has been licensed to a private sector under the trade name of Talsur. The tal is from my name and the sur is from the name of the worker who tested it."

Essentially, this injectible can be used to sterilize male animals without affecting their virility. This vaccine can arrest the proliferation of scrub animals and is crucial to the success of artificial insemination.

That is not all. Dr Talwar and his team of brilliant scientists are also working in many other "departments" of immunology. He says, "Along with my colleagues, I have also developed diagnostic kits for the detection of pregnancy, typhoid, amoebiasis and blood group screening. These have been licensed to Indian companies. Two of them are already in the market."

Dr Talwar also lists the NII among his achievements. He says, "I created this from scratch in 1983. Over the years it has achieved international eminance." The NII leads research in some fields of immunology and is one of the premier institutes of immunology in the world.

Dr Talwar was also the head of the department of biochemistry at the All India Institute of Medical Sciences (AIIMS) for 18 years. He did his master's degree from Punjab University and his doctorate from the prestigious Pasteur Institute in Paris. "So, now you know my French connection," he quips.

Awards are nothing new for Dr Talwar. He has received a number of prestigious awards and lectureships, including the Basanti Devi Amir Chand senior prize of Indian Council of Medical Research, the national award in biomedicine, the Alexander Von Humboldt Foundation medal and the Sir JC Bose award.

He has published over 200 original papers and is the author/editor of 13 books. One of the hybrid cell clones developed by him, was the first Indian bio-technology product to be acquired by a leading U.S. company.

So much about the scientist. What about the man? "Well, I am basically a refugee from Punjba. We came over during the partition. Now, for all practical purposes, I belong to Delhi. I have three children — two daughters and a son. My son is an architect. He is studying at MIT (the U.S.). My wife used to be a teacher."

Are any of his children into scientific research? "I hope my grandson will be a scientist," replies Dr Talwar, with a twinkle in his eyes. Interview over, he disappears into the laboratory.

Table 1 - Priorities for Biotechnology in India

Priorities	
Health	Energy
Prophylactic	Biomass
Therapeutic	Energy Plantation
Diagnostic	Biofuels and Bioreactors
Hygiene	
Population Control	Environment
Industry	Conservation of Forests and Afforestation
Fermentation (Antibiotics, Organic Acids)	Pollution Recycling
Biofuels	Waste Recycling
Food and Feed	Communication, Informatics
Metallurgy and Mining	Computer Based Information Collection and Dissemination
Oil Recovery	
Agriculture	Education and Training
Soil Fertility	University Level Education
Bio-Fertilizers	Specialized Training Program
New Varieties	
Nitrogen Fixation	
Quick Propogation through Tissue Culture	
Improvements to Animal Health and Productivity	

Source: Government of India, Department of Science and Technology, National Biotechnology Board, *Long Term Plan for Biotechnology in India*, New Delhi: The Department, April 1983, p. 14.

Table 2 - Biotechnology Activities with Time Horizon in Different Sector in India

Health

Time Target	Project Initiation	Activities
3 Years 1985-86	Immediate	1. Production of established viral vaccines but using new methods of tissue culture. 2. Hybridoma based monoclonal antibodies as diagnostic agents and tools. 3. Production of genetically-engineered insulin and interferon.
5 Years 1987-88	1983-84 →	1. Production of variety of peptide hormones, amino acids and enzymes. 2. Production of a host of viral and subunit antigens and antibodies. 3. Production of diagnostics for various diseases. 4. Treatment of certain genetic diseases. Kits for tissue matching for grafting, etc. 5. New drug delivery systems for hormonal regulations and cancer treatment. 6. Polyvalent subunit vaccines and eradication of several infectious diseases. 7. Vaccines against hepatitis.
10 Years 1993-94	1983-84 and later →	1. Highly effective safe and reversible vaccines for contraception in female and male. 2. Vaccines against leprosy, malaria, amoebiasis, helminth infestations, filariasis. 3. Vector and hormonal treatment against several cancers such as leukemia, breast cancer, and other soft tissue cancers. 4. Tissue and subcellular targetting of drugs.
Beyond 10 Years	1983-84 and later	1. Gene preparations against diseases such as sickle cell anemia, thallasemia, hemophilia, diabetes, PKU.

Agriculture

Time Target	Project Initiation	Activities
1 to 5 Years 1987-88	Strengthen on-going projects, and initiate new work immediately	1. Large scale production of suitable rhizobial strains for soil inoculations and seed treatment in the case of various legume crops. The strains must be tested and certified for various soil, climatic and crop conditions. 2. Making available suitable strains of blue green algae and *Azolla* for different climatic and soil condition of wet land graduated cultivation. 3. Development of soil inoculation packages of *Azotobacter* and a variety of other non-symbiotic nitrogen fixers. 4. Development of production and application technology of *B. Thuringiensis* and *B. Sphaericus* for the biological control of insect pests of crops and mosquito.
5 to 10 Years 1993-94	Strengthen on-going work and initiate new work	1. Development of multi-infective rhizobial strain for inducting nodulation in a variety of leguminous and non-leguminous plants. 2. Development of rootfibre adhering ability to non-symbiotics nitrogen fixing bacteria. 3. Development of disease resistance and stress tolerance varieties of crops using tissue culture and somatic hybridization and selection technologies. 4. Improving the nutrition, quality and flavor of food grains and plants through gene cloning. 5. Rapid propagation of high yielding vegetables and fruits and fast growing elite trees.

Industry

Time Target	Project Initiation	Activities
3 Years 1985-86	Immediate	1. Improve currently used industrial strains to international levels of productivity (antibiotics, organic acids, vitamins, amino acids, etc.) 2. Introduce yeast strains in alcohol industry to yield 12-16% ethanol from molasses. 3. Introduce better designs to save energy, and improve yields. Introduce better fermentation monitoring and control and end product recovery. Introduce waste minimization, utilization and recycling. Wherever possible introduce biogas generation, production of fuel and reducing pollution. 4. Improve indigenous fermentation techniques such as coconut and jute retting, food and fuel processing, etc. 5. Set up new products such as various hormones, enzymes, amino acids, vitamins and biofuels, etc., using new techniques of cell cultures and bioreactors. 6. Establish units for blood fractionation by products biologically produced plasma extender, etc.
5 Years to 10 Years 1987-88 1992-93	1983-84 and later	1. Production of several new biological products, such as vaccines, hormones, amino acids, vitamins, pesticides, sweeteners, and a host of organic chemicals and drugs produced primarily through techniques of genetically engineered and fused cells of microbial, animal and plant origin. 2. Industrial exploitation of yeast and other genetically tailored organisms for the utilization of cellulose, hemicellulose and lignins for producing a variety of biofuels, chemicals and protein and fat as food and fuel. 3. Develop decentralized industrial base for conversion and utilization of woody plants and other biomass from energy plantations and social forestry for producing fuel, chemicals, food and materials. 4. Produce portable and field usable diagnostic and treatment kits for detection and treatment of a variety of metabolic and pathogenic diseases of man and animals.
Beyond 10 Years		1. Industry through investment and management should be ready to exploit the extraordinary new developments coming out of modern genetics and biotechnology

Source: Government of India, Department of Science and Technology, National Biotechnology Board, *Long Term Plan for Biotechnology in India*, New Delhi: The Department, April 1983, pp. 22-24.

REPORT OF THE PUBLIC BOARD OF INQUIRY ON DEPO-PROVERA
17 OCTOBER, 1984

FINDINGS OF FACT

I. DATA AVAILABLE ON THE LONG-TERM RISKS OF DMPA ARE INSUFFICIENT AND INADEQUATE TO PROVIDE A BASIS FOR A DECISION WHETHER THE BENEFITS OF THE DRUG AS A CONTRACEPTIVE OUTWEIGH ITS DISADVANTAGES UNDER CONDITIONS OF GENERAL MARKETING IN THE U S A

There are adequate data to assess the efficacy and benefits of DMPA as a contraceptive. There is also sufficient information on its short term side effects and risks. The drug is clearly a highly effective contraceptive with certain specific advantages, and it does not appear to pose any immediate irreversible serious side effects. However, the facts relating to the long term consequences of the use of the drug are inadequate and insufficient to provide a basis for risk assessment. This is a serious deficiency in light of the specific questions that have been raised that the drug may have major adverse effects following use for long term use or that may become evident only after a latent period. Most important among these has been the concern over the drug's carcinogenic potential.[9]

The long term consequences of the use of DMPA on neoplasias, in particular of the breast and uterus, as well as osteoporosis and atherosclerosis are of particular relevance for any risk/benefit assessment of the drug's use in the United States because of the susceptibility of the population in this country to these diseases.

In the absence of adequate data on the long term consequences of the drug it is not possible to arrive at any scientifically defensible conclusion whether or not the benefits of the drug, when used as a contraceptive, outweigh the risks for the average healthy individual in the United States. It also makes it impossible to compare the risk/benefit ratio of DMPA with that of other drugs available for contraception.

II. DATA FROM THE STUDIES OF RHESUS MONKEYS AND BEAGLE DOGS CAN NOT BE DISMISSED AS IRRELEVANT TO THE HUMAN WITHOUT CONCLUSIVE EVIDENCE TO THE CONTRARY. SUCH EVIDENCE IS NOT AVAILABLE AT THIS TIME. THEREFORE, THE FACT THAT MALIGNANT NEOPLASIAS DEVELOPED IN TWO SPECIES IN TARGET ORGANS OF SEX STEROIDS MUST BE CONSIDERED AS AN INDICATION OF A POTENTIAL OF PROGESTOGENS, INCLUDING DMPA, TO PROMOTE THE DEVELOPMENT OF MALIGNANCIES IN TARGET ORGANS

The findings from animal tests implicate DMPA as a potential promoter of neoplasias because:

1) Chronic administration of DMPA was associated with the development of malignant neoplasias in two mammalian species.

---

9. Data are also inadequate to establish effect of MPA on bone and on the profile of plasma lipoproteins, information needed to evaluate whether the long term use of the drug will or will not predispose the individual to osteoporosis or to atherosclerosis. Our conclusions of Law do not rely on this finding.

2) The neoplasias developed in target organs of sex steroids.

3) There is good evidence to support the conclusion that in both species the malignancies were drug related.

4) There is no evidence to support the conclusion that the effect of the drug is to be attributed only to the administration of excessively high doses and that the effect of lower doses would differ qualitatively from those of higher doses.

Therefore, DMPA in these experiments exhibited the characteristics of a potential carcinogen according to generally accepted criteria. Under the circumstances, to dismiss the findings as irrelevant to the human would require conclusive experimental evidence of fundamental differences among the species in the basic mechanisms of action of the hormone or in the responses of target cells. There is as yet no such evidence at hand. Specifically, there are no data on the histogenesis of the neoplasias nor on the mechanism of action of progestogens on the presumed cells of origin of the neoplasias in the test animals. Therefore, there is no evidence to support the claim that the malignancies developed either in cell types unique to the species or as a result of a species specific response of target cells to progestogens. Conversely, data on women who have been exposed for prolonged periods to the relatively unopposed action of progestogens are inadequate to warrant the conclusion that their response to this hormonal state in terms of neoplasias would differ in some fundamental way from the two species of test animals.

III. THE DATA ON THE HUMAN ARE INSUFFICIENT AND INADEQUATE TO EITHER CONFIRM OR REFUTE THE IMPLICATION OF THE ANIMAL DATA THAT DMPA MAY INCREASE THE RISK OF CANCER IN WOMEN USING DMPA AS A CONTRACEPTIVE.

The available data on the human can not provide a basis for concluding whether DMPA, used as a contraceptive, does or does not influence the incidence of carcinomas in general or of the accessory organs of reproduction in particular, because:

1) They fail to provide information on an adequate number of long term users of DMPA, or on ex-users who have been followed for a long enough period of time. There are only minimal data on subjects that have used DMPA for 5 years or longer with most of the data reported having been obtained from women who have used the drug for 2 years or less.

2) In the majority of the studies there were no controls followed in parallel with those using DMPA. In many studies from developing countries there is not even information on the background incidence of the diseases being studied in DMPA users that could serve as a basis for comparison.

3) In a number of the retrospective studies there is reason to question the adequacy of the record keeping on subjects receiving DMPA and, therefore, of the possibility

of retrieving the data subsequently for any valid analysis.

To obtain the direct evidence needed to resolve the issue would have required purposeful, systematic collection and recording of data on users of DMPA and appropriate controls with consideration of the natural history of the diseases being monitored. Not until recently have subh studies been initiated. Until they are completed and full reports of them available their value as evidence is limited.

IV. IN CASE OF CONTRACEPTIVE FAILURE WITH DMPA, THE RISK OF A MOTHER GIVING BIRTH TO A MALFORMED CHILD IS UNLIKELY TO BE MEASURABLY GREATER THAN THAT POSED BY THE ORAL CONTRACEPTIVES; The chance IN EACH CASE CAN BE ESTIMATED TO BE SMALL ENOUGH NOT TO POSE AN OBSTACLE TO THE USE OF THE DRUG AS A CONTRACEPTIVE WHEN OTHERWISE INDICATED.

Data have not been systematically collected on offspring that have been inadvertently exposed to DMPA in utero. Conclusions, therefore, can only be based on the body of epidemiological data obtained on the effects of a variety of sex steroids, including progestogens, on the developing human fetus. In these cases, the drugs had been administered for a variety of indications and at various times during pregnancy. This is clearly a less than ideal data base. Nonetheless it can provide some general estimate of the magnitude of the risk.

According to these data the risk of various malformations attributable to protestogens for the various malformations implicated is low. The rate of contraceptive failure with DMPA when used appropriately is also low. Consequently, the chance of a mother bearing a malformed child following contraceptive failure can be estimated to be small. However, because DMPA is a long acting depot preparation, the exposure of any susceptible fetus to the drug is likely to be more prolonged than with oral contraceptives. Consequently, the range of critical and vulnerable events that may come under the drug's influence may also be expected to be greater than with oral contraceptives. It should be possible to counter balance this disadvantage of DMPA by ensuring that contraceptive failure is kept at a minimum and taking the necessary steps to avoid inducting women already pregnant. As with oral contraceptives this risk should not, in itself, constitute a reasonffor not using the drug if otherwise indicated.

There have been no direct determinations of the concentrations of MPA in the blood of breast fed infants of mothers receiving DMPA as a contraceptive nor if the amount of the drug transferred passed onto the infant is sufficient to have a biological effect. This information is needed before advocating the use of DMPA as a contraceptive to lactating mothers in the postnatal period and before it is possible to conclude that the drug does not pose any risk of funotional teratogenicity.

.....

The Effects of Quality of Services upon IUD Continuation Among Women in Rural Gujarat

Daxa Patel*
Anil Patel*
Ambrish Mehta*

*Action Research in Community Health (ARCH)
Mangrol, Rajpipla
Gujarat

Introduction

India is one of the first developing countries that adopted the reduction in population growth as a national goal more than four decades ago, in the 1950s. Although initially the policy focused on child spacing methods (oral contraceptives, condoms, IUDs) as well as limiting methods (sterilization), the focus gradually shifted over entirely to sterilization. The 1992-93 National Family Health Survey[1] reports that contraception prevalence rate in India was 41 per cent. Of these the vast majority (75 per cent) were covered by sterilization, 5 per cent were covered by IUD, and about 9 per cent were covered by condoms and oral contraceptive pills. Acceptance of IUDs in urban areas was reported to be three times more than in rural areas.

Program managers have tended to take the non-acceptance of IUDs, and other spacing methods like condoms and pills, for granted and have assumed that women would not accept IUDs or other spacing methods. Relatively few efforts have been devoted to understanding reasons behind low acceptance of non-permanent methods such as IUDs, oral contraceptives and condoms, and there have been very few efforts to devise intervention approaches to improve IUD acceptance and continuation. This paper presents data concerning an intervention programme in which the response to the IUD was quite positive among the target population of rural women.

Background of ARCH

Action Research in Community Health (ARCH) has been working in the eastern part of rural Gujarat since 1980 to develop appropriate primary health care programs. Ten villages with a population of about 8000 are intensively covered by the program. This is a predominantly tribal area where 70 per cent are tribals and 30 per cent others including Harijans (out-castes), upper castes, other backward castes and Muslims. The economy is dominated by dry land agriculture, although there has been an expansion of irrigation facilities in recent years. The literacy rate is expectedly very low. About one-third of the women in 1995 were illiterate and another 15 per cent completed their primary education without significant numerical or reading ability.

Modern health services are virtually non-existent; there is a heavy reliance on traditional healers and other unqualified local practitioners. Our field data from 1996 indicate that ninety percent of deliveries are home deliveries conducted by traditional birth attendants. There is a government primary health centre about 8 kilometers away, but its focus is upon female sterilization. People recognize that health workers from the health centre visit their houses mainly to encourage sterilization, so they do not

rely on these workers for regular health services. For the first decade of our work in this area (1980-1990) ARCH intentionally chose to avoid advocating contraceptive services in the project area, since doing so would antagonize the rural population. As women began to trust us, they became more willing to discuss their needs during pregnancy; this included seeking information for ending unwanted pregnancies, preventing future pregnancies and asking about routine care during pregnancy. Nearly 30 per cent of the pregnant women who came for antenatal care in 1994 said that they did not want the pregnancy. It was clear to us that women, while reluctant to accept permanent sterilization soon after the birth of a second or third child, wanted some means of spacing their pregnancies. People in this area are not aware about, and do not use condoms or oral contraceptive pills to prevent pregnancy. The IUD is the sole spacing method known to a relatively large number of women of all socio-economic classes. Despite their desire for spacing, most of the women are very reluctant to accept IUDs and most of those who accept it retain this method for only a limited time. This reluctance of women in rural India to accept and continue using IUDs and other spacing methods is generally well-known. However, the reasons for this reluctance are still not adequately understood.

In a major review of the research studies on family planning dropouts, Kreager (1992) observed that the varieties of determinants usually studied are a basic set devised for medical purposes but undeveloped with reference to social, cultural and psychological factors.[2] He further observed that the interrelations of medical, cultural, social and psychological factors in early discontinuation of oral contraceptives and IUDs are not clear. Studies reviewed by him do not generally attempt to identify the reasons for discontinuation in terms of these factors. The review article, which encompassed 20 studies on IUDs across the world, repeatedly stressed the importance of socio-cultural factors and one of its important conclusions is "the extent of personal, cultural, social and psychological factors in this pattern of initial difficulty (in acceptance of IUD) and the extent to which they can be manipulated to improve the continuation is unknown".

On the other hand Huezo, et al.(199_) in a multi-centre study involving six countries on acceptability and discontinuation of contraceptive methods, reported a paradoxical and unexpected finding that high levels of counseling tend to be associated with higher risk of discontinuation.[3] The authors call this finding counterintuitive and have tried to explain it. However, when the content of the counseling is examined, it is clear that it does not relate to relevant socio-cultural factors which shape women's expectations and apprehensions. Counseling devoid of such socio-cultural sensitivity may only accentuate women's fears and apprehensions about the side effects they are informed about.

Our intimate and long interaction with all segments of this rural population has shown that women did not know where the IUD is inserted in the body, what it does, nor how it works. The majority of women have revealed to us that they believe that it would ascend up into their chests or could be lost in the abdomen, that it causes 'heat', or that it could cause a loss of weight and energy. A strong fear exists that with an IUD in place, the partner would get stuck during sexual intercourse and that separation would be impossible without a doctor's intervention. Some women even fear that IUD insertion could result in death. We have also come to know that similar apprehensions and misconceptions are not limited to the ARCH project area, but are also prevalent in other parts of rural Gujarat as well. These perceived fears and apprehensions, rooted as they are in false conceptions of their bodies, must be addressed systematically by means of a sensitive and specific health education program. This paper describes the experience in developing such a program, and explores the impact of this program upon levels of contraceptive continuation.

Methods and Materials

At the very outset, we should state that ARCH had not initially planned a study of IUD acceptance and continuation in the population. This study evolved in response to an emerging need in the community. As in ARCH's other health programs—including antenatal and postnatal care, iron-folic distribution for pregnant women, immunization, child weaning practices—ARCH maintained proper records, followed standard medical procedures and undertook proper follow-up care. The findings present our experiences in eliciting information concerning women's perceptions and needs related to family planning.

Intervention Strategy

Phase I

During the initial phase of the ARCH project (1980-86) the focus was on curative services and children's health. While women's reproductive health problems were becoming increasingly apparent, we were still extremely reluctant to undertake an initiative with regard to family planning because of the strong negative reaction against the family planning program run by the Government.

We began, however, to perceive a need for fertility control among community women we interacted with. As a result, from the beginning of 1987 onwards, we took the initiative to offer spacing methods to those who came to the dispensary seeking these services. Through the end of 1990, a total of 56 women of various castes and economic categories came forward for IUD insertion. The IUD was inserted by an experienced senior doctor (one of the authors). We followed the usual textbook

Our intimate and long interaction with all segments of this rural population has shown that women did not know where the IUD is inserted in the body, what it does, nor how it works. The majority of women have revealed to us that they believe that it would ascend up into their chests or could be lost in the abdomen, that it causes 'heat', or that it could cause a loss of weight and energy. A strong fear exists that with an IUD in place, the partner would get stuck during sexual intercourse and that separation would be impossible without a doctor's intervention. Some women even fear that IUD insertion could result in death. We have also come to know that similar apprehensions and misconceptions are not limited to the ARCH project area, but are also prevalent in other parts of rural Gujarat as well. These perceived fears and apprehensions, rooted as they are in false conceptions of their bodies, must be addressed systematically by means of a sensitive and specific health education program. This paper describes the experience in developing such a program, and explores the impact of this program upon levels of contraceptive continuation.

Methods and Materials

At the very outset, we should state that ARCH had not initially planned a study of IUD acceptance and continuation in the population. This study evolved in response to an emerging need in the community. As in ARCH's other health programs—including antenatal and postnatal care, iron-folic distribution for pregnant women, immunization, child weaning practices—ARCH maintained proper records, followed standard medical procedures and undertook proper follow-up care. The findings present our experiences in eliciting information concerning women's perceptions and needs related to family planning.

Intervention Strategy

Phase I

During the initial phase of the ARCH project (1980-86) the focus was on curative services and children's health. While women's reproductive health problems were becoming increasingly apparent, we were still extremely reluctant to undertake an initiative with regard to family planning because of the strong negative reaction against the family planning program run by the Government.

We began, however, to perceive a need for fertility control among community women we interacted with. As a result, from the beginning of 1987 onwards, we took the initiative to offer spacing methods to those who came to the dispensary seeking these services. Through the end of 1990, a total of 56 women of various castes and economic categories came forward for IUD insertion. The IUD was inserted by an experienced senior doctor (one of the authors). We followed the usual textbook

precautions of clinically screening women with obvious gynecological infections, using sterilized instruments and followed an aseptic technique of insertion. Routine advice were also given to clients about the need for reporting in case of excessive bleeding or pain and to have the IUD removed in three years time. More women from higher castes accepted IUDs, most likely because they had heard more about this method. Our understanding of women's fears and misconceptions regarding IUDs was poor. Women, hesitant and non vocal as always, rarely revealed to us their deep fears and apprehensions. In this context, there was little education and counseling being provided which would accurately respond to their deeply-rooted and legitimate apprehensions.

In 1989, ARCH conducted a small study to assess family planning needs and the use of different contraception methods. In six project villages, 492 eligible couples were registered, out of which 282 (57 per cent) had already undergone sterilization. From the remaining 210 (43 per cent), 44 women were randomly selected from different caste groups for open ended, in-depth interviews. 88 per cent of these women expressed a desire for spacing between births. Only 20 per cent were familiar with oral pills, about 40 per cent knew about condoms, and 70 per cent knew about IUDs. However a large majority of these women had deep fears about IUDs. Actual acceptance levels of any of the spacing methods was extremely low.

During the early years when women came for IUD removal, any physical problems which they had were attributed to the IUD. For example, one woman had a sore throat and thought this was due to the IUD which had come up to her throat. She was understandably desperate for its removal. Another woman was very apprehensive and could not sleep for two nights because a neighbor told her that she had pain in her abdomen because of the IUD and that it might have entered her liver. During the internal examination when we told her that her IUD was still inside the womb and the thread in the vagina was visible, the relief on her face was palpable. She still insisted, however, upon its removal. In numerous cases no amount of reassurance worked and we found it necessary to remove the IUD.

Phase II

By 1990, intensive informal interaction had begun with our female health workers belonging to the same community and sharing the same fears and beliefs before they joined ARCH. By that time, our relationships with the village women had also improved. Intimate and informal discussions with these women revealed their understanding about the female anatomy –especially the relationship between the reproductive and the gastro-intestinal systems. They had no knowledge that the reproductive system is comprised of the vagina, cervix, uterus, etc., and that it is a separate and completely independent system

from the gastro-intestinal system. They did not know that the stomach and the uterus are two different organs and that the uterus, where the IUD is placed through the vagina, is closed from above. We realized that merely screening for infections and using aseptic techniques for insertion, though essential, were by themselves insufficient to ensure acceptance. A specific health education program about women's bodies had to be introduced.

From January of 1991 onwards, we initiated a process of free and friendly exchange of information in the community group meetings, and also in our clinic when women came for an antenatal check up, in an effort to bridge the gap between the different conceptions of the woman's body. For the first time, women were presented, through slides, models, posters and pictures, that the reproductive organs were completely separate from the gastro-intestinal tract in the abdominal cavity. We also developed a simple low-cost thermocol model (a light weight polymer plastic material used in packaging) of the uterus, cervix, vagina and fallopian tubes for the purpose of demonstration. All women who came for an IUD insertion were first shown the entire process of IUD insertion on this model. Even women who came in the clinic for different reasons were encouraged by the female health workers to see for themselves the models and pictures. This demonstration included actual insertion of IUD in the model through the cervix, into the uterus and leaving it in the uterus with a small thread freely hanging in vagina. This demonstration, which only took a few minutes, was helpful because women could see that the uterus is a separate organ which is closed from above. Thus, they could see that the IUD cannot go up into the chest and similarly the fear of partner getting stuck during intercourse because of the IUD was also not real. It also became apparent to them that, with the help of the thread hanging freely in the vagina, the IUD could easily be removed at any time by the doctor or the female health worker in the clinic. All the possible problems of initial discharge, bleeding and pain were explained at the time of insertion, and women were asked to visit the dispensary if any such problems occurred so that appropriate measures could be taken.

During the second three-year phase (1991-93), 80 women accepted IUDs. In this phase, medical screening of women's reproductive tract infections (RTIs), and the aseptic technique of insertion and instrument sterilization were performed largely unchanged from the first phase. For each woman, a separately sterilized set of instruments, towels etc., was used. A senior woman health worker was also trained to insert the IUDs, while in Phase I only a doctor inserted the IUDs. In both phases, the same brand of IUDs were supplied in standard sterilized packs from the nearby government health centre. Records were kept of all complaints, clinical findings and treatment given in all subsequent visits, and the reasons for IUD removal were also recorded. Follow up contacts were made in cases where women

did not visit the dispensary on their own to learn whether the IUD was still in place or had been removed, as well as the reason for removal.

For purposes of statistical analyses of the differences in the rates of IUD removal / continuation, we have followed the life-table technique described by Kahn and Sempos (1989).[4] Rates of IUD removals in each 2-month time interval after the date of insertion up to 24 months were calculated for both groups. Those cases where no follow up contacts could be made (two cases in Phase I and one case in Phase II) have been considered as withdrawn in the very first time interval. Those cases in Phase II (1991-93) where the women were still continuing with the IUDs on April 1, 1995 and had not yet completed two years since insertion, were considered as withdrawn at appropriate time interval by taking into account the time they had already retained the IUDs. There were no such cases in Phase I (1987-90) as all women who got IUDs inserted in this initial period could be followed for at least two years on April 1, 1995.

Results

Table 1 shows that IUD acceptors in both phases are essentially similar with regard to age, education and desire for spacing. Their composition differs decisively, however, with regard to caste. Whereas upper caste women predominate in Phase I, tribal women predominate in Phase II, indicative of greater acceptance among tribals.

Table 2 shows the number of women who complained of discharge, excessive menstruation or pain during the first six months after IUD insertion in both phases and also the percentage of women who had their IUDs removed within six months due to these problems. The proportion of women who complained of these problems is slightly higher among the first group of acceptors, although not statistically significant. However, among women who complained of complications, the number of women who subsequently had their IUDs removed due to these problems is significantly higher in Phase I (80 per cent) than in Phase II (22 per cent). The possible reason is that during Phase I, in the absence of specific and relevant counseling about woman's body, even normal or usual difficulties of initial period were magnified by women. In addition, these women were continually advised by other women that the IUD is very problematic.

Table 3 shows the number of women who complained of excessive menstruation, pain in the lower abdomen and other complaints, which were clinically investigated, within two years after IUD insertion. This information was based on follow-up visits in the clinic. It shows that the proportion of women who complained of these problems was high in both groups, but the number of problems appears

less in the Phase II group. The number of women who retained the IUD in Phase II was significantly higher, however.

Table 4 shows that six women (16 per cent) in Phase II reported spontaneous expulsion. This is probably related to the fact that 4 out of 6 such IUDs were inserted by a senior female health worker who was under training. More women complained of leucorrhoea, pain and excessive menstruation and had the IUD removed in Phase I than in Phase II. This likely reflects changes in perceptions due to appropriate health education.

Figure 1 shows curves of IUD continuation rates in the two phases, based on life-table analysis shown in Appendix 1. At the end of six months after insertion, 89 per cent in Phase II versus 66 per cent of the women in Phase I continued to have IUDs in place. The corresponding figures at the end of one year were 77 per cent versus 48 per cent, respectively, and at two years, 52 per cent versus 28 per cent, respectively. These differences are highly significant ($P = 0.001$). The rate of IUD continuation for all intervals was also significantly higher in Phase II ($p<.01$). The above difference is obtained when removals of IUDs for all reasons are considered as drop-outs. The difference increases further when only the removals due to IUD related problems like leucorrhoea, pain, excessive bleeding are considered. Removals due to desire for child or permanent sterilization, etc., are not considered as drop-outs.

Figure 2 shows curves of IUD continuation rates in two phases considering removals due to IUD related problems only (Appendix 2). Here also as in Figure 1, the differences in continuing rates at all intervals are highly significant ($P = 0.0002$).

Discussion

This study does not argue that the IUD is either the best spacing method available for rural women or the most preferred method. What can be demonstrated, however, is that given the voluntary choice of methods made by women, IUD's continuation rates can be improved markedly by providing specific health education which effectively addresses women's perceived fears and apprehensions.

Although it is possible that this study may have overlooked other influential differences between the two intervention phases, we do not believe that differences in the rates of IUD removals are the result of any other positive time trend operating in the project communities under study. The living conditions and amenities available to these communities remained essentially unchanged over the two study phases. The difference in the rates of IUD retention between the two groups could possibly be related to the fact that Phase II includes a significantly higher number of tribal women, who may have greater capacity to bear with body pain and discomfort. This may be true but the point to be made is, it is the anxiety and

apprehensions about the IUD that prevent poor women from accepting the method in the first place. Once these fears are allayed, women are most probably ready to tolerate the discomforts rather than risk another unwanted pregnancy.

The proportion of women who reported leucorrhoea, bleeding, or pain in first six months or even later on after IUD insertion is essentially the same in both groups; however, the rate of IUD removal due to these problems is significantly higher in Phase I (Table 2). This finding strongly supports our contention that dissemination of specific, easily understandable information, dealing directly with peoples' deeply held fears and beliefs related to woman's reproductive system, has had a positive effect on the continuation of IUDs.

Discussions with our female health workers revealed how the information network within the community was gradually established. They said that in Phase I, their own understanding about the IUD was much less than in Phase II. In Phase II they worked in the clinic as well as in the community and undertook other activities related to women's health in the community including antenatal and postnatal care and health education. They were thus able to win the trust of the community much more in Phase II than in Phase I. In Phase I, if women had any problem after IUD insertion, they would only attribute this to the IUD. However during Phase II, they regularly discussed their problems with the female health workers and were usually reassured. The fieldworkers explained that the reproductive system was like a box closed from above, which most women found very reassuring. During Phase I, family members and neighbors often made women more apprehensive and scared, and advised them to remove the IUD if there were even any trivial problem. Later because of wider health education, the understanding of the community as a whole increased.

The data obtained in this clinical setting while limited in number, are interesting and need to be followed up in a community setting. During both phases of this study, we have not been able to carry out bacteriological tests on women with specific complaints. There was no evidence of infection upon pre insertion clinical examination, with the exception of one woman in Phase II whose IUD was promptly removed. It should be noted that despite complaints, a large majority of women who had been given appropriate health education could be reassured and willing to continue with the IUD. On follow-up, these women were usually found to have no adverse effects. This is an important finding at a time when the IUD has been abandoned by many programmes concerned with family planning. With respect to the replicability of our intervention strategy, we would like to point out that although a good relationship with the community was necessary to learn about deeply rooted conceptions of women's bodies and functions and associated fears, it should be clear that the counseling of women does not require intimate interactions and an exceptionally high order of dedication of the health staff, for the fears are understood.

The important point is that any pre-insertion counseling must incorporate quite specific information about the female anatomy, using easily available visual materials. Intimate and prolonged interaction is not necessary to successfully do this. The method itself and the models used were extremely simple and cheap, and easily reproducible. Typical government clinic and staff could easily use these methods and contents of counseling and health education to replicate these results. It can be cautiously concluded that the IUD can be one of the choices to women, who in large numbers but subdued voices, are demanding child spacing rather than unwanted pregnancies or permanent sterilization.

The important point is that any pre-insertion counseling must incorporate quite specific information about the female anatomy, using easily available visual materials. Intimate and prolonged interaction is not necessary to successfully do this. The method itself and the models used were extremely simple and cheap, and easily reproducible. Typical government clinic and staff could easily use these methods and contents of counseling and health education to replicate these results. It can be cautiously concluded that the IUD can be one of the choices to women, who in large numbers but subdued voices, are demanding child spacing rather than unwanted pregnancies or permanent sterilization.

Life table analysis of IUD continuation rates in two phases:

Appendix 1.

Time at beginning of interval (Months)	Number at beginning of interval	Cases with-drawn in the interval x to x+2	IUDs removed in the interval x to x+2	Ox adjusted for with-IUD drawals Ox-2wx/2	Probability of IUD Removal during interval (2dx/O'x)	IUD Continuation during interval (1-P1)	Continuation from time interval up to x+2 (x+2)PO
x	Ox	2wx	2dx	O'x	2qx %	2px %	%
			Phase I (1987-1990)				
0	56	2	2	55	4	96	96
2	52	0	8	52	16	84	81
4	44	0	8	44	19	81	66
6	36	0	4	36	12	88	59
8	32	0	4	32	13	87	52
10	28	0	2	28	8	92	48
12	26	0	0	26	0	100	48
14	26	0	2	26	8	92	45
16	24	0	1	24	5	95	43
18	23	0	0	23	0	100	43
20	23	0	3	23	14	86	37
22	20	0	5	20	25	75	28
24	15						
			Phase II (1991-1993)				
0	80	1	5	80	7	93	93
2	74	0	2	74	3	97	91
4	72	0	2	72	3	97	89
6	70	0	4	70	6	94	84
8	66	0	5	66	8	92	78
10	61	0	1	61	2	98	77
12	60	0	1	60	2	98	76
14	59	0	3	59	6	94	72
16	56	6	6	53	12	88	64
18	44	0	6	44	14	86	56
20	38	4	1	36	3	97	55
22	33	2	2	32	7	93	52
24	29						

Life Table Analysis of IUD Continuation Rates in two Phases:

(Removals due to Problems like Leucorrhoea, Bleeding, or Pain Considered Drop-outs.)

Time at start of interval in months	No at begi-nning of interval	Cases with-drawn in the interval x to x+2	IUDs Removed due to			Adjusted Ox for withdr-awals. Ox-2wx/2-2dx1/2-2dx2/2	Probability of		
			Leucor-hoea, heavy bleed-ing or Pain	Desire of child or want sterili-zation	Sponta-neous Expul-sion or other reason		IUD Removal ue to Leu.. Bleed. etc. during interval	IUD Continuation during interval (1 - P1)	IUD Continuation from time of insertion up to x+2
x	Ox	2wx	2dx	2dx1	2dx2	O'x	2qx	2px	(x+2)P0
Phase I (1987 - 1990)									
0	56	2	2	0	0	55	4%	96%	96%
2	52	0	6	2	0	51	12%	88%	85%
4	44	0	7	1	0	44	16%	84%	72%
6	36	0	3	0	1	36	9%	91%	66%
8	32	0	2	2	0	31	7%	93%	62%
10	28	0	2	0	0	28	8%	92%	58%
12	26	0	0	0	0	26	0%	100%	58%
14	26	0	1	1	0	26	4%	96%	56%
16	24	0	0	1	0	24	0%	100%	56%
18	23	0	0	0	0	23	0%	100%	56%
20	23	0	3	0	0	23	14%	86%	49%
22	20	0	3	2	0	19	16%	84%	42%
24	15								
Phase II (1991-1993)									
0	80	1	1	1	3	78	2%	98%	98%
2	74	0	2	0	0	74	3%	97%	96%
4	72	0	1	0	1	72	2%	98%	95%
6	70	0	3	1	0	70	5%	95%	91%
8	66	0	3	0	2	65	5%	95%	87%
10	61	0	1	0	0	61	2%	98%	86%
12	60	0	1	0	0	60	2%	98%	85%
14	59	0	2	1	0	59	4%	96%	82%
16	56	6	1	5	0	51	2%	98%	81%
18	44	0	2	4	0	42	5%	95%	77%
20	38	4	0	1	0	36	0%	100%	77%
22	33	2	0	2	0	31	0%	100%	77%
24	29								

Table 1. Selected characteristics of women accepting IUDs during 1987-90 and 1991-93

Characteristic		Phase I (1987-90)	Phase II (1991-93)
	Mean Age (years)	23.9	23.4
Education	None	21%	25%
	Primary (1 to 4)	16%	11%
	Primary (5 to 7)	27%	21%
	Secondary (8)	34%	48%
Social Groups	Upper castes	61%	39%
	Scheduled tribes	13%	41%
	Scheduled and other backward castes	15%	14%
	Muslims	13%	6%
Desire of spacing through use of IUD	Spacing before first child	4%	0%
	Spacing between children	58%	58%
	Spacing before permanent sterilization	38%	42%
	Total (N)	100%	100%

Table 2. Complaint of discharge, bleeding or pain: Phase I and II IUD acceptors

	Phase I[1] (1987-90)	Phase II[2] (1991-93)
Percentage of women who complained of leucorrhoea, bleeding or pain within six months of IUD insertion	36%	29%
Of those who complained, percentage who:		
had their IUD removed	80%	22%
retained IUD	20%	78%

[1] Total number of women who accepted IUD: 56
[2] Total number of women who accepted IUD: 80

Table 3. Problems anytime after IUD insertion

	Phase I	Phase II
Information available	80%	87.5%
No problems	29%	40%
Excessive menstruation	22%	14%
Vaginitis	13%	13%
Cervicitis	7%	10%
PID	22%	20%
Pain in abdomen	7%	3%
No information	20%	12.5%
Total (N)	100%	100%

Table 4. Reasons for IUD removal in 2 phases

Reasons for IUD removal	Phase I (1987-90)	Phase II (1991-93)
Leucorrhoea and pain	46%	27%
Excessive menstruation	28%	19%
Desire child	15%	30%
Desire permanent sterilization	8%	8%
Spontaneous expulsion	0%	16%
Other	3%	0%
Total	100%	100%

Figure 1. Life after IUD Continuation Rates: 1989-90 and 1991-93

(When Removals for All Reasons are Considered.)

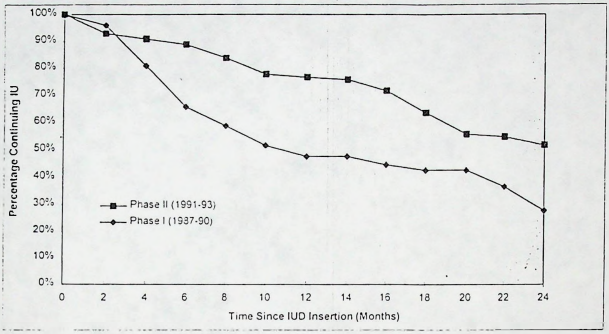
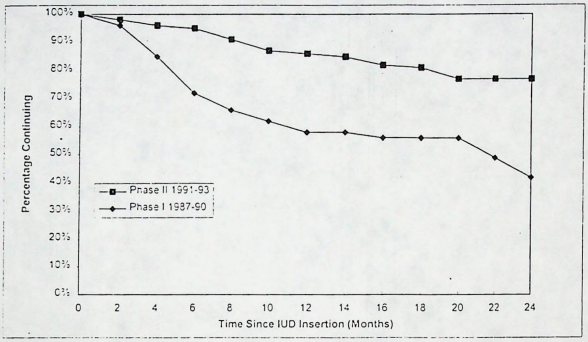


Figure 2. Curves of IUD Continuation Rates in two Phases:

(When only Removals due to IUD related Problems are Considered Drop-outs.)



References

1 National Family Health Survey, India: 1992-93

2 Kreager Philip: 'Family Planning Drop-outs Reconsidered - A Critical Review of Research and Research Findings', International Planned Parenthood Federation, London, November 1977.

3 Huezo C. M., Malhotra U., Sloggett A. and Cleland J: 'Acceptability and continuation of use of /full reference contraceptive methods', A multi-centre study.

4 Kahn Harold, Sempos Christopher: 'Statistical Methods in Epidemiology' Oxford University Press, 1989 pp. 168-180

Mythic Origins of Menstrual Taboo in Rig Veda

Janet Chawla

A crucial subtext can be read in feminist agitations against the injectable contraceptive, Depo-Provera. The female body is not to be problematised as the site of pathology and victimised for its potential fertility. Menstruation is a normal, natural female physiological function. In this context it is appropriate to reflect upon traditional cultural constructions of the female body and the meanings of menstruation within Indian symbolic systems – meanings which have undoubtedly shaped Indian women's (and men's) experiences of female bodily processes.

MENSTRUATION is the monthly bleeding of non-pregnant women of childbearing age. This article explores aspects of uniquely Indian cultural meanings of menstruation and constructions of woman's body. I will first contextualise these meanings and constructions in relation to the contemporary discussion of and feminist agitation against the injectable hormonal contraceptive Depo-Provera.

Feminist groups have been agitating against the Drug Controller of India's attempts to allow the introduction of Depo-Provera in the Indian marketplace. Opposition to Depo (and other hormonal contraceptives, Net-en and Norplant) has been articulated by critics utilising various discourses. Women's groups have used the medical research and language to expose the many negative side-effects of injectable and implantable contraceptive technology and emphasised the dangers of its use with poor and rural women where health is already compromised. Human rights and feminist organisations as well as the socially concerned medical community have used the issue of resource distribution to question those 'developmentwallahs' and bilateral funding agencies who advocate a 'quick technological fix' approach to family planning and population control. Critics of the New Economic Policy point out that in the name of liberalisation, free trade, and 'development' foreign multinationals and their Indian collaborators (such as Upjohn and Max Pharma – the purveyors of Depo) will have *laissez-faire* access to the Indian consumer without the monitoring and protection of a coherent national drug policy.

This is, of course, a gross oversimplification of a complex debate. Nevertheless, there is a significant omission from this discussion. The most frequently encountered consequence of Depo-Provera (or its active ingredient DMPA – a synthetic form of the female hormone, progesterone) is alteration in the menstrual cycle. "Some women will experience unpredictable or prolonged bleeding or spotting...*most users develop amenorrhea* (suppression of menstruation) *after several months of use*"[1] (emphasis mine).

In this current age of ecological awareness, many people are beginning to recognise that the cycles and processes of nature (seasons, the atmosphere, river waters, the earth) must be respected and sensitively handled. Ironically it seems as though this sensitivity does not extend to the natural physiological cyclicity of women's bodies: menstruation. One group of women's health activists have accurately described the situation. "In the case of hormones used for oral, injectable and implantable contraception, never before have so many women been given potent medicine continuously to suppress a condition (fertility) that is not a disease[2].

I would suggest that a crucial subtext can be read in feminist agitations against Depo-Provera: the female body is not to be problematised as the site of pathology and victimised for its potential fertility. Menstruation is a normal, natural female physiological function.

Within this context it is appropriate to reflect upon traditional cultural constructions of the female body and the meanings of menstruation within Indian symbolic systems – meanings which undoubtably have shaped Indian women's (and men's) experiences of female bodily processes.

Obviously traditional Indian cultural constructions of menstruation differ considerably from the bio-medical model. In many parts of south India a girl's first menstruation was until recently celebrated publicly; after emerging from seclusion the young woman was bathed, dressed in bridal finery, and garlanded with flowers. Aesthetic renderings of a young woman kicking an Ashoka tree imply that it is her shakti which causes the tree to bloom. In tantric rituals, which probably have their origins in tribal and folk cultures, menstrual blood was one of the offerings made to the goddess.

According to historian N N Bhattacharyya, different areas of India have had notions of the menstruating goddess. In Punjab it was believed that Mother Earth ('Dharti Ma') 'slept' for a week each month. In some parts of the Deccan after the 'navaratra' goddess temples were closed from the tenth to the full moon day while she rests and refreshes herself. In the Malabar region, Mother Earth was believed to rest during the hot weather until she got the first shower of rain[3]. Still today in the Kamakhya temple of Assam and in parts of Orissa the rituals of the menstruation of the goddess are celebrated during the monsoon season. Both the fertile earth and woman must rest, be venerated and celebrated.

Bhattacharyya notes that the auspiciousness of menstruation, representing potential fertility, is symbolised by blood or the colour of blood and is regarded as sacred. Sindur applied in the part of the married woman's hair symbolises the sacredness of her fertile potential (when exercised within the confines of patriarchal marriage!) Deities and sacred objects are daubed with red colouring as a part of ritual worship. Within Indian culture, red signifies auspiciousness and potential growth – these ancient religious ideas and symbols are definitely linked to the blood of menstruation.

Understanding these nuances of India's cultural history it is not surprising to find that some studies have shown that Indian women experience menstrual irregularity, spotting, or lack of menstruation as significant problems[4]. Sociologist Veena Das explains: the cultural assumptions which underlie this experience – "the female body makes the notion of regularity of nature available to mankind. For the Hindus, it is the regular periodicity of menstruation that is the guarantee of the regularity of nature. Thus, the word 'ritu' stands for both seasons and the menstrual cycle. Similarly the word for the woman's menstrual cycle and the moon's cycle is the same, showing that the rhythms of the body and the rhythms of the cosmos are in harmony"[5]. However, the Hindu traditions themselves are also deeply ambivalent in their constructions of menstruation as the following investigation of the menstrual taboo reveals.

Commentary on the Rig Veda has occupied human minds for literally millennia. Very few of those minds happened to be women's. I began my study of the Rig Vedic text in order to understand the mythic origins of the ritual taboos associated with menstruation. In this article I will present the woman-centred concerns which I bring to the Rig Veda, a feminist interpretation of the textual material, and

speculations about the historical meaning of the mythic and symbolic elements of the narrative.

Having worked as a childbirth educator and advocate of 'natural childbirth' among voluntary organisations I became increasingly frustrated with the medical model of pregnancy and birth. Surely, I reasoned, there must be traditional, indigenous and empowering knowledge about women's bodies. I decided to document traditional Indian childbirth practices which seemed to me to be more congruent with my natural childbirth orientation. I worked with the Ankur-Action India women's health group in Delhi to collect stories of women from all classes and religious backgrounds about their experiences with menstruation, pregnancy, birth and mothering.

From these interviews emerged two conceptual areas which appeared significant. One was ritual pollution. Almost every woman spoke of her body as being considered unclean or impure during the time of menstruation and post-partum. Women told of being prohibited from going to the Mandir, Masjid or Gurdwara performing or participating in Pujas, not reading holy books as well as the importance of bathing rituals after menstruation. One basti woman described the blood of childbirth as 'rook hua' (stagnant) and the placenta as 'nau mahena ka narak kund' (nine months' hell vessel).

Second was the well worship ritual[5]. Many of the 'basti' women mentioned a ritual worship of the well (or in the resettlement colonies the 'nal', or water tap) on 'chatti' after childbirth. As they described the ritual it was actually worshipping the water source rather than a purification ritual.

Thus I encountered two seemingly contradictory ritual and belief systems. In brahmanical Hinduism woman's body and procreative capacity is defined as a source of ritual impurity. Water or bathing is understood to be purifying; washing away bodily pollution. On the other hand the worship of the water source, a woman-centred ritual involving singing and celebration, constructs both the well and water as sacred. Symbolically the well is analogous to the yoni. Wells in many parts of India are constructed in a yonic shape. Just as the baby emerges from the watery womb – the source of life – so the well, in the traditional Indian setting, was the source of water, necessary for the continuing life of people, plants, animals. Interestingly some slum women in resettlement colonies around Delhi reported the community water tap (in the absence of the village well) as the focus of ritual celebration post-partum.

I asked myself rather simple questions: why are menstruation and the blood of childbirth considered ritually polluting? What are the origins of a belief which so categorises women's body and the miraculous biological processes which bring new human life into the world? (I should acknowledge that defining women's bodily processes as polluting and antithetical to religious practice is not unique to Hinduism. It is also a part of the Judeo-Christian-Islamic tradition.) I got my first inkling of an answer when I discovered the myth of Indra slaying Vritra.

Myths are traditional stories which serve to unfold part of the world-view of a people and or explain a practice, belief or natural phenomena. Myth serves various functions in any given society. First, a metaphysical function; myth orients a person *vis-a-vis* the world, the cosmos, and society and imbues experience with meaning, often understood as religious or spiritual. Second, myth serves a social function of providing role models, prescribed or tabooed actions and dramatically revealing consequences of behaviour. Third, myth provides a pedagogical tool: as the young hear the stories of their elders, they learn about themselves and the world and begin to understand their environment and the behaviour expected from them in ways acceptable to their family and group [6].

In the Rig Veda Indra's slaying of Vritra (or the Vritras) is referred to over 100 times. Most Vedic scholars agree that this killing is the central dramatic event in India's oldest existing text.

In the Rig Veda, Vritra is depicted as the withholder of the waters, the demon of droughts, a snake or dragonlike figure who dwells in the rivers or celestial waters, or in a cavern in the earth. He lives in the caves with the cows. Indra kills Vritra with his thunderbolt, thus releasing the waters, the cows, and wealth, prosperity, and progeny.

Keith notes that Vritra is the primary enemy of the Vedic gods: "He is a serpent with power over the lightning, mist, hail and thunder, when he wars with Indra; his mother is Danu, apparently the stream or the waters of heaven, but he bears that name himself as well a Danava, offspring of Danu." According to Keith, Vritra paradoxically resides within the waters, but also on lofty heights which suggests the waters of the air. His name denotes "... the encompasser of the waters, rather than the holder back by congealing them: the cloud mountain is therefore said to be in his belly" Indra, the Vritra slayer, is also the breaker of forts. Keith notes that Vritra "has 99 forts which Indra shatters as he slays him"[7]. It is this frequently used epithet of Indra as 'fort-breaker' which has led some scholars to speculate that the aboriginal peoples (the Vritras, Asuras, Dasas or demons of the Rig Vedic text) were the occupants of the Harrapan cities such as Mohenjodaro.

I will attempt to understand the figure of Vritra in two ways. First, by reading the text as an historical document reflecting the Aryan encounter with, and subordination of pre-Aryan indigenous peoples; simultaneously seizing and exploiting natural resources and appropriating pre-existing cultural forms. How did the deification of Indra and the demonisation of Vritra construct an ideology which legitimised the Indo-European domination over the native peoples? What can be inferred from the narrative and symbolic content of the text about the social organisation, values and cultural forms of the original inhabitants of the subcontinent? Second, I will use as a working hypothesis the idea that the figure of Vritra is inextricably linked with a pre-existing matristic social system and a world-view which valued the sacred (or powerful) feminine.

Existing critical literature recognises the marginality of women in the Rig Veda. J Gonda acknowledges that "Women are a rare subject; they are mainly mentioned in metaphors and, as a collectivum, in similes"[8]. Wendy Doniger O'Flaherty categorically states "The Rig Veda is a book by men about male concerns in a world dominated by men; one of these concerns is women, who appear throughout the hymns as objects, though seldom as subjects"[9].

The text, however, speaks for itself on the general category of women: "Indra himself hath said, the mind of woman brooks no discipline. Her intellect hath little weight' (RV VIII 33 17). (Ironically this aphorism is put in the mouth of a heroic warrior known for neither his intellect nor his self-discipline.) "With women there can be no lasting friendship: hearts of hyenas are the hearts of women" (RV X 95.15).

Indologists have interpreted natural symbolism in the Rig Veda within various conceptual frameworks. However the task of decoding what Gonda refers to as 'similes and metaphors' as real human persons, not just part of the natural flora and fauna, has not, to my knowledge, been attempted. Androcentric scholarship, both Indian and western, has been quite happy to leave unchallenged categories of 'man = culture whereas woman = nature' (and primal peoples = nature whereas dominant peoples = constructed culture). I suggest that the cows, rivers, and caves can be read as referents to both the mythic feminine and to real historical women and groups of women. (More precisely, 'proto-historical' because there is considerable evidence that our hypothesised matristic society was, in fact, the pre-Vedic, Harappan civilisation. The Harappans had a form of writing which has not yet been deciphered, and is thus technically 'proto-historical'.)

Interestingly Vritra, in fact all the demons of the Rig Veda, are known by matronymics rather than patronymics. Vritra is a Danava, son of Danu. In one passage, describing his death, the Rig Veda links the two in imagery of cow and calf: "The vital energy of Vritra's

mother ebbed away, for Indra had hurled his deadly weapon at her. Above was the mother, below was the son; Danu lay down like a cow with her calf" (RV 1.32.9, translation O'Flaherty).

My hypothesis is that Vritra is mythically and symbolically linked to pre-patriarchal, pre-Vedic social formations. By re-interpreting the slaying of the 'son of the mother', we discover the mythic origin of the later brahmanic pollution ideology which devalues and de-sacralises the female bodily processes of menstruation and childbirth while simultaneously glorifying the patriarchally constructed institution of 'motherhood'.

The *Dharmashastras*, the lawgivers' treatises on how to live a proper life, contain various proscriptions on what a menstruating woman should and should not do. In this text, Chapter 5 of the *Vasishtha Dharmashastra*, menstrual taboos and woman's subordinate social position are related to the myth of Indra's Vritra slaying.

(1) A woman is not independent, the males are her masters. It has been declared in the Veda, "A female who neither goes naked nor is temporarily unclean is paradise".

(2) "Their fathers protect them in childhood, their husbands protect them in youth, and their sons protect them in age; a woman is never fit for independence."

(3) The penance to be performed by a wife for being unfaithful to her husband has been declared in the section of secret penances.

(4) For month by month the menstrual excretion takes away her sins.

(5) A woman in her courses is impure during three days and nights.

(6) During her period she shall not apply collyrium to her eyes, nor anoint her body, nor bathe in water; she shall sleep on the ground; she shall not sleep in the day-time, nor touch the fire, nor make a rope, nor clean her teeth, nor eat meat, nor look at the planets, nor drink out of a large vessel, or out of joined hands, or out of a copper vessel.

(7) For, it has been declared in the Veda, "When Indra had slain Vritra, the three-headed son of Tvashtri, he was seized by sin, and he considered himself to be tainted with exceedingly great guilt. All beings cried out against him saying to him "O thou slayer of a learned Brahmana!" He ran to the women for protection and said to them, "Take upon yourself the third part of this my guilt caused by the murder of a learned Brahmana." They said, "Let us obtain offspring if our husbands approach us during the proper season, at pleasure let us dwell with our husbands until our children are born." He answered, "So be it". Then they took upon themselves the third part of his guilt. That guilt of brahmana-murder appears every month as the menstrual flow. Therefore let him not eat the food of a woman in her courses; for such a one has put on the shape of the guilt of brahmana-murderer.

(8) Those who recite the Veda proclaim the following rule: "Collyrium and ointment must not be accepted from her; for that is the food of women. Therefore they feel a loathing for her while she is in that condition saying "she shall not approach".

(9) "Those brahmanas in whose houses menstruating women sit, those who keep no sacred fire, and those in whose family there is no Srotiya – all these are equal to shudras."

In this text we find practices relating to the seclusion and restrictions of menstruating women explicitly linked to the mythic drama of Indra's slaying of Vritra. This myth is found first in the Rig Veda and subsequently woven through various texts – in this paper we shall only consider the Rig Veda, but the *Satapatha Brahmana* and the *Taittireya Samhita* of the Black *Yajur Veda* also are germane to an understanding of how female physiology is constructed, symbolically and narratively linked to the mythic slaying of Vritra, and incorporated into Vedic sacrificial liturgy and ritual.

Mircea Eliade, writing of the Vritra myth, notes the Indian practice of astrologically determining the placement of a peg into the earth before building a structure. The peg is to secure the head of the snake (thought to reside in the earth) and prevent it from shaking and destroying the building. "But the act of foundation at the same time repeats the cosmogonic act for to "secure" the snake's head, to drive the peg into it is to imitate the primordial gesture of Soma (RV 2.12.1) or of Indra when the latter "smote the Serpent in his lair" (6.17.9) when his thunderbolt "cut off its head" (1.52.10)." According to Eliade's interpretation the serpent Vritra symbolises chaos, the formless and non-manifested. He supports this understanding by textual references to Vritra as "undivided (aparvan), unawakened (abudhyam), sleeping (abudhyamanam), outstretched (asayanam)." Eliade proceeds to state that Indra's "hurling of the lightning and the decapitation are equivalent to the act of Creation, with passage from the non-manifested to the manifested, from the formless to the formed [10].

Eliade's notion of primal chaos is outdated and androcentric. The new physics is radically changing scientists' conceptions of order and chaos. Phenomena previously understood as chaotic now seem to display an underlying sense of order. It is masculine 'creation' which involves hurling of lightning (read sperm) and decapitation is a rather anomalous symbol for creativity. What has previously been understood as 'primal chaos' might now reveal itself as a matristic social and symbolic order. The creative order of the menstrual cycle and the rhythms of labour may involve stress and pain – but not the violence to the 'other' depicted in the Indra-Vritra slaying. The essential question remains "what/whom is really being killed?"

Eliade reasons that because Vritra had confiscated the waters and was keeping them in the hollows of the mountains that either "Vritra was the absolute master – in the same manner as Tiamat or any serpent divinity – of all chaos before the Creation; or that the great serpent, keeping the waters for himself alone, had left the whole world ravaged by drought."

But Sjoo and Mor interpret the pervasive Indo-European serpent and dragon metaphor in a radically different fashion. They state unequivocally that "the serpent of chaos is originally and always a woman's body. As the Great Mother of Chaos, of matter still unformed and undifferentiated, she holds the earth like an egg in the pure energy of her coils." Sjoo and Mor understand the "Great Mother of Chaos" to represent the 'time before the gods', which preceded the establishment of patriarchal hierarchies and distinctions. Within this woman-centred interpretation, "the dragon of matter, the Undivided One older than the individuation of forms", also signified the flesh and blood bonds which unified the people. These authors link the snake/dragon with "the indigenous 'masters of the ground' – the matrifocal peasantry – who are invaded, conquered, plundered, co-opted by the 'dragon-slayers' of patriarchal history..." In Sjoo and Mor's analysis Indra's murder of Vritra initiates the creation, not of the cosmos, but of patriarchy "...In the Indo-European view the dark, serpentine Danu and Vritra had 'withheld the waters in the mountain hollows' and so hindered the world from coming into being. The Indo-European patriarchal world, that is"[11].

The violence of the Vritra murder is recapitulated in the ritual metaphor of the serpent needing to be pegged for masculine 'construction' to take place. (That this metaphor is still operative in the folk mind is obvious from the worship of the Nag which took place in many Garhwali villages after the Uttarkashi earthquake.) We are claiming that another paradigm of order, not primal chaos, can be discerned in the text; one that is congruent with women's procreative capacity, menstrual and lunar cycles and the hypothesised matrifocal social order. I am suggesting that what preceded Vedic ideology on the sub-continent was not the primal chaos of chythonic peoples, but a previously unrecognised, humanly constructed, social order. The death and dismemberment of Vritra can be viewed as a metaphor for the Indo-European exercise of power, symbolic and martial, over the pre-existing peoples and their culture.

The mythic Indra was, after all, a warrior par excellence; the Rig Veda is a martial document. Scholars have debated whether the warfare was literal, ritual, symbolic – between groups of men, men and demons, gods and demons, etc. But Vedic study, both Indian and foreign, has neglected a crucial question which Uma Chakravarty poses: "Whatever Happened to the Vedic Dasi?"

Chakravarty, in her deconstruction of "the myth of the golden age of Indian womanhood as located in the Vedic period", emphasises the historiographic foregrounding of "the Aryan woman (the progenitor of the upper-caste woman) as the only object of historical concern". Chakravarty notes "It is no wonder then that the Vedic dasi (woman in servitude), captured and subjugated, and enslaved by the conquering Aryans, but who also represents one aspect of Indian womanhood, disappeared without leaving any trace of herself in 19th century history"[12].

The Indo-Europeans infiltrated the sub-continent in different waves, c 1500-1200 BC. The Aryan hymn singers of the Rig Veda lionised the exploits of Indra – his swigging of Soma, his rape of Ushas, his plundering of booty for his followers and also his killing of Vritra. Sukumari Bhattacharji calls Indra a culture hero [13].

As Chakravarty's historiographic essay implies, a focus on the dasi and the figure of Vritra implicitly questions the legitimacy and sanctity of this heroic paradigm. Warfare has always been a different experience for men and for women.

Gerda Lerner describes the historical process of the enslavement of women in west Asia and a similar situation probably existed in ancient India as well. "Biological and cultural factors predisposed men to enslave women before they had learned how to enslave men". Lerner suggests that physical terror and coercion, which were an essential ingredient in the process of turning free persons into slaves, took, for women, the form of rape. "Women were subdued physically by rape; once impregnated, they might become psychologically attached to their masters... Free sexual access to slaves marks them off from all other persons as much as their juridical classification as property..." Lerner concludes that there exists "overwhelming historical evidence for the preponderance of the practice of killing or mutilating male prisoners and for the large-scale enslavement and rape of the female prisoners"[14].

Lerner's view is entirely congruent with historians' views of Rig Vedic times. R S Sharma describes Vedic life. "Spoils of war and cattle formed the main forms of property. Cattle, horses, and women slaves were generally given as gifts"[15]. I am suggesting that the Rig Veda, however, tentative an historical source, can be read as a mythic version of a lived past. Indra's slaying of Vritra, like his rape of Ushas, can be understood, not just as a phantasmagorical metaphor, but as the mythic rendering of real human experience; of the encounter between the Indo-European patriarchal infiltrators and the extant social formation.

D D Kosambi interprets Indra's rape of Ushas, the goddess of dawn and renewal, "an otherwise inexplicable event" in terms of a conflict of belief and ritual systems. "The only possible explanation lies in a clash of cults, that of the old mother-goddess being crushed on the river Beas by the new war-god of the patriarchal invaders, Indra." Kosambi explains the survival of the independent feminine represented by Ushas in terms of her redefinition; she assumes, within an androcentric pantheon, the more familiar patrilineal roles of women – mother, wife and daughter. "That she survives after being 'killed' can only indicate progressive, comparatively peaceful, assimilation of her surviving pre-Aryan worshippers who still regarded her as mother of the sun, wife of the sun, daughter of heaven"[16]. That the metaphor of rape is used, within the text, to assert the domination of god over goddess implies that the practice of actual rape was utilised as a method of pacification of human women as well. Bloodshed, rape and plunder are all masked in the Rig Veda as the heroism of the solar god, pushing back the frontiers of darkness and primal, chaotic disorder.

Evidence of a Rig Vedic overlay on a pre-existing meaning system is provided by Dipak Bhattacharya in his chapter on the birth of Agni. In a section interestingly titled "The flow of rta from the obscured mothers of Agni", Bhattacharya grapples with the imagery of 'rta' (cosmic order) and 'rajas' (menstruation). Agni is said to be born 'in the depth of the great' and 'in the yoni of this rajas' and is referred to as 'the embryo of the waters'. The aqueous origin of Agni in the atmospheric region is a well recognised vedic idea. Bhattacharya writes of the symbolic meaning of 'the waters'. "It has to be noted that in a different context Pischel and Geldner recognise that the waters are imagined as females with their regular peculiarities, mainly periods. The high waters of the rains are regarded as catamenia (menstruation) and their drying up as menopause. In the context of the birth of Agni the rains may symbolise not catamenia, but foetal (childbirth) discharge"[17].

This symbolic nexus of the waters, rajas (also meaning atmospheric vapour) and rta or cosmic order indicate an original mythic structure which sacralises menstrual and lunar rhythms and recognises these rhythms, embodied by women, as principles of clarity and order, as well as the source of life.

Perhaps to the indigenous peoples, woman's blood was awesome and numinous. Women bled monthly, in cyclical harmony with the moon, and yet did not die – rather miraculously produced new life. The blood shed by them, during menstruation and childbirth may have been considered sacred emblems of cosmic order. Indra's slaying of Vritra ended that symbolic connection. As the Dharma shastras elucidate, menstrual blood comes to be considered loathsome – powerful, dangerous and threatening. Indra expropriates women's function of bloodletting. The warrior is socially sanctioned to shed his enemy's blood – that act is constructed as being heroic, dharmic and sacred, as exemplified in Krishna's advice to Arjuna in the Bhagavad Gita.

We have foregrounded the symbolic connection between the idea of rta or cosmic order and menstrual rhythms. Other scholars, Bhattacharya more recently, and the older Vedic Sanskritists, Pischer and Geldner, have also noted this symbolic connection. Further validating this line of understanding rta is the scientifically documented phenomenon of menstrual synchrony.

In 1971 the American researcher, Martha McClintock documented the phenomena of human intra-group menstrual synchrony[18]. She observed that the menstrual cycles of frequently interacting women tend to become synchronised over time, and that this synchronisation is related to the extent and frequency of contacts between individual women. Anthropological work on the Yurok Indians of northern California and aboriginal Australians point towards the 'precontact' existence of menstrual synchrony among the women of these groups, as well as describing ritual forms celebrating menstruation and female bonds. The work of McClintock and these anthropologists has tremendous relevance to woman-centred attempts to understand early human culture.

Returning to the mythic Vritra-slaying two questions remain in this interpretation. One, why in the Rig Veda is Vritra grouped with the dasas, and in the later texts, including the Dharmashastras quoted above, his slaying is referred to as a brahminicide, which would lead us to see him as a brahmin? Second, why is Vritra usually rendered in the neuter, rather than masculine, gender? It seems to me that although the Rig Veda is the earlier document actually the later texts contain more information about the aboriginal peoples. In the later Vedas, puranas and epics, Vritra is further personified, fleshed out, and conceptualised. The process of assimilation and absorption of pre-Indo European material allowed for what we might call 'prakritisation', i.e. the transformation of the Aryan world-view, which we find more starkly presented in the Rig Veda. Brahmins, as a priestly caste, did not yet exist in Rig Vedic times. The notion of brahminicide describing Indra's slaying of Vritra is thus an anachronism. Perhaps the brahmins, while formulating these later texts were appropriating some of the power and legitimacy of Vritra (or proto-brahminic forms) to themselves. This is a reasonable assumption because Vritra is textually identified as having special powers and may have functioned among the autochthonous peoples as a shaman. Nevertheless the device of the 'brahminicide' shows that the later brahmin priests in some way identified themselves with the Vritra figure.

The Rig Vedic Vritra is both a demon, dasa, and magician or priest. He exercises the power of 'maya' or illusion. The use

of the neuter gender in referring to Vritra and the Vritras can be related to the literal meaning of 'vritra' which is concealing-covering-hiding and defending-resisting-protecting. (The root vr conveys the idea of aiding or succouring, in a positive sense, sheltering [18]. Most interpreters have favoured a natural phenomenal understanding as mentioned above. This level of meaning is certainly present but not exclusive of a socio-symbolic as well biological-symbolic (women's biology) reading. The neuter gender may have been used because the reference is finally to the indigenous people's system, a social and symbolic formation. Within the Vedic text this system is represented in the form of protective resistance and concealment – masking the beliefs and practices, ruses and manoeuvres, of a defensive aboriginal population.

II

In this section I will present other textual evidence which supports this woman-centred reading of the Rig Veda. First I will further substantiate the argument that the similes and metaphors of cows, waters, maids, mothers in fact are signifiers for the generative capacity of women and that this imagery can be read historically as referring to the Aryan assimilation of women from a pre-existing matrifocal social order. Then I will consider two different, but not mutually exclusive, meanings of rta: Rta as the cosmic order of menstrual and lunar rhythms, and a Marxist understanding of rta as denoting a pre-vedic, egalitarian food distribution mechanism. I shall then present grammatical and symbolic material relating to the notion of 'mothers-in-common' which further documents the existence of a matrifocal familial pattern. Within this context I will examine the symbolic significance of the few references to blood in the Rig Veda.

Cows-Water-Women-Mothers Cluster of Meaning

In RV 6.47.2-4 the 'sweet juice' of Soma "boldened Indra when he slaughtered Vritra... He who hath created the breadth of earth, the lofty heights of heaven. He formed the nectar in the three headlong rivers." This cosmogonic act of Indra/Soma involves the slaying of Vritra and depositing the nectar (read sperm) into the headlong rivers (read genealogies of women). Wilson comments "Thus Soma has deposited the ambrosia in its three principal receptacles". This mythic death and creation, of course, operate on many levels. Traditional scholarship has emphasised the cosmological symbolic (Indra as solar god); the world of nature (Indra as vegetation god); and the ritual context of the Vedic sacrifice (hymns with liturgical function). But social and biological strata of meaning also are evident.

In RV 3.61.3-5 the "Bull, who wears all shapes" is the male inseminator, the "Everlasting Ones' impregner".

"The Goddesses, the Waters, stayed to meet him; they who were wandering separate enclosed him. Streams! the wise Gods have thrice three habitations."

"Child of three mothers, he is the lord in synods."

"Three are the holy Ladies of the Waters, thrice here from heaven supreme in our assembly."

The 'child of the three mothers' is Agni. We have already put forward Dipak Bhattacharya's thesis of rta and the obscured mothers of Agni. Griffith supposes "the Ladies of the Waters" to be the Ila, Sarasvati and Bharati[20]. In a socio-physiological interpretation the 'cows' (which are inseminated by the bull) – 'holy Ladies of the Waters' (women) – 'Mothers' cluster signifies in both social and symbolic realms. Clans or genealogies of women which were 'wandering separate' that is not attached to any male, or matrilineally constituted, become assimilated into the Indo-European patriarchy[21]. They are thus honoured as 'supreme in our assembly' as Aryan progenitrices. And the salutation 'Streams!' (indeed the omnipresent metaphor of women as water) is thus honouring the facts of female physiology – bodily fluids which indicate generative capacity as producers of progeny: menstrual, vaginal and amniotic fluids.

Part of the interpretive problem is that not only were previous commentators androcentric, they also shared the patriarchy's discomfort with frank discussion of women's bodies and sexuality. The facts of female biology stream out of the text. From the pundit Savana to the Victorian Indologists, commentators were more comfortable with interpretations involving heavenly bodies than female ones. It has taken the Freudians to legitimise a discussion of sexuality, but this discussion is still phallocentric and individualistic (not exploring the textual evidence for an alternative social formation).

The present interpretation foregrounds women as persons capable of full participation in the formulation of societal and symbolic systems and female physiology as a locus of power. (When we speak of female physiology we do so in a gynocentric sense of the total range of female bodily process; menstruation, female capacity for sexual pleasure, as well as potential for pregnancy, childbirth and lactation.) Such a holistic, woman centred – and biologically accurate – definition of female physiology implicitly questions the patriarchal assumption of woman's value as 'the mother of sons'.

We are positing that female physiology (inclusive of the later desacralised aspect of menstruation) may have been a powerful and positive symbolic referent in the meaning systems of indigenous peoples. Emblematic of the generative natural world and cosmic rhythms, woman's physiology may have functioned as a pre-patriarchal gynocentric ordering principle which was both symbolic and matrifocal. This involves recognising both the processes of menstruation (as a sign of the independent, cosmically synchronised rta) and the biological primacy of the mother (human beings are not a sexually dimorphic species – the central human drama of creating new human life happens in the female body not in the male body).

The Rig Vedic hymns reified the female body and provided the symbolic structure which sacralised patriarchal, Aryan motherhood (Aditi) while demonising the independent female energy ('diti', 'danu', the demon of defloration, 'druh') and begins the process, developed in later texts, of assigning a negative valence to menstruation as death fluid.

RV 3.60.16-17 reads:

Let the milch-kine (read women) that have no calves stream downward, yielding rich nectar, streaming, unexhausted. These who are ever new and fresh and youthful...

What time the Bull bellows in other regions, another herd receives the genial moisture; For he is Bhaga, King, the earth's protector...

In RV 3.33.6-10 the waters-women are encouraged to co-operate and be easily traversed after the demon is slain.

Indra who wields the thunder dug our channels: he smote down Vritra, him who stayed our currents..

That hero deed of Indra must be lauded forever that he rent Ahi in pieces. He smote away the obstructors with his thunder and eager for their course, flowed the waters. List quickly sisters, to the bard who cometh to you from far away with car and wagon. Bow lowly down: be easy to be traversed; stay Rivers, with your floods below with our axles.

Yea, we will listen to thy words, O singer. With wain and car from far away thou comest. Low, like a nursing mother, will I bend me and yield me as a maiden to a lover.

The hymn encourages the sisters to listen or accommodate the bard; receiving the word of the singer is analogous to receiving the seed of Indra ('bow lowly down', 'be easily traversed'). The extension of the imagery to 'like a nursing mother' and 'a maiden to her lover' further validates this reading and reminds us of Lerner's suggestion that the motivation for women to submit to slavery was the experience of being impregnated, giving birth, and forming attachments within the patrilineal family.

Cosmic Rta and Young Maids

In the text we find ample evidence to support Dipak Bhattacharya's interpretation of "the flow of Rta from the obscured mothers" as a veiled reference to menstruation. RV 4.19.2-7 reads:

Thou slewest Ahi who besieged the waters, and duggest out their all-supporting channels. The insatiate one, extended, hard to waken;

who slumbered in perpetual sleep, O Indra, The Dragon, stretched against the seven prone rivers, where no joint was, thou rentest with thy thunder...
They ran to thee (Indra) as mothers to their offspring: the clouds, like chariots, hastened forth together. Thou didst refresh the streams and force the billows...
He (Indra) let the young Maids skilled in Law, unwedded, like fountains, bubbling, flow forth streaming onward.

Indra slays the Ahi/Vritra/Dragon figure who is "stretched out against the seven prone rivers". The rivers-women then run to Indra subdued, in a childlike fashion. He 'refreshes the streams' in imagery which almost sounds like contributing genetic material to a gene pool. But most interesting is the fact that these maids are 'skilled in Law', or rta. This description reinforces the association of rta with menstrual rhythms. These young women are 'unwedded', or not within a system of patriarchal marriage. Once impregnated they 'flow forth' with much sought after Aryan offspring.

In RV 4.23.7-10 Indra turns his hand against an independent female spirit and the next three stanzas elaborate on rta. The commentators are creative in their explanations of what rta symbolises in this context.

(7) About to slay the Indra-less destructive spirit he sharpens his keen arms to strike her [according to Griffith, druh-the mischievous female spirit who does not acknowledge Indra]...
(8) Eternal Law hath varied food that strengthens; thought of eternal law removes transgressions. The praise hymn of eternal law, arousing, glowing, hath opened the deaf ears of the living.
(9) Firm seated are eternal law's foundations; in us far form are many splendid beauties. By holy law long lasting food they bring us; by holy law cows come to our worship.
(10) Fixing eternal Law he, too, upholds it: swift moves the might of Law and wins the booty. To Law belongs the vast deep Earth and Heaven: milch-kine supreme, to Law their milk they render.

Commenting on stanza 8 Sayana writes "the word rta means Aditya, or Indra or sacrifice". Griffith claims "its meaning varies slightly in this and the two following stanzas, but the original idea of regularity, conformity to or establishment by eternal order or law is found throughout". About Rk 10 Griffith claims the establisher of the law is also its upholder. Wilson translates "the worshipper subjecting rta to his will verily enjoys rta".

Rk 8 relates rta with 'food that strengthens'. O'Flaherty mentions that "the Vedic materials abound in texts in which semen is regarded as a form of food. Butter and honey, frequent metaphors for Soma come to be compared with semen"[22]. But in the context of this hymn, and following the interpretation that the menstrual rhythms are emblematic of cosmic rhythms, the 'food that strengthens' may connote female fluid (in later texts female 'seed'). During pregnancy, when menstruation ceases, that female blood is often understood to grow or 'strengthen' the foetus. In the Rig Vedic hymn singers preoccupation with offspring, this 'food' is also seen to strengthen the Aryan patriline. Within the context of the Vedic sacrifice that 'food' becomes Soma. Perhaps within the previous ritual system of the indigenous 'demon-priests', like Vritra, female bodily fluids were considered the symbolic 'food'.

Finally we must ask about the significance of the female demon in this passage. I would argue that the Aryan appropriation of a pre-existing social and symbolic form is a violent act; the indigenous reaction, and the continuation of non-Aryan ritual and social process is constructed in the Vedic text as an anathema, demonic. As we shall see with the demon of defloration in Surya's Bridal and the demon-priest Vritra himself, it is entirely plausible to read the demonic as signifier for what is being excluded or forcefully appropriated by the emerging Aryan world-view.

Thus ambiguous meanings exist not just because of the multi-levelled planes of reality operating within the text, but also because the Vedic poets are switching back and forth attempting to reconcile conflicting symbolic and social systems of the pre-Vedic cosmic rta and the 'new world order' of Aryan hegemony.

Within a Marxist interpretive framework, N N Bhattacharyya suggests an alternative, but not mutually exclusive, meaning for the Vedic rta. He identifies gambling and dice, always heartily condemned in the canonical texts, with an ancient tribal redistribution system which was egalitarian, not hierarchical. His understanding provides another dimension to the phrase 'food which strengthens' mentioned above.

Bhattacharyya writes that "Evidently dice were the symbol of ancient social justice and casting the lot was a means of equal distribution of wealth in early Vedic times..." I understand Bhattacharya to be describing something like an ancient 'kitty party' where the harvest or available resources were allocated via a game of chance. All would sooner or later receive their share, but the timing would depend on the throw of the dice.

As Bhattacharyya points out, rta cannot possibly only denote cosmological or natural laws because these laws would not have been subject to change. "There is no doubt that rta stood for a peculiar complex of moral and physical laws, but this is not all. Rta also stood for other principles... One point which should be stressed is that the Vedic poets eventually felt the loss of rta and strongly urged for its revival. If it were exclusively the physical and cosmic laws, there was no need of such lamenting..."[23].

Bhattacharyya proceeds to argue that "the Vedic rta must have originally been what Engels called 'the simple moral grandeur of ancient gentile society', and this explains why the Vedic poets felt the loss of rta for which the breakdown of ancient collective life was responsible". He also notes the moral and ethical qualities originally attributed to the character of Varuna, friend to all and the guardian of rta. (These moral and ethical qualities of Varuna stand in complete opposition to the amorality of Indra.) Although Bhattacharyya's Marxist methodology may seem obtrusive today, his scholarship stands. "Rigvedic passages relating to the rta convincingly prove that the said concept had direct or indirect bearing on the process of obtaining means of subsistence".

N N Bhattacharyya thus provides a plausible explanation of the mechanism, the dice game, by which a pre-Vedic egalitarian society may have implemented distribution of resources. (Thematically the motif of the dice game is often linked with women in Hindu mythology. In the Uma-Maheshwar iconography Uma is depicted as winning a game of dice, beating an emaciated Shiva. In the famous dice game sequence of the Mahabharata, Draupadi is gambled away by her husband.)

Veena Das, in writing of Draupadi, has indicated that the motif of pollution is dominant in the rendering of her character. This pollution motif allows her to "reveal the dark side of the male codes of heroism and chivalry"[24]. According to Das the symbols of menstrual pollution were used by Draupadi to interrogate the male-centred events in the *Mahabharata* discourse. This irony would be even more pronounced if, in fact, the motif of the dice game hearkens back to a pre-existing moral order of rta in which women were not rendered as property and menstruation was not depicted as polluting.

It is relevant that at Mohenjodaro and other Harappan sites (which, as previously noted, some Indologists suggest may have been inhabited by the Dasas or demons of the Rig Veda) many small, cubed artifacts have been unearthed which archaeologists have called 'dice'. In addition no system of coinage (for a city of 60,000 inhabitants) has been found that is pre-Buddhist.

Collective Mothers

The cows-waters-rivers-mothers cluster of imagery leads to a consideration of the group or collective mothers concept. D D Kosambi has written "There is, moreover, an ancient tradition of mothers-in-common that cannot be reconciled with Vedic father-right. It would be difficult to explain Panini 4.1.115 unless mothers-in-common were taken for granted by the master grammarian." Kosambi

states that Tryambaka, which was later explained away as meaning 'with three eyes' originally meant 'with three mothers'. He suggests that this notion, which seems fantasy to the patrilineal mind, appears in "the legends of Jarasamdha born of two, and Jantu, born of a hundred mothers-in-common show". According to Kosambi this demonstrates "that there was an undeniable tradition of many mothers with equal status, even for a single child".

Kosambi appropriately identifies this 'mythology' as the historical patriarchal reworking of an original matrifocal culture. "These legends were meant to explain the record away when society had changed to the extent that the original concept seemed fantastic...However, seen mothers who equally bear a child-in-common (without any particular father) is a primitive concept in some kinds of pre-patriarchal society, and the inexplicable notion is present even in the Rig Veda"[16].

Kosambi, although he gives no reference, may have been referring to RV 3.55:

(3) My wishes fly abroad to many places: I glance back to the ancient sacrifices. Let us declare the truth when fire is kindled.

(4) King (Agni) Universal, born to sundry quarters, extended through the wood he lies on couches. One mother rests, another feeds the infant...

(5) Now lying far away, child of the two Mothers, he wanders unrestrained, the single youngling. These are the laws of Varuna and Mitra...

Interpretations of the two mothers have included 'heaven and earth', and 'the lower and upper branches of the wood for the sacred fire'. But the reference to ancient sacrifices (which probably means ancient rituals) combined with the realistic domesticity of "one mother rests, another feeds the infant" combine to suggest previous matrifocal familial and ritual patterns.

In RV 10.54.14-18, a hymn to Viswadevas, themes of group mothers, the Vritra-slaying, rta, and fear of childlessness appear.

(14) To Visnu rich in marvels, songs and praises shall go as singers on the road of Bhaga, the Chieftain of the Mighty Stride whose Mothers, the many young Dames, never disregard him.

(15) Indra, who rules through all his powers heroic, hath with his majesty filled earth and heaven. Lord of brave hosts, Fort crusher, Vritra-slayer, gather thou up and bring us store of cattle.

(18) Aryaman, Aditi deserve our worship; the laws of Varuna remain unbroken. The lot of childlessness remove ye from us, and let our course be rich in kine and offspring.

The 'road of Bhaga' is noted by Griffith as meaning "on the path of good fortune or felicity". Actually one of the meanings of 'bhaga' is vagina or yoni. The ancient conception seems to have been one of yoni as metaphoric source of all things, acknowledging the power and generativity of the female body. 'The Chieftain of the Mighty Stride' is Visnu as the sun. His mothers (plural), the many young Dames (plural), are, according to Sayana "the regions of space which generate all beings". Here we encounter the Vedic (and probably pre-Vedic) notion of the generative power of air or space which is, within the text continually subordinated or appropriated by the power of Indra (lightning, seed, semenic rain) to create life.

Keith writes of the opposition of the gods to the demons or dasas. "That in many cases historic men may be meant when Dasas are overthrown is true; but gods of the defeated aborigines may also be denoted, and more generally powers of the air, opposed to the gods". Keith explains that the Dasyus seek to scale heaven, but Indra vanquishes them from birth. Indra wins the sun and the waters after defeating them. Keith also mentions that "a Dasa is husband of the waters..."[25] further corroborating our socio-symbolic interpretation.

In one context (RV 8.66.5) Vritra is referred to as a Gandharva, or celestial (air) being. "Indra in groundless realms of space pierced the Gandharva through, that he might make brahmans' strength increase". This notion of generativity and sexuality (not involving patriarchal marriage or procreative intent) continues in the male-air-Gandharva, female-water-Apsara personification of sexual elements. In the Arthashastra and Manusmriti the term 'Gandharva marriage' refers to a love marriage, by mutual consent, which is not considered in the ideal or dharmic category. Manu commented that "it has sexual intercourse for it's purpose"[26].

The acquiescence of the 'cows-waters-women-mothers' to the designs of progeny-obsessed Aryans involved leaving behind her 'airy fairy' consort (now symbolically killed by Indra) and accepting another model of generativity which located power-source-seed in the male god, in this case Agni. (RV 3.57.3) "Fain to lend vigour to the Bull, the sisters with reverence recognise the germ within him". Within the dominant patriarchal Aryan symbolic formulation, ideological justification for assimilation of the much needed indigenous women-mothers, it is the seed-germ which becomes sacralised and deposited in the stream mothers; the blood of women, and blood generally, is excluded or demonised.

Blood in Rig Veda

O'Flaherty in her analysis of "the origins of the sexual fluid hydraulic systems of Hindu texts" writes that blood is seldom mentioned in the Rig Veda – surprising for such an earthy and martial document. She mentions that "one late and notoriously problematic hymn asks, 'Where is the earth's breath, and blood and soul'? (RV 1:164:6)". O'Flaherty points out the commentator Sayana's anachronistic understanding of this passage. Sayana "interprets this as a reference to the gross body (of earth and blood) and the subtle body (of breath and soul)...despite the probable anachronism of this interpretation, the Vedic text itself is certainly a clear reference to blood as the essence of the earthly body"[22].

This nostalgic paen to the "breath and blood and soul" of the earth, located in a hymn to Viswadevas, displays the Vedic poets' longing for the lost rta, as N N Bhattacharyya has noted. The text assigns equal value to the elements of earth, blood and soul which differs from the later Vedic hierarchical distinction of subtle body/gross body understood by Sayana.

Relevant portions of the hymn as translated by Griffith read:

(4) Who has beheld him as he sprang to being, seen how the boneless One supports the bony? Where is the blood of earth the life, the spirit? Who may approach the man who knows, to ask it?

Griffith and other commentators relate the boneless one to the unsubstantial, Prakrti or Nature and the source of the substantial, material world. Still common as a traditional image is the belief that the mother contributes the fleshy, unsubstantial material for the foetus, and the father contributes the bones. Patrilineal and patrilocal familial structure may be projected onto the body of the foetus in this Vedic notion of embryology.

(8) The mother gave the Sire has share of Order, with thought, at first, she wedded him in spirit. She, the coy Dame was filled *with dew* prolific; with adoration men approached to praise her.

The mother is identified as source, gifting the sire with his procreative function, share of order, rta, congruent with Dipak Bhattacharyya's notion of the 'obscured mothers of Agni". The initial wedding exists in the realm of mind and spirit. She is subsequently impregnated by the dew prolific or semenic rains. This shift marks the transition from the matrifocal to the patriarchally constructed mother.

(15) Of the co-born they call the seventh single-born; the six twin pairs are called Rsis, children of Gods. Their good gifts sought of men are ranged in order due, and various in their form move for the Lord who guides.

(16) They told me these were males, though truly females: he who hath eyes see this, the blind discern not. The son who is a sage hath comprehended; who knows this rightly is his father's father.

Griffith cites Wilson's observation that the males/females reference is 'a piece of grammatical mysticism' – but there is nothing mystical about the formal transfiguration of seven 'rivers' or genealogies of women into seven families of rishis. Griffith himself demures 'the meaning is obscure'. This rk may be an

acknowledgement of the appropriation of metaphors of fertility and the substitution of the patriline for the matriline. The knowledge of the sage of being his father's father operates on two levels: the pre-existing esoteric knowledge of all human life of divine origin – the lack of human paternity within a matristic system being attributed to a divine father; and the brahmanic construct of the pitrs or male ancestors who are continually reborn within the same patriline.

(17) Beneath the upper realm, above this lower, bearing her calf at foot, the Cow hath risen. Witherward, to what place hath she departed? Where calves she? Not amid this herd of cattle.

[This rk echoes in structure and tone rk 4. The sentiment expressed is a questioning lament – something has been lost and that something relates to the blood and breath and soul of the earth and to the Cow giving birth. The independent feminine truly 'calves not' within the Aryan herd of cattle.]

Although this hymn has been interpreted cosmologically, in relation to months, years, the sun, lightning, fire, dawn, etc, it is perfectly congruent with a socio-physiological reading.

Another mention of blood (RV 1·87.16) refers to demons who are smeared with blood of men, horses and cattle and who steal away the milk of cows. This reference seems to reflect a practice of applying blood to the body. We can understand this literally as camouflage for cattle raiders or symbolically, as a ritual practice using blood or both. In any case the reference clearly associates the demons with application of blood to the body.

According to O'Flaherty "There is in the Rig Veda one veiled but highly charged reference to female sexual blood – not menstrual blood, but the blood of defloration"[19]. The divine prototype for patriarchal marriages is found in a passage referred to as 'Suryaa's Bridal'. Her Suryaa (the daughter of Surya, the sun) is wed to Soma – according to O'Flaherty the only time in the Rig Veda when Soma is regarded as the moon. Relevant portions of the hymn (RV 10·85) read:

(27) May happiness be fated for you here through your progeny. Watch over this house as mistress. Mingle your body with that of your husband...

(28) The purple and red appears, a magic spirit; [Griffith translates 'fiend'] the stain is imprinted...

(29) Throw away the gown, and distribute wealth to the priests. It becomes a magic spirit walking on feet, and like the wife it draws near the husband.

(30) The body becomes ugly and sinisterly pale, if the husband with evil desire covers his sexual limb with his wife's robe...

(34) It burns, it bites, and it has claws as dangerous a poison is to eat. Only the priest who knows the Surya hymn is able to receive the bridal gown.

(35) Cutting, carving, and chopping into pieces – see the colours of Surya which the priest alone purifies (RV 10.85.27-30, 34-35 trans O'Flaherty).

O'Flaherty comments that verses 28-30 and 34-35 concern the defloration of the bride and the staining of the bridal gown with her blood. She explains that "this blood becomes a magic spirit, potent and dangerous though not necessarily evil; the defloration is an auspicious event but too powerful to allow its emblem to remain present afterwards". According to O'Flaherty the magical power of the blood of defloration is transferred to the bride's family and to the husband, but it becomes evil if allowed to pollute the husband. Thus Soma performs a mediating function "by exercising his *droit de seigneur*, Soma takes upon himself the first and most powerful stigma of the blood of defloration".

O'Flaherty emphasises the multiple meanings of stanza 33-35. Literally, of course, this verse describes the cutting up of the blood-stained robe: "but the words usually refer to the cutting up of the sacrificial animal, and there is a further overtone of the physical injury of the defloration itself, the sacrifice of the maidenhead on the altar of marriage"[27]. The hypothesis of a pre-existent matrifocal social order presupposes expression of female sexuality, unfettered by patriarchal marriage and not identified with the production of progeny for the patriline. The demon of defloration then can be read as a signifier for the violation of the independent and powerful feminine on many levels:

– The political because the institution of patriarchal marriage renders woman as an object of exchange.

– The personal violence involved in the forcible breaking of the hymen of the newly-married girl.

– The sexual as androcentric preoccupation with penetration, for example Urvashi's reprimand of Puruvas' aggressive sexuality (RV 10.95.5 trans O'Flaherty "Indeed you pierced me with your rod three times a day and filled me even when I had no desire. I followed your will, Puruvas...").

– The religio-symbolic in which the woman's experience is excluded from determination of collective meaning, and she instead is rendered a cipher in an androcentric symbolic system. In this case, the textual analogy between the girl's bloody garment's and the sacrificial animal. (This demon of defloration bears a striking resemblance to the traditional popular notion of the churel – the demonic spirit of the woman who dies in childbirth.)

The demonisation of the blood of defloration demands the construction of a heroic masculine figure in order to, borrowing Uma Chakravarty's phrase, "manage female sexuality". Hence the priest does Soma's work of "*droit de seigneur*" literally the right to 'deflower' the 'virgin' bride. (I use the word 'virgin' here in the patriarchal sense of unpenetrated, inexperienced sexually; not in it's original sense of not belonging to any man – free, unexploited yet fecund as in contemporary usage, 'a virgin forest'.)

I would argue that the defloration sequence located in Suryaa's bridal involves a misreading or distortion of pre-existing esoteric knowledge[28]. This misreading subordinates other conceptions of the sacred masculine (linked with mountains, etherial space, withholding of the waters, the Gandharva, the shamanic Vritra). The marriage-defloration passage in the tenth mandala is a late addition to the Rig Veda. All the citations regarding rta and the maidens, the collective mothers, and cows-water-women-mothers imagery are in the earlier family books. It may be that the earlier esoteric notions of the mystical generative power of woman's body, admittedly already defined in the masculine voice and rendered poetically and symbolically, in the tenth mandala become institutionally harnessed in the construction of the patriarchal marriage ritual.

Suryaa, cosmically nominated as daughter of the Sun, is wed to Soma who, as O'Flaherty noted, is here linked with the moon for the only time in the Rig Veda. Suryaa, adorned with red flowers symbolic of menstruation, is encouraged to enter the world of patriarchal immortality (as the mother of sons), at the same time another male figure (Visvavasu, a Gandharva) is banished and her cosmic connection with Varuna (guardian or rta is severed (RV 10.85.21-25 trans O'Flaherty).

Mount the world of immorality, O Suryaa, that is adorned with red flowers... Prepare an exquisite wedding voyage for your husband.

'Go away from here! For this woman has a husband'. Thus I implore Visvavasu with words of praise as I bow to him. 'Look for another girl who is ripe and still [illegible] in her father's house. That is your birthright find it.

'Go away from here, Visvavasu, we implore you as we bow. Look for another girl, willing and ready. Leave the wife to unite with her husband'.

May the roads be straight and thornless on which our friends go courting. May Aryaman and Bhaga united lead us together. O Gods, may the united household be easy to manage. I free you from Varuna's snare, with which the gentle Savitr bound you. In the seat of the Law, in the world of good action, I place you unharmed with your husband.

I free her from here, but not from there. I have bound her firmly there, so that through the grace of Indra she will have fine sons and be fortunate in her husband's love.

The banishment of the Gandharva is another version of the slaying of Vritra. The woman's role is now that of faithful wife

a problem to Indra, the guilt of the slaughter of Vritra, alluded to in verse 7." If we take the slaying of Vritra as the symbolic equivalent of the decline of matrifocal social groupings and the desacralisation of the independent cosmic feminine then the holistic meaning of this hymn is clear. Indra's flaw (which his own mother recognised as a threat to her life) is his independence of a matrifocal moral order, his strength and tendency towards violence, his violent birth, his violent dismemberment of Vritra, his slaying of his own father – indeed his rupture of a pre-existing, peaceable, matristic social and symbolic order.

The issue within this violence then becomes protection. Indra's mother, within the context of the Vedic hymn, first functions to protect Indra (both from his father and from his own violent character) and then abandons him to the protection of the waters.

In stanza 6 Indra's mother speaks of the waters who are now flowing happily and onomotopoetically. Through Indra's mother's words the waters are rendered in the male voice, symbolically constructed as free and happy. But previously they were "screaming together like righteous women". O'Flaherty succumbs to androcentric perspective and reads this as referring to screaming for help when Vritra assaults them. But nowhere in any version of the Rig Veda have I read of imagery which speaks of Vritra's "assault" on the waters/women. Vritra encloses, contains and lies with the waters, but does not assault them. I read 'screaming together like righteous women' as the protest of the violated feminine/females which is silenced (by the poets) and then becomes poetically and aesthetically rendered. The text itself acknowledges the problem of interpreting the message of the waters. "Ask them what they are saying..."

In stanza 7 Indra's mother continues in a tentative and questioning voice betraying the ambivalence of the shifting positions of the waters from righteous protest to gurgling poesy, to praise and invitation, to willingness to take on Indra's guilt. And again the Vritra slaying is mentioned as releasing the waters.

In stanzas 8 and 9 Indra's mother repeatedly uses the phrases 'not for my sake' and 'for my sake' indicating that she may be faulted for the motivation of her actions. First she claims that her rejection of Indra as a child, and his subsequent swallowing by the demon-child-birth was 'not for her sake'. (According to Sayana, 'demon-childbirth' was Kusava, a rakshasi who swallowed Indra at his birth, and Roth states this reference is the name of a river – again the river-women-mothers, in this case demonic, imagery.) But Indra's mother will take credit for the waters nurturing the child and his own independence. The question of acting in one's own self-interest is operative here; Indra triggers the entire drama by rejecting birth through the vagina and endangering his mother. She reacts ambivalently, by rejecting him – but "not for her own sake".

She distances herself from the swallowing evil-childbirth (obviously symbolic of the rejected power of the ('yoni') and in the next stanza proceeds to distance herself from the shoulderless one (Vritra) who is said to have not acted for her sake. Why the need for this disavowal of both demon-childbirth and Vritra unless both are linked to her rage at her son's heroic strength which threatens and marginalises her? But she also allies herself with the nurturing waters and Indra's independence because these are congruent with the construction of the heroic masculine and maternal feminine, ultimately espoused by the Vedic poets. The contradictory nature of the maternal waters is a continuing theme throughout later texts and mythology.

As O'Flaherty notes "none of the principals in the drama is named except Indra; later commentary identifies the mother with Aditi and the father with Tvastr". "I would argue that Indra's mother has no name here because she is still generic for Mother – or more appropriately within the early Vedic period – Kosambi's 'mothers-in-common'". She is singular only because she is the mother of Indra and thus patriarchally constructed. But the hymn is permeated by her deep ambivalence towards her hero-son.

Finally Indra's violation of the integrity of the female body within the pre-existing symbolic system emblematic of cosmic and natural order, and rupture of matristic indigenous social groupings is his moral flaw and crime. The Vedic poets silence the protests of the righteous women/waters and the discourse excludes the female voice. Women as persons are subordinated to gendered symbols within the emerging brahmanic context.

Women taking on the sin of Indra, in the form of their menstrual blood, elaborated on in the later texts, is only hinted at in the Rig Veda. But Indra's avoidance of his mother's yoni, and the silencing or symbolic construction of the waters/women are narrative elements which precede the suggestion that they will absorb his culpability.

III

Thus within the Rig Veda the elemental and numinous power of the feminine/female is nominated, symbolised, appropriated – managed and controlled. Vedic gender categories of primal female power are constructed. Those able to be controlled are designated as sacred – Vac (the word), and 'Aditi' (patriarchal motherhood). Those more difficult to manage are demonised – Nritti (death), Danu and Diti (mothers of the aboriginal peoples) or raped, Ushas (independent cosmological feminine). The earlier elemental imagery of cows-waters-maids-mothers is replaced by the patriarchal institution of marriage in Suryaa's bridal hymn from Book Ten. Rta, cosmic order, is subordinated to dharma, right action, as defined and elucidated by the emerging priestly caste.

The patriarchal synthesis effected by the Vedic poets involved the construction of a symbolic structure which glorified women in their role of mothers and simultaneously excluded or mystified and demonised the female biological fluid of blood. Imagery of cows-waters-women-mothers facilitated articulations of feminine generativity which were developed into mechanisms of social and symbolic control of female sexuality. Both the religious ritual of the sacrifice and the social grouping of the patrilineal family structurally reflect a focus on the masculine figures of Indra and Agni as the source of sacred authority, object of ritual practice, and dominant biological metaphor.

The mythic slaying of Vritra, son of the mother, symbolises this paradigmatic shift from the female body to the male body as principle social and symbolic metaphor. The generative female power of childbirth is eclipsed by the sacrificial dismemberment of the cosmic male: it is out of Purusha's body which the world is created – the Vedic, androcentric world, that is.

My initial investigation was prompted by the seemingly contradictory attitudes towards the female body displayed by the basti women's rituals of well worship after childbirth and observations of menstrual taboos. The Dharmashastra outline of menstrual prohibitions and beliefs linked this practice to the Vedic myth of Indra slaying Vritra. I was not familiar with any textual or historical sources which would give information about the well worship ritual so my efforts have been to detect an alternative positive valence to water as sacred source rather than merely ritual purification or washing away sins within the context of the Rig Veda.

My working hypothesis of pre-existing meaning systems and matristic indigenous kinship groupings evolved into a methodology of a socio-physiological reading of the text. A foregrounding of Vritra reveals his, and all demons, matrilineal origins, linkage to the transformative elements of air, water, and earth (as opposed to the Indra-Agni element of fire), and ritual function as demon-priest. The symbolic nexus of cows-waters-women-mothers, read within the historical context of Aryan assimilation of indigenous women and concern with progeny, validates this socio-physiological interpretation. Dipak Bhattacharya's analysis of "the flow of Rta from the obscured mothers of Agni" and

NH- 3.

संयुक्त राष्ट्र
जनसंख्या कोष

UNFPA
United Nations
Population Fund

DEPO/Injectable study proposal/ January 22, 2002

Dear Dr. Narayan,

As you are aware, injectable contraceptives approved by Government of India, are being offered to women in India through private clinics/social marketing outlets. However, concerns have been expressed by different sections of civil society about the conditions, especially at the service delivery level at which injectable contraceptives are likely to be made available to women. As women have a felt-need for effective contraceptives, it has been stated that providers may highlight or women may choose injectable contraceptives due to the convenience of injection, and during counseling health risks and side effects may be down played by the provider or ignored by the women resulting in abuse of women's right to information. On the other hand, excluding or limiting availability of the Injectable contraceptive has been viewed as undue restriction on women's choice in India since women in India and many other countries have free access to injectable contraceptives.

Studies have been sponsored by private agencies/pharmaceutical companies to address some of these issues but a few questions still remain. Therefore, UNFPA in collaboration with Government of India proposes to support a people-centered research that would offer insights about clients and providers' perspectives on injectable contraceptives. This research will be done in a transparent manner.

The broad terms of reference of the proposed study are:

1. To identify client perspectives vis-à-vis injectable contraceptives with a special focus on women's perceptions. These would include attitudes/attributes on side-effects, availability, efficacy, accessibility, confidentiality, return of fertility after discontinuation, choices offered and attitudes of service providers, quality and adequacy of counseling, product image, affordability, etc.
2. To ascertain and analyze providers' views on client barriers/ inhibitions, quality of counseling, technical expertise, choice of provider, follow up mechanisms, client satisfaction with injectable contraception service delivery.
3. To identify any individual, social, gender and cultural issues related to decision making for injectable contraceptive use and its continuation in different regions and groups in the country.
4. Identify programmatic implications emerging from the research findings.

Dr. (Ms) Thelma Narayan
Community Health Cell,
367, 1st Main, 1st Block, Koramangala,
Bangalore
Karnataka

TN
1066
Rec'd (PIO)
Lib- Injectable Contraceptive Research file
25/1/02
4/2/02.

55, Lodi Estate, New Delhi-110 003 - India
Phone : 4628877 Fax : 4628078, 4627612 Email :india@unfpa.org
Website : www.unfpa.org.in

The study will be multi centric so as to capture regional diversities, if any, with respect to clients/providers perspectives. Accordingly it has been agreed to conduct the study in four regions of the country i.e. North, West, East and South.

A Technical Advisory Group having representation from experts, academic institutions, non-governmental agencies and Government has been constituted to advise UNFPA throughout the process of designing and monitoring this multi-centric study. Similarly a larger Reference Group has been constituted consisting of stakeholders with diverse points of view.

Considering your long experience in conducting research on such issues, we look forward to receiving a proposal from your organisation on the following format.

1. Details of study design
2. Tools for data collection
3. Proposed time frame
4. Analysis plan both for an initial short term phase (3 months) and long term phase
5. Budget(including justification)
6. CV of Principle Investigator/s
7. Citations from published work of Principle Investigators/organisation

We are also enclosing terms of reference for the proposed study. We will very much appreciate receiving a line in confirmation by email dinesh.agarwal@unfpa.org.in, in case your organisation is interested in participating in this multi-centric study. If we do not receive any response from you by **4 February 2002**, we will presume that your organisation is not interested to be a partner for this study. A detailed proposal should be send to us by ***25 February 2002.***

With best regards,

Yours sincerely

Francois.M.Farah
UNFPA Representative

Encl: Terms of Reference

2/2/02
Email (obtained - underlined address)
Dear Dr Francois Farah, Greetings from the Committee!
Thank you for your letter regarding the study of Injectable Contraceptives.
Our organisation will not be able to participate in the proposed
multicentric study. From a public health + woman's health
perspective and with medical ethics point of view - we feel that
injectable contraceptives are not safe and should not be
introduced into family welfare work, be it in the private or public
sector. This issue has been long debated, and this surprising

Terms of Reference

A Multi-centric Study on User and Provider Perspectives on Injectable Contraceptives in India

I. Background

Following Drug Controller of India approval, the injectable contraceptive, DMPA, was approved by Government of India in for use in private sector and social marketing. The other injectable contraceptive, Net-En, though registered in India in 1986 was also only marketed for use in 1994 along with DMPA. Depot-medroxyprogesterone acetate (DMPA), an injectable contraceptive approved by Government of India, is being offered to women in India through private clinics/social marketing outlets. However, concerns have been expressed by different sections of civil society about the conditions, especially at the service delivery level at which injectable contraceptives are likely to be made available to women. These include non-availability of facilities for counseling, clinical examination and follow up, lack of proper information-sharing with clients and providers particularly about the health-risks and side effects of injectable contraceptives. As women have a felt-need for effective contraceptives, it has been stated that providers may highlight or women may choose injectable contraceptives due to the convenience of injection, and during counseling health risks and side effects may be down played by the provider or ignored by the women resulting in abuse of injectables. On the other hand, excluding or limiting availability of the Injectable contraceptive has been viewed as undue restriction on women's choice in India since women in many other countries have free access to injectable contraceptives.

A review of literature on experiences with injectables in India articulated a need for research in the Indian context related to users and provider perspectives. Taking into cognizance, GOI's interest in expanding method choice in NPP-2000, UNFPA proposes to support research that would offer insights and analysis in this area and contribute towards development of client-centred and gender-sensitive contraceptive delivery programmes.

This brief note spells out the terms of reference for a multi-centric collaborative research study to identify client and provider views and concerns on injectables in India (primarily DMPA). The terms of reference are to be used for inviting detailed proposals from interested research institutions/ organisations from different parts of the country.

II. Objectives

1. To identify users' perspectives vis-à-vis injectable contraceptives. This will also mean understanding the evolving perspective of clients at different times.
2. To analyze providers' views on service provision with reference to injectable contraceptives.
3. To identify Individual, social, gender and cultural issues related to decision making for injectable uses and its continuation.
4. To identify policy and service provision implications that may emerge from research findings.

III. Research Design

1. ***Suggested categories of respondents:*** The longitudinal study design is proposed to incorporate perspectives of different groups and from diverse settings. This is suggested to include settings such as socio-economic, rural vs urban, users and service providers from private clinics, government hospitals, NGO FP clinics. Categories of different service providers such as doctors, nursing personnel, health workers serving (prescribing as well as not prescribing),and users (continues users , discontinuing users, non-users) in different age groups (women in reproductive age group, youth/college students). Other respondent categories suggested are spouses of acceptors and non-acceptors. Besides types of concerns of users, responses regarding who should provide injectables and willingness to pay, ability to pay would also be included.

2. ***Time frame***: It is suggested that this study is conducted in two phases. First phase for three months duration will provide information on a cross section of multiple cohorts ie those started using injectable contraceptive recently, those using for 9-12 months and also those using for a much longer duration. All clients accepting injectable contraceptive from identified private clinic or social marketing organisation, during the first three month period will be included in the study and data gathered will be processed as per analysis plan. Second phase will last for 24-30 months so as to provide comprehensive information on reasons for discontinuation as ascertained during follow up visits and also on return of fertility. Individual organisations would submit the time frame and plan of activities in the detailed proposal.

3. ***Methodology***: The studies would be conducted by using qualitative methodologies. The study will have following two dimensions:

imp * □ First, an *overview paper compiling issues in India*. The objective of this paper would be to review existing studies on the subject in India and establishing further research needs. This will help to pull together the contentious issues needed to be looked at in the client/provider perspective research. This would build a common understanding among the agencies as well as facilitate development of comprehensive research tools/questionnaires. This paper would be done either by one of the participating

organisations or some independent researcher. In case your organisation is interested in developing this overview paper, a separate proposal may be submitted, independent of larger research proposal.

- Second, *qualitative study* employing focus group discussions, loosely structures open-ended questions, in-depth probing of key informants etc. will be considered for collection of data.

4. ***Research tools***: A set of research instruments would be prepared by the research teams in a methodology workshop jointly at a workshop where methodological issues would be discussed and common research tools finalised. The tools would include both open and closed-ended questions and carry clear instructions for investigators. The tools would need to be translated into regional languages as necessary.

5. ***Training:*** Special attention will need to be given to train staff about the concept and objectives of the research as well as on gender dimensions. The study staff will be made aware about injectables, contraceptive dosage types, effects on women's health. A meeting of research teams to orient all members on approach and methodology is important since injectables is a sensitive and new area.

6. ***Involving different partners:*** A technical advisory committee to the research teams comprising of policy makers, women's health advocates, health care providers/users is proposed and would assist in planning and support to the multi-centric research project.

IV. Data collection and analysis

The proposal submitted would include a plan for data collection and analysis for both phases. A common data analysis plan will be finalised during the methodology workshop. The plan for data collection would include information on field work and planning tasks such as pre-testing designing of formats, questionnaires, deciding on number of interviewers/facilitators, writing job descriptions, training of interviewers, materials and administrative arrangements.

The document would describe in details the plan of analysis, each of the analytical techniques to be used indicating how these would meet the study objectives. Information on what software will be needed and how data entry will

be accomplished, whether transcription of tape recordings will be necessary is also suggested to be included as feasible.

Analysis is suggested to be carried out separately for each respondent groups. In addition to quantitative analysis, qualitative data would be analyzed to make observations regarding both commonalities and contrasts in information, attitudes and practices in respondent groups. The analysis is proposed to would include discussion on the biomedical and gender dimensions to the research findings, as appropriate and feasible. A

secondary data analysis of existing studies has been suggested to provide the context and emerging issues.

V. Limitations and anticipated constraints

The proposal should include discussion on limitations of the study and the possible situational factors that might influence the research. Explanation of the limitations and assumptions of the study and also how to overcome the constraints are suggested to be discussed in the document.

VI. Utilization of results and dissemination plan

The study proposal should include a section on the utilisation of the study's findings. This section should:

- identify organisations who be most interested in the study
- Discuss how you will involve these organisations in planning, implementation analysis and dissemination stages of the study
- Indicate what you believe will be the most likely policy or programme implications to arise from the study

The research proposal should include a section that describes the plan for dissemination. The plan should specify:

- who are the potential users of the findings
- which particular finding will be of most interest to each user group
- what channels would be used to reach each group.

VII. Budget, phasing and time frame

A line item budget and detailed work plan needs to be included with the proposal. Justifications for all aspects of the budget should be included in the proposal as well as the suggested sample size and sampling design.

VIII. Ethical considerations

Last but not the least, a plan is needed for the protection of human subjects. The plan should be in accordance with international human rights documents and the laws of the country. Three basic ethical principles guide research involving human subjects: respect for persons, beneficence, and justice. These three principles, in turn, are applied in research involving human subjects through the procedures of informed consent, risk-benefit assessment and the selection of subjects for research (8).

IX. Annexure

An annexure including the following is also suggested to be submitted with the proposal: brief bio-data of the principle investigator, list of related research studies conducted, resources and facilities already available, availability of trained interviewers etc.

X. References

1. Contraceptive Efficacy, side effects and acceptability of Norethisterone enanthate: Indian experiences. ICMR. New Delhi. 1981-1983.

2. Analysis of price change on the perceptions and use of DMPA among users using RH services in Uttar Pradesh. Population Council and PSS. March 1998.

3. Post Marketing Surveillance study on Injection Depo-Provera. Final Report. October 1999. Pharmacia and Upjohn

4. Introducing DMPA Injectable Contraceptive to Private Medical Practitioners in urban Gujarat. Population Council. DKT, AVSC, (*ongoing study*)

5. Miles MB, Huberman AM. Qualitative data analysis: an expanded source book 2nd edition. Thousand Oaks: Sage 1995.

6. Varkevisser CM, et al. Designing and conducting health systems research projects. Vol 2 Part 2. HSR Training Series. WHO Geneva 1991.

7. Qualitative research in Women's Health. Guideline for Critical Appraisal of proposals. UNICEF.

8. Stephenson P. The protection of human subjects in biomedical and behaviour research: principles and applications. A discussion paper. Bucharest R0:UNICEF 1991

Main Identity

From: Jodi L. Jacobson <CHANGE@genderhealth.org>
To: "Thelma" <sochara@vsnl.com>
Sent: Thursday, July 31, 2003 12:44 AM
Subject: New Article: Beyond the Magic Bullet - Emergency Contraception in India

Dear Thelma,

I am writing to send you a new article on Emergency Contraception (EC) in India written by Rupsa Mallik, Program Director for South Asia at the Center for Health and Gender Equity (CHANGE). The article can be accessed from our homepage at www.genderhealth.org or directly through this link http://www.genderhealth.org/pubs/MallikECPillsIndiaJul2003.pdf. This article - one in a series examining government and donor policy shaping reproductive and sexual health and rights in South Asia - is based on extensive research on contraceptive choice conducted by CHANGE over the past several years.

Throughout India, marriage and child bearing patterns are changing, and a rising number of married women face the risks of unintended pregnancy for a longer portion of their lives. Unmet need for modern methods of contraception to space or limit births is increasing apace. Today, modern spacing methods, such as birth control pills and intrauterine devices accounts for only 7 percent of the current 48 percent of contraceptive use. A much larger share some 34 percent is accounted for by female sterilization. High rates of female sterilization in India reflect a historical emphasis by the government on efforts to limit population growth rates at the expense of individual choice. While in theory government policy has changed, in practice access to modern methods of contraception remains severely limited. Moreover, little has been done to address the social and cultural constraints - such as low levels of female empowerment and high rates of sexual violence and coercion with
in marriage - that limit women's ability to exercise control over when and whom they marry and when they bear children.

As a result, high rates of unintended pregnancy and complications of unsafe abortion pose a major public health problem throughout India. While abortion is technically legal, real access to early, safe abortion services is highly uneven in much of the country. Half of an estimated 6.7 million abortions that take place in India each year have been deemed to be unsafe, and complications of unsafe abortion account for a large share of maternal illness and death. By increasing access to EC, the Government of India and major international donor agencies can substantially reduce the number of unintended pregnancies and unsafe abortions throughout India. Yet while EC is officially sanctioned for use in India, access to this method also remains highly limited. In her article, Mallik examines these factors including both the constraints to and potential for expanding access to EC throughout the country. Her analysis is based on field trips, extensive interviews with key actors
and literature review. We hope you find it helpful.

With best wishes,

HRH - pl. print out the article on laser jet for the Lib - Women's Health (contraception) file
Ta
4/8

Jodi L. Jacobson, Executive Director
Center for Health and Gender Equity (CHANGE)
6930 Carroll Avenue, Suite 910
Takoma Park, Maryland 20912 USA
Phone: (301) 270-1182 Fax: (301) 270-2052
www.genderhealth.org

GTH 8/8

The Center for Health and Gender Equity is a U.S.-based international reproductive health and rights organization. We conduct research, policy analysis, and evidence-based advocacy in our efforts to make public health and human rights principles integral to U.S. international population and health policies and programs. For more information or to be added to our database, please e-mail Seneca Pappas at spappas@genderhealth.org.

Beyond the Magic Bullet: Introduction of Emergency Contraceptive Pills in India

by Rupsa Mallik

July 2003

Introduction

Recently, emergency contraceptive pills[1] have been introduced as part of the national Reproductive and Child Health (RCH) program in India (Ministry of Health and Family Welfare 2002). Emergency contraception (EC) can play a unique role in providing women in India with a 'second chance' to prevent an unintended pregnancy. In turn, EC can also be part of an effective strategy to reduce persistently high rates of death and illness from complications of pregnancy and childbirth in India. Finally, EC can also help reduce heavy reliance on unsafe abortion, complications of which alone account for 13 percent of all maternal deaths nationwide (Canatra and Johnston 2002, 159).

As part of a broader spectrum of choices in reproductive technologies, EC can dramatically increase women's agency and ability to make informed choices regarding pregnancy and reproduction. As with other methods, real access to EC will be determined only in part by the efforts of the government and donor agencies to increase supplies and services. Deeply embedded gender disparities persist across regions, classes and castes in India, limiting women's autonomy in marriage, sex, and reproduction, and, particularly in areas where son preference remains strong, also severely restricting women's access to and use of contraception and safe abortion. The failure to address these and other constraints facing women will undermine efforts to increase use of EC and other contraceptive methods. This article assesses the potential role of EC to increase women's reproductive choices and prevent unwanted pregnancies and unsafe abortion in India, and examines the steps required to increase access to EC to women throughout the country.

The Role of EC in Reducing Unwanted Pregnancies and Unsafe Abortions

Over the past decade, desired family size in India has fallen, but the rate of contraceptive use has remained low, particularly for spacing methods. An estimated 53 percent of all currently married women have ever used contraceptives, a high share of whom have completed their families and been sterilized. Only 6 to 8 percent of married women use spacing methods, a very low proportion given that a large share of currently married women are young and have yet to complete their desired family size (IIPS and ORC Macro 2000, 129).

Low rates of contraceptive use have contributed to a high rate of unintended pregnancy in India, which in turn has contributed to heavy reliance on induced abortion. According to one study, there are an estimated 6.7 million abortions annually in India (Chhabra and Nuna 1994). Abortion is legal but safe procedures remain relatively inaccessible. Some studies suggest that at least half of all abortions conducted in India are unsafe as a result of crude abortions and lack of post-abortion care (Coyaji 2000). A recent study conducted in Madhya Pradesh, one of the largest states in India, indicates that 23 percent or close to one-fourth of all women decide to undergo an abortion at least once by the time they reach their late thirties (Malhotra et al. 2003, 17).

High rates of unintended pregnancy and unsafe abortion in India are the result of a range of factors. One is the persistently high level of unmet need for birth spacing methods among married women of reproductive age. Despite a long history of support for family planning, at least 23 percent of all married women below age 20 still lack access to birth spacing methods, according to NFHS-II.[2] This high level of unmet need among those most at risk of unintended pregnancy is a product of both the government's population policy, with its historical and continuing emphasis on female sterilization as the primary means of birth control, and of the broader failure of the health system to meet women's needs.

Lack of access to modern methods of contraception is compounded by social and cultural constraints

on women. In some cases, for example, opposition to contraceptive use by husbands and mothers-in-law prevents women from gaining access to contraception. Socio-cultural practices such as child marriage, which is widespread in India, mean that even young adolescent girls are exposed to the risk of early and repeated pregnancies. More than half of all girls in India marry before the age of 18 and about 33 percent of births occur at intervals of less than 24 months (MOHFW 2000, 6). The combination of early age at marriage and early childbearing contributes significantly to high rates of unintended pregnancy and high rates of maternal and infant mortality.

Sexual violence and coercion, including rape within marriage, also contribute to high rates of unintended pregnancy, as well as adverse reproductive and sexual health outcomes resulting from both psychological and physiological trauma. Domestic violence is widespread in India and rape within marriage commonplace. A study in several districts of Uttar Pradesh, for example, revealed that between 14 and 36 percent of married women had been forced by their husbands to have sex against their will (Narayana 1996). Emergency contraception can play a critical role in reducing unintended pregnancy from all these causes, by enabling women who lack access to contraception, experience contraceptive failure, or are the victims of sexual violence to prevent an unintended pregnancy.

Increased access to EC can be used as a bridge to sustained increases in contraceptive use over the long run. *EC is not recommended as an effective or safe method to prevent unwanted pregnancies over the long term, i.e. they are not intended to be the primary form of birth control for any woman and therefore cannot be used as a substitute for ongoing efforts to increase access to spacing methods.* But by increasing access to EC among those in need, health services can provide a point of contact for women facing unintended pregnancy due to non-use of other spacing methods. With increased information, supplies, and appropriate counseling a large share of these women would become regular users of birth spacing methods. Again reducing the risk of unintended pregnancy in the first place. For example, data from a study conducted in Delhi by the All India Institute of Medical Sciences (AIIMS), a premier medical institution, shows that almost 70 percent of non-users of contraception became regular users after first seeking access to EC. While data is not currently available to confirm a connection between use of EC and counseling of male partners, it is possible to speculate that, at least in some cases, use of EC might also be used to counsel husbands of EC users to foster increased and equitable communications on matters of sex and contraceptive use.

Access to EC can also prevent additional trauma to victims of violence. It is now an established fact that violence against women has a direct and significant bearing on women's reproductive well-being. In addition to high rates of gender violence and sexual coercion from intimate partners, large numbers of women living in conflict war zones, and refugee camps have been subjected to rape. Sexual trafficking, another violation of women's rights, also contributes to unintended pregnancy and unsafe abortion. It is imperative that EC be made available to women subject to violence in all of these settings.

Current Status of EC Introduction in India

Despite its potential, use of EC in India remains low due in part to very low rates of knowledge about the method among both providers and users. For example in a recent survey of 1125 urban and 375 rural women of reproductive age, only 8 and 3 percent of the women in the two groups, respectively, expressed knowledge of emergency contraception (Puri and Sarvandeep 2001, 58).

In another study conducted among general practitioners and obstetrician/gynecologists in New Delhi, only 40 percent of general practitioners knew about ECS. The study found that even those who knew about the method displayed little knowledge of correct use and administration of the method, with only 12 percent of GPs displaying awareness of the availability and correct dosage of levonorgestrel, the product now being marketed by various private sector companies in India. Similarly 67 percent of obstetrician/gynecologists were familiar with the product but only 12 percent knew the correct dosage (Mittal 2001, 61).

None of those interviewed in a study conducted among users in urban Chennai were aware of the availability of this method. In the same study a sample of 50 doctors and 60 paramedics were also interviewed. Awareness of the product and its accurate use was approximately 30 percent (Sundaravalli 2001, 68).

A number of actors are working to improve this situation. The recent introduction by the Government of India of EC into the RCH program was the result of concerted efforts of a number of national and international organizations that have helped build consensus on the safety and efficacy of EC as post-coital contraception, as well as on the urgent need to introduce dedicated EC products as part of the RCH program (ICMR 1997; Nayyar 2000; AIIMS and WHO 2001). A number of private manufacturers have been simultaneously granted approval for marketing dedicated EC products by the Central Drug Standard Control Organization (2002)[3].

Currently, EC pills are being made available through medical officers at the district and sub-district level and guidelines have been published by the Ministry of Health and Family Welfare (MOHFW) providing comprehensive information on counseling, eligibility criteria for EC, and client assessment, side effects, and procedures for initiating regular use of contraception (MOHFW 2002). The Government of India has completed procurement of EC pills from private manufacturers and distributed supplies to local and district hospitals. The Government of India has also proposed a monitoring system at the national level that will examine the profile of users to accurately gauge the real benefits of the provision of EC pills as part of the RCH package.

Plans are in place to increase awareness of EC pills through the National Strategy for Social Marketing (2001). A number of social marketing organizations have already taken the lead in promoting EC pills as part of their program. Parivar Seva Sanstha (PSS) has developed its own brand of EC pills and intends launching the product as part of its social marketing initiative in Rajasthan. PSS has been actively collaborating with the MOHFW to conduct action research on awareness and access to this method. The Family Planning Association of India has also introduced EC pills on a pilot basis as part of its basket of choices in select districts of Madhya Pradesh.

The private sector is a key player in making EC pills available. Currently a number of companies have the license to manufacture EC pills in India. Levonorgestrel, the raw material for EC pills, is not available in India and needs to be imported. Some of the companies that are currently marketing dedicated products include CIPLA under the brand name Pill 72, and HRA Pharma Laboratoire, a French company, that has entered into a joint venture with a company in India, Contech Devices Private Limited to market its product, Norlevo. Gennan Remedies and its Indian subsidiary Cadila Healthcare have approval from the Central Drug Standard Control Organization to market an EC product under the brand name Evee-2. More recently other companies too have received approval to market their products, increasing the potential number of dedicated EC brands to between four and seven. As a result of the increased competition for market share the price of one dose of the levonorgestrel regimen has declined from Rupees 120 (approx $3) to Rupees 20 (approx $1) during the past year.

The role of international organizations has been critical in promoting EC globally as well as in India. The formation of the International Consortium for Emergency Contraception in the mid-nineties helped catalyze efforts to promote EC in developing countries. Some of the original Consortium members—such as the Population Council and WHO—played a key role in promoting EC in India. The Federation of Obstetrics and Gynecological Societies of India (FOGSI), the Indian Council of Medical Research and the National Institute for Research in Reproductive Health have also played a key role in advocating for EC introduction as part of the RCH program and remain active individually in addition to their participation in existing networks on EC.

Some women's groups too continue to provide inputs to expand the Government of India's efforts. Some have pointed out the need to create an enhanced package to help women develop a better understanding of their own bodies and reproductive processes, which in turn increases understanding of the difference between long-term contraceptive methods, EC, and induced abortion. These and other efforts to expand access to basic reproductive health information have become even more critical now that abortions become available. For example, EC use for medical abortions has recently been approved for marketing in India and is likely to become part of the method mix in the RCH program.

The valuable role that EC can play in preventing unwanted pregnancies and reducing the risks from unsafe abortions and complications of unintended pregnancy are clear. Randomized controlled trials place the efficacy rate of the levonorgestrel regimen at 83.9 percent (Ho and Kwan 1993; WHO 1998) with limited side effect. However, repeated use of EC pills

raise the risk of hormonal imbalances, disrupted menstrual cycles, and increased risks of complications in pregnancy. In other words the benefits of EC rest as much on its limited use as it does on the efficacy of the actual product as post-coital contraception. Moreover, while EC can help prevent an unintended pregnancy it does nothing to protect women against STDs and HIV/AIDS.

For all these reasons the role of EC as a back-up and a bridge to sustained use of spacing methods needs to be a important component of all efforts to increase access to EC.

Beyond the Magic Bullet

Given these realities, it is critical that, in making EC as part of the RCH program, the Government of India and major international donor agencies simultaneously guarantee access to EC along with other methods of contraception, in particular spacing methods. In theory, a number of spacing methods are available in the family planning program in India. In practice, millions of women remain without access to such methods. The decision of the MOHFW to include ECs as part of the RCH program is an important first step towards ensuring informed choice and quality of care in family planning services for women.

In the past several years, however, a resurgence of concern about population growth in India has led to renewed emphasis on a two-child family, as well as on sterilization and target-driven health services. In Andhra Pradesh, for example the state population policy resorts to introduction of incentives and disincentives to meet family planning goals (GOAP 1997). Evidence indicates that these measures have resulted in pressure on women seeking abortion services in public health facilities to agree to be sterilized as a condition of receiving such services. These types of norms are being reintroduced into the policies of other states as well (GOUP 2000). The danger exists that access to emergency contraception too will be made contingent on acceptance of sterilization in states where the two-child norm is being aggressively promoted and health providers are feeling the pressure of fulfilling 'informal' targets. Given these realities, it is important for the government, donor agencies, and civil society to work to ensure that EC is not used simply as a tool to help attain demographic goals.

Any effective strategy to reduce unintended pregnancies and unsafe abortion in India has to involve access to both information on and supplies of a wide range of contraceptive options, including, but not limited to EC. Today, however, several obstacles remain, including the lack of financial and technical resources, lack of skilled providers, and poor infrastructure, among challenges within the health sector. In addition, neither the government nor major international donors have done nearly enough to address the deep-rooted constraints on women's ability to make sexual and reproductive health decisions or even to gain access to health services.

Bringing about significant improvement in the sexual and reproductive health of women is a formidable task. It can only be attained as a result of a better understanding of the complex interrelationship between society, people, services and technology (Yitbarek 2001). In that context while the specific benefits of a method, in this instance EC, can and should be highlighted, this method also needs to be integrated within a broader more holistic framework to promote reproductive health and rights. The following recommendations include both immediate steps that need to be undertaken to improve access to EC in India as well as long-term strategies that need to be simultaneously pursued to guarantee at a minimum expanded access and informed choice with regard to contraception use for women in India.

Designing gender sensitive information tools on EC for chemists and pharmacists

This constituency urgently needs to be reached as they are currently playing a leading role in marketing the various brands of EC pills in urban and peri-urban areas in India. Social marketing organizations can play a positive role by working through their distribution networks to create enhanced awareness. Also they can use their long-standing knowledge and familiarity of working with chemists and pharmacists in the private sector to help design suitable and accessible information packages.

Developing training modules and undertaking training of providers in the public and private sector

There is a need to develop training modules that can be used to raise knowledge about and in turn increase prescription of EC pills. Systematic training of providers needs to be undertaken at all levels of service delivery. This component is critical as it provides the window of opportunity to also counsel women and

couples on the use of a regular spacing method. The various medical associations through their national and state-level chapters can play a proactive role by hosting meetings for private medical doctors who easily number in the thousands. Similarly, the MOHFW and international donor institutions can work with training institutes to include training modules as part of its on-going RCH training programs.

Undertaking campaigns that can help raise public awareness about EC

It is evident from various studies that current knowledge about ECs is extremely low particularly among contraceptive users in both rural and urban settings. Raising awareness in both these groups needs to be jumpstarted. This is critical, as the market has already been flooded with various dedicated EC products. However, efforts to speedily deliver product-related information should in no way compromise the quality of information that is given to women. One stakeholder that I met in India put it aptly when she said "IEC material needs to be able to communicate the ideology behind the product as much as product related information."

Incorporating WHO contraceptive method-mix guidelines for policy and service

It is now a commonly acknowledged fact that a contraceptive method mix approach at the level of service delivery is the minimum basis for assuring informed choice and guarantee of quality in family planning services for women (Baveja et al. 2000; WHO 1994). This framework provides the basis for designing information and knowledge based tools for both providers and users and needs to be incorporated while implementing the above recommendations. A first step to further a comprehensive approach could be taken by the various stakeholders who are promoting new technologies.

Renegotiating population policies

It is also evident that past policies designed to catalyze India's demographic and fertility transition did not take into account gender-based norms and inequities and in some instances even served to exacerbate them. The most glaring evidence of this is the emergence of severe sex ratio disparities in the 0-7 age group as a result of sex selection.[4] Another piece of evidence is the fact that of the current 48 percent contraceptive use, female sterilization accounts for 34 percent of that use (IIPS and ORC Macro 2000). This is irrefutable evidence that gender-based inequities result not only in limiting the choice and timing of contraceptive use but also place a disproportionate burden on women. These need to be addressed at all levels, but in particular at the level of government and donor policies and programs. Unless they are addressed the introduction of a new method, however beneficial, is unlikely to result in meaningful choices for women.

---

[1] Intra-uterine devices (IUDs) can also be recommended as emergency contraception. However, currently the Government of India has approved the two-dose levonorgestrel EC pills for introduction in the RCH program.

[2] Unmet need for spacing includes pregnant women whose pregnancy was mistimed, amenorrhoeic women whose last birth was mistimed, and women who are neither pregnant nor amenorrhoeic and who are not using any method of family planning but who say they want to wait two or more years for their next birth (IIPS and ORC macro; 2000:172).

[3] The recommended dosage that has been approved is the following. The first dose of levonorgestrel to be taken within 72 hours after an incident of unprotected intercourse followed by a second dose within the next twelve hours. It is important to note that recent publication of findings of a WHO randomized controlled trial conducted in 12 countries including India indicate that the levonorgestrel regimen is equally effective if administered in a single dose of 1.5 mg. This has important implications for simplifying the administration of EC pills in the future.

[4] This has been discussed in detail in a previous article, Mallik, Rupsa. *A Less Valued Life: Population Policy and Sex Selection in India*. (Takoma Park, MD: Center for Health and Gender Equity, October 2002).

Rupsa Mallik is Program Director -South Asia at the Center for Health and Gender Equity (CHANGE). Correspondence about the paper should be directed to Rupsa Mallik at rmallik@genderhealth.org. For additional copies, send an e-mail to info@genderhealth.org.

References

All India Institute of Medical Sciences (AIIMS) and World Health Organization (WHO). 2001. *Consortium on National Consensus on Emergency Contraception – Report and Recommendations*. New Delhi: AIIMS and WHO, January.

Baveja, R. K., Buckshee, K. Das, et al. 2000. 'Evaluating Contraceptive Choice Through the Method-Mix Approach.' *Contraception*. US: Elsevier Science. 61: 113-119.

Bhatt, R.V. 1996. 'Role of Family Planners and Service Providers in Emergency Contraception' in (eds) C.P. Puri and P.C. A. Van Look. *Emergency Contraception. FOGSI Focus*, Federation of Obstetrics and Gynecological Societies of India. pp 1-24.

Chhabra, R and S.C. Nuna. 1994. *Abortion in India: An Overview*. Delhi: Ford Foundation.

Coyaji, K. 2000. 'Early Medical Abortion in India: Three Studies and Their Implications for Abortion Services.' *Journal of Maharashtra Medical Women's Association (JAMWA)*. Volume 55:191-94.

Ellertson C., Webb A., Blanchard K., Bigrigg A., Haskell S., Shochet T., and I. Trussell. Modifying the Yuzpe regimen of emergency contraception: A multicenter randomized controlled trial *Obstetrics and Gynecology* 2003; 101(6): 1160-1167.

Ganatra, B and H.B. Johnston. 2002. 'Reducing Abortion-Related Mortality in South Asia: A Review of Constraints and a Road Map for Change?' *JAMWA*. 57:159-164.

Government of Andhra Pradesh (GOAP). 1997. Andhra Pradesh Population Policy.

Government of Uttar Pradesh (GOUP). 2000. Uttar Pradesh Population Policy.

Ho, P.C. and M.S.W. Kwan. 1993. 'A Prospective Randomized Comparison of Levonorgestrel with the Yuzpe Regimen in Post-Coital Contraception.' *Human Reproduction* 8: 889-92.

Indian Council of Medical Research. 1997. Emergency Contraception. *ICMR Bulletin*. March. Volume 27(3).

International Institute for Population Studies (IIPS) and ORC Macro. 2000. *National Family Health Survey (NFHS-2), 1998-99: India*. Mumbai: IIPS.

Johnston, H.B. 2002. *Abortion Practice in India: A Review of Literature*. Mumbai: CEHAT and Healthwatch Trust.

Mallhotra, A; Nyblade, L. Parasuraman, et al. 2003. *Realizing Reproductive Choice and Rights: Abortion and Contraception in India*. Washington DC: International Center for research on Women (ICRW).

Mittal, S. 2001. 'Profile and Perceptions of Emergency Contraception Users and Providers: AIIMS Experience.' Presented at the Meeting of the Consortium on National Consensus on Emergency Contraception. New Delhi, January.

Ministry of Health and Family Welfare (MOHFW). 2002. *Guidelines for Administration of Emergency Contraceptive Pills by Medical Officers*. New Delhi: Government of India.

--- 2000. *National Population Policy, 2000*. New Delhi: Government of India.

Narayana, G. 1996. Family violence, sex and reproductive health behavior among men in Uttar Pradesh, India. (Unpublished paper)

Narvekar, A. 2000. 'Increasing Access to Emergency Contraception in India.' *Health and Population – Perspectives and Issues*. New Delhi: National Institute of Health and Family Welfare. 23(3):107-114.

Puri, C.P. and L. Sarvardekar. 2001. 'Constraints in Introduction of Emergency Contraception in the National Family Welfare Program.' Presented at the Meeting of the Consortium on National Consensus on Emergency Contraception. New Delhi, January.

Sundaravalli, A. 2001. 'Should Emergency Contraception be Widely Publicized?' Presented at the Meeting of the Consortium on National Consensus on Emergency Contraception. New Delhi, January.

Von Hertzen, H. et al. 2002. 'How does mifepristone and two regimens of levonorgestrel for emergency contraception, a WHO multicenter randomized trial' *Lancet*. 360:1803-10.

World Health Organization (WHO). 1998. 'Randomized Controlled Trial of Levonorgestrel Versus the Yuzpe Regimen of Combined Oral Contraceptives for Emergency Contraception.' *Lancet*. 352: 428-33.

--- 1994. *Contraceptive Method-Mix Guidelines for Policy and Service Delivery*. Geneva: WHO.

Yasin, W. 2001. *Report and Recommendations – Consortium on National Consensus for Emergency Contraception*. New Delhi: AIIMS, January. pg 10.

~~IUD~~
WH-3

Uterine

ICMR - Task Force on I U D.

Randomized Clinical Trial with IUD (Levonorgestral Intrac~~ervical~~ne Device (LNG) CUT 380 AG, CUT 220C and CUT 200B.

A 36 month study.

National Programme of Research in Human Reproduction.

Division of Human Resource Development Research.

Institutions which participated - M L N Medical College, Allahabad Medical College, Aurangabad K E M Hospital, Pune, Queen Mary's Hospital, Lucknow, Gauhati Medical College, Gauhati, Medical college, Baroda, Kasturba Hospital, Delhi, Medical College & Eden Hospital, Madurai, Medical College, Madurai, SCB Medical College, Cuttack, Safdarjung Hospital, New Delhi, G S V M Medical college, Kanpur, R M S P Hospital Calcutta, J J Hospital Bombay.

Division of HRDC, ICMR, New Delhi.

A total of 1905 subjects were randomly allocated to four types of IUDs and were observed for 45,683 women months of use.

While no method failure was observed with levonorgestrel (LNG) IUD, 11 women became pregnant with other devices. 4 with Coppeer T 380 AG. 1 with Copper T 220 C and 6 with using Copper T 200B, indicating method failure rates of 1.0, 0.3 & 1.6 respectively at 36 months of use.

ICMR initiated a multicentre comparative randomized clinical trial in August 1983 at its HRDC located in different parts of the country. The main objective of this study wasto compare the newer IUDs. Levonorgestrel (LNG) CuT 380 AG and CuT 220C with CuT 200B which is currently in the National Family Welfare Programme.

The enrolment of the study started in August 1983, a total of 1964 subjects were enrolled at 14 centres upto February 1986 after which enrolment was stopped. Of the 1964 data on 59 subjects (15 subjects with LNG, 10 with CuT 380AG, 14 with CuT 220C and 20 with CuT 200B were deleted from analysis due to non adherence to the criteria for subject selection.

Results - This report included results of 1905 subjects of these 475 subjects were allocated to LNG IUD, 434 to CuT 380AG, 496 to CuT 220C and 500 to CuT 200B. The women were observed for 10589, 10869, 12076 and 12149 women months of use, respectively.

Continuation rates at 12, 24 & 36 months were significantly lower with LNG IUDs as compared to copper devices.

Discontinuation due to partial or complete expulsion of device ranged from 10.6 in the case of LNG (IUD) to 8.3 (Copper-T 220C) to 8.5 (Copper-T 200B) to 7.6 (Copper-T).

Pelvic Infection/Vaginal Infection:-

A total of 30 subjects were discontinued due to vaginal & Pelvic infection. Out of these, 14 cases were for vaginal infection and 16 cases were pelvic infection. The pelvic infection for 36 months ranged from 1.8 (LNG IUD) to 1.2 (CuT 380AG), 1.7 CuT 220C) to 1.2 (CuT 200B).

Menstrual Abnormalities:-

Major reason for removal of IUDs was altered menstrual pattern. Discontinuation due to this reason was highest in subjects using the (LNG IUD) (13.8, 21.9, & 27.9 at 1 year, 2 years & 3 years respectively). Compared to Copper IUD users - what is interesting

that while the rates due to prolonged bleeding were comparable for all the devices the LNG, IUD had significantly higher discontinuation rates due to amenorrhoea and irregular bleeding.

cumulative net discontinuation rates per 100 users due to different types of Menstrual Abnormalities.

Reasons for discontinuation	Months	LNG Rate+SE	Copper T 380 AG Rate + SE	Copper T 220 C Rate + SE	Copper T 200 B Rate + SE
Prolonged bleeding	12	6.2+1.2	5.4+1.1	5.4+1.1	
	24	7.7+1.3	8.3+1.4	8.5+1.3	
	36	8.8+1.4	10.5+1.7	13.8+1.8	
Irregular bleeding	12	2.7+0.8	1.1+0.5	0.7+0.4	0.9+0.5
	24	5.6+1.2	2.0+0.7	1.2+0.5	1.5+0.6
	36	7.9+1.5	2.4+0.9	1.6+0.6	3.2+1.0
Amenorrhoea	12	5.4+1.2	0.8+0.4	0.0+0.0	0.7+0.4
	24	10.3+1.6	0.8+0.4	0.3+0.2	0.7+0.4
	36	14.1+2.0	0.8+0.4	0.3+0.3	0.7+0.4

Other Medical Reasons :

A total of 51 subjects discontinued due to other medical reasons such as abdominal pain, urinary infection, allergy, weight changes, chest pain, jaundice, weakness/headaches etc.

Another interesting feature while a previous study carried out by the ICMR with CuT 200 it was observed that the continuation rates with CuT 200 were 69.9 & 52.6 per 100 users at the end of 12 & 24 months. But in the present study the continuation rates with this device were higher (82.4, 68.8 & 45.4 per 100 users at the end of 12, 24 & 36. Therefore the difference between the continuation rates observed in these studies could be due to changes in attitudes and perceptions of providers as well as acceptors towards this method of fertility control.

Indians test ancient herb recipe as a contraceptive

By David Orr, in Delhi

(Filed: 28/09/2003)

Indian scientists are developing the first herbal contraceptive pill, using a recipe rediscovered in a 2,500-year-old medical text.

The drug's origins lie in India's ancient system of medicine known as ayurveda, meaning "science of life" in Sanskrit. The main ingredients of the herbal contraceptive, pippalyadi yoga, are two shrubs that grow in the Himalayan foothills: false pepper (embelia ribes) and long pepper (piper longum). These are mixed with borax, a naturally occurring mineral.

The drug is about to undergo clinical trials on humans, and scientists hope that it could be on the market within two to three years, offering a relatively cheap, non-toxic contraceptive.

"The indications are very promising," said Prof Roy Chaudhury, the president of Delhi Medical Council and head of India's herbal contraceptive development task force. "This would be a great gift from India to the world."

In the ancient world, Europeans are also believed to have used herbal contraceptives. One, a resinous plant called silphium, was highly valued by the Romans; in fact it was over-harvested and became extinct.

More recently, Europeans seeking inner well-being have embraced ayurvedic medicine. Scientists too are starting to recognise its merits: trials on a herbal diabetes treatment used by Indian forest dwellers have been completed and the product is due on the market soon.

Traditionally, pippalyadi yoga is taken as a powder

Lib - Rpd Health resource file JH 30/9

TH 30/9

contraceptive would be taken as a daily pill for three weeks each month. It is believed to inhibit a woman's ovulation.

In all, dozens of plants are mentioned in India's ancient medical texts as being effective in preventing pregnancy, but whether they contributed to the carefree coupling of the Kama Sutra is unknown. When trials resume in coming months, scientists will also test Chinese hibiscus (hibiscus rosa sinensis), a small tree native to southern India, for its contraceptive properties.

Developing an effective and safe herbal female contraceptive would be a coup for India. With a population in excess of one billion, it has the world's lowest consumption of the modern contraceptive pill, with two per cent of females using it.

While hundreds of claims for natural birth control products have been made around the world, none has yet met the standards demanded in clinical drug trials. Herbal products that are effective can also have harmful or unpleasant side-effects. When Chinese scientists developed a male contraceptive pill based on the seed of the cotton plant, large-scale trials showed that it lowered men's sperm counts but also diminished libido.

"It's too early to say if we're looking at a big breakthrough with the herbal contraceptive," said Dr Gerard Bodeker, a senior clinical lecturer in public health at the University of Oxford Medical School. "But the work being done in India is very important and it merits close attention," he added.

Prof Chaudhury said: "Ayurvedic practitioners say there's no need to test the herbal contraceptive because they know it works.

"But it's got to be subjected to modern, clinical trials. The way it's used by tribal people, it might be only 60 to 70 per cent effective. That sort of percentage might be all right with another drug, but with a contraceptive, I wouldn't be satisfied unless we could guarantee 98 per cent effectiveness."

23 September 2003: Britons lead the way for vasectomies

Previous story: New Yorkers rage at 'silly summons' blitz

Next story: Giant Komodo dragon terrorises streets of Lebanon

Strengthening Decentralisation
Key Issues for Action

Presentation for the Gender and
Decentralisation Forum

Bhubaneswar, 30 October 2000

Purpose

- Assess constraints and potentials of decentralised governance in India
- Address concerns of inclusiveness, accountability and efficacy of local governance institutions
- Identify priority areas for strengthening decentralisation initiatives

Decentralisation and the Indian Context

- Economic Reforms in the 1990s
  - Structural Adjustment and impact on public expenditure, especially at the state level
- 73rd and 74th Constitutional amendments and follow up (1996 Act)
  - panchayats to prepare plans for economic development and social justice
- Differential Progress in states

Panchayati Raj and Livelihood Security

- Skepticism about Panchayati Raj
  - Reincarnation of existing bureaucracy
  - Concerns regarding inclusiveness, accountability and effectiveness of PRIs
- Livelihood security for the poor is a key to their effective participation
  - better wages, decent work and rights over common property resources
- Need for a supportive macroeconomic policy framework

Theme Areas

- Legal and administrative anomalies
- Panchayat finance and budgets
- Urban context
- Gender Issues
- Current Imperatives and strategies for the future

Legal and administrative anomalies

- Status of the Gram Sabha
  - Extension of Panchayati Raj to Scheduled Areas Act, 1996
- Inter-tier relationships
- Issue of rotation
- Administrative and procedural anomalies
  - Relationship with treasury, line departments and agencies
  - Relationship with existing people's institutions (both customary and informal bodies)

Panchayat finance and budgets

- Funds
  - Untied funds
  - Revenue raising powers
  - Rationalization of Centre- State fiscal transfers
- Innovative approaches
  - Kerala People's Plan
  - District Budgets in Madhya Pradesh
- Eleventh Finance Commission Recommendations

Urban context

- 74th Amendment gives constitutional mandate to Urban Local Bodies (ULBs)
  - Role of elected bodies and representatives (ward councillors, mayors)
  - Metropolitan and District Planning Committees
- Parastatal Bodies
- Municipal Reform:
  - Focus on urban poverty
  - Productive neighborhoods and slum networks

Gender Issues

- Women's role as leaders
  - Constitutional provision for reservation
  - Field reality: surrogate representation, marginalisation, victimization for speaking out
  - Linkage with participation in user groups and village committees
- Lessons from two rounds of panchayat elections
  - Empowerment through participation
  - Improvement in literacy levels
  - Training issues

Two-pronged Strategy

- Decentralisation from above
  - transfer of "funds, functions and functionaries"
- Decentralisation from below
  - role of informal groupings and campaigns
  - social mobilization
  - audit and accountability initiatives
- Both should mesh together, not oppose

Issues for International Partners

- National priorities
  - Ninth Plan focus on "cooperative federalism"
  - Eleventh Finance Commission
- Dialogue with state governments
- Grassroots decentralisation as the response to globalization: ensuring community driven management:
  - Linkage between user groups and Panchayati Raj Institutions (PRIs)/ Urban Local bodies (ULBs)
- Moving from advocacy to action

CIS → Stand one Resource file - WH-3.

Saheli
Women's Resource Centre
ABOVE SHOP NOS. 105-108, DEFENCE COLONY FLYOVER MARKET (SOUTH SIDE), NEW DELHI 110 024. TEL: 4616485

Campaign Against Anti-Fertility Vaccines

25.11.98

Dear friends,

This is brief report of the campaign events around the International Immunology Congresses. Our interventions were very effective, and we really made our presence felt. Some of us attended the Congress on Reproductive Immunology (27-30th October) and made interventions at the end of relevant sessions. In the inaugural session on 27th October, GP Talwar blatantly stated the 'population control agenda' of AFV research and publicly admitted that his earlier line of research on the anti-hCG vaccine had reached a dead-end. Instead, he said, he was shifting focus to 'active immunisation' for 'emergency' contraception - which has many associated problems, which we will critique in detail in the near future.

Saheli, the Forum for Women's Health, Mumbai (FFWH) and the Women's Global Network for Reproductive Rights jointly drafted a Statement on behalf of the International Campaign which outlined our concerns regarding the hazards of the vaccines and potential for abuse. The next day, on the 30th, after the session on immuno-contraception, we read out the statement, which was met with a lot of hostility from scientists, who felt it was not the 'right forum' to raise such questions. We then distributed the Statement, and discussed issues of ethics and social context of medical research with the scientists present.

On the afternoon of the 30th, we held a Press Conference jointly organised by Saheli and FFWH. Members of the International Campaign also addressed the journalists. Although AFVs and contraceptive research are not a "burning issue" in the Indian context, over the years, our work has managed to generate considerable interest in the issue. This groundwork helped us mobilise a wide cross section of the press, so it was a very well attended Press Conference. Saheli released the report, "Target Practice: Anti-FertilityVaccine Research & Women's Health".

On the 31st, we had a campaign meeting, co-organised by Saheli and FFWH. First, we had a session by Imrana Qadeer (Prof. at JNU University), giving an overview of health policy in India, and the shifts in the Reproductive Health Policy. The other session was on the direction, and politics of Contraceptive Research and the challenges ahead of the women's movement, presented by Saheli. The afternoon session was on the International Campaign, by Judith Richter, followed by a session on social responsibility of scientists by Shree Mulay. Finally, we had a strategy planning session. Although we did not reach any 'conclusions', there was a good discussion, especially about co-option of the agenda of the women's movement by the population control establishment, and the role of advocacy groups in this context. About 35 women attended this meeting - a few groups from outside Delhi, and the majority were local groups.

On the 1st of November, we held a protest demonstration at the inaugural ceremony of the International Immunology Congress. In this protest we were joined by women's groups like Sabla Sangh, students groups like Democratic Student's Union, and democratic groups like Peoples' Union for Democratic rights. In all, the protestors (men and women) totalled about 60. Since the President of India was inaugurating the Congress, there was a lot of security and police presence. Yet, we managed to sneak right up to the hall, and hand out leaflets to hundreds of scientists who were attending the event. We shouted slogans, sang songs and displayed placards for about an hour (quite an achievement considering the heavy security and threats to arrest us, and strong-arm tactics by the lone police-woman present !). According to journalists who were inside the inauguration, our presence was very noticeable, and everyone was discussing us and our pamphlets. We also got quite a bit of press coverage the next day.

Please let us know if you would like a copy of our report (Suggested contribution Rs 25, + Rs10 mailing cost), or any campaign material - pamphlets etc.

In solidarity,

(For the Saheli Collective)

सहेली वुमेन्स रिसोर्स सेन्टर, दुकान 105-108 के ऊपर, डीफेन्स कालोनी फ्लैओवर मार्केट (दक्षिण),
नई दिल्ली - 110 024. फोन : 461 6485

942
2/12/98

Saheli
WOMEN'S RESOURCE CENTRE
ABOVE SHOP NOS. 105-108, DEFENCE COLONY FLYOVER MARKET, NEW DELHI - 110024. TELEPHONE: 4616485.

TARGET PRACTICE:

ANTI-FERTILITY VACCINE RESEARCH & WOMEN'S HEALTH

- Synopsis of a Saheli Report. Released 30.10.98.

The world-wide obsession with 'over population', propagated by the population control establishment has resulted in making women the target of coercive policies, and subjected them to the trials and use of many invasive contraceptives. In the name of 'increasing women's choices', long-acting, hazardous contraceptives are dumped on women. Implants and injectables such as Norplant, Net-En and Depo Provera have been tested and used on countless women, especially in the Third World.

All over the world, **a relentless search continues for 'appropriate sites' within a woman's (or a man's) body that can be targeted** by Anti-Fertility Vaccines for contraceptive effect. In India, as in several other countries, countless animal and human trials have resulted in a method that is scientifically unsound and inherently unsafe.

In medical terms, the potential risks that all subjects of human trials have been exposed to range from allergies and hypersensitivities to auto-immune diseases and permanent infertility. Almost three decades after the research on Anti-Fertility Vaccines began, the method still has an efficacy rate that at best is an unacceptable 80%, its safety is not yet conclusively established; long term toxicity and teratological effects not ruled out and the effect on pregnant women or children born during or after the trial not conclusive. While scientists and institutions engaged in the pursuit of Anti-Fertility Vaccines cite lack of data as the very reason for continuing this line of research, women and health groups have consistently contested this argument on several grounds.

Opposition has been raised against the very principle of 'treating pregnancy as a disease' and causing an immune response against it. Other characteristics of Anti-Fertility Vaccines like the long duration of effect, and the fact that they can distributed on a mass scale, and administered to people without their knowledge, open up another critical area of concern : their inherent potential for abuse. Experiences of women all over the world have highlighted the numerous situations in which such long-acting, invasive and provider-controlled methods of contraception are abused. This is of particular significance in a country like India where the 'population control' agenda of the state, has already cost countless women their health and well-being.

The unethical research so far carried out has further substantiated these apprehensions. Human trials have been initiated without adequate or conclusive animal studies, internationally accepted requirements for 'informed consent' have been flouted and long term follow-up remains, till date, completely unsatisfactory. Contrary to all ethical norms of 'scientific practice', the interests of science and society have taken precedence over the interests or well-being of trial subjects.

While the development of Anti-Fertility Vaccines has broadly followed the pattern of other invasive, provider-controlled contraceptives, certain new elements have characterised

it. The media has been consistently used to garner support against mounting protests from the women's health movement. Many of the criticisms of the women's movement about long-acting, provider controlled contraceptives are also sought to be turned on their heads. Researchers claim that Anti-Fertility Vaccines do not cause hormonal disturbances and disruption of the menstrual cycle like other long-acting hormonal methods. Such a claim masks the fact that these vaccines do interfere with the hormonal balance, and in addition have serious potential heath risks. Researchers claim that they are in agreement that long-acting duration are not in women's interests, and that these vaccines are not 'provider controlled' because a woman can 'choose' whether or not to get a booster shot and continue with the vaccine. And so, while these hazardous Anti-Fertility Vaccines work to control women's fertility by any means, we are told that women's choices are being widened by the development of these vaccines.

National and international action by women's groups and health activists has opposed the development of the 'vaccine-approach' for the last five years now. It has highlighted the unethical and unsound scientific basis of this research, the health hazards it poses for women and the social implications of its use.

On one hand, this debate has forced the scientific establishment to become more accountable to health activists. But on the other hand, concerted attempts have been made to obscure the issues at hand. Changes in the nomenclature of Anti-Fertility Vaccines, from Birth Control Vaccines to Fertility Regulatory Vaccines and now, to Immunological Contraceptives reflect no real shift in the perspective of the developers of such a technology. The co-option by the population control establishment of the language and concerns of the women's movement masks the extreme dichotomy between the needs of women and the priorities of providers. Research and funding institutions claiming to be pro-women repeatedly reassure women's groups that the development of Anti-Fertility Vaccines for men is also under way. Yet, serious concerns about the health risks of these vaccines on men persist. Moreover, the fact is that most of the vaccines being developed are designed to be used on women.

We need to question why there is a need for a population policy at all, and change the terms of the debate. Land reforms, provision of basic needs, ensuring equitable access to food, housing, health, education and other necessities will contribute to moving towards a more humane society. Top-down, resource-intensive research and planning can only serve the interests of the dominant in any society. A radical reorientation of contraceptive research must necessarily encompass women's need for safe and effective barrier methods which are within the control of women. Scientific research must take into account the real needs of people, and patriarchal and class biases have to be challenged. Only tackling the real inequalities between men and women and addressing women's needs, would contribute to overall change. The scientific community must take social responsibility and consider the full consequences of their research. They must take up the challenge and have the courage the immediately stop such research!!

WE CALL FOR A HALT TO THE DEVELOPMENT OF ANTI-FERTILITY VACCINES !

Contact Nilanjana Bismas (Bangalore) Tel: 642 630
876, 1st Floor, 14th Cross, 31st Main, J.P. Nagar, 1st Phase, Bilkere

Copies Available From Saheli Women's Resource Centre (Rs 25 + Rs 10 mailing = Rs 35/-)

VII International Congress of Reproductive Immunology
Time to Stop Research on Anti-fertility 'Vaccines'

Over the past week, around 200 scientists and clinicians met at the National Institute of Immunology, New Delhi with the aim to 'discuss the latest advances in basic and applied reproductive immunology'.

We, members of the International Campaign Against Population Control and Abusive, Hazardous Contraceptives attended this conference to learn about recent 'developments' in immuno-contraception and share our concerns. We also hoped to stimulate a debate within the scientific community about the feasibility and desirability of the direction of this research.

The World Medical Association's Helsinki Declaration on ethics in clinical trials states that "the purpose of medical research involving human beings must be to *improve* diagnostic, therapeutic and prophylactic procedures" (our emphasis).

Having heard the scientific communications over three days, we fail to be convinced of the advantages of immunological methods of fertility control over currently existing contraceptives in terms of efficacy, reliability, safety for users and their potential children, or for the expansion of people's reproductive choices. Three decades after the commencement of this research significant drawbacks persist, namely:

- an unacceptably low efficacy rate (<80%)
- unreliability due to unpredictable variations in immune responses
- an initial lag phase before the method is effective as a contraceptive
- inability to 'switch off' immune response if a person changes their mind or experiences adverse reactions.

We believe that such an efficacy profile cannot justify exposing women to potential adverse effects such as the possibility of auto-immune diseases, immune-complex diseases, allergies (including potentially fatal anaphylactic shock), permanent infertility and interference or exacerbation of existing diseases or immune-disturbances.

We are also very concerned about the potential for abuse that is inherent in anti-fertility "vaccines". Such a method can be easily administered on a mass scale with or without a person's knowledge or consent. The stated aim of the research community has been to develop a method which acts for at least 1-2 years after a single administration. The impossibility discontinuing the action of the method on demand will put them beyond any means of preventing or containing such abuse.

In fact, it is disturbing that none of the discussions at the congress considered the social and ethical implications of the anti-fertility 'vaccine' research. It has been the historical experience of women that they are targeted for eugenic and population control purposes with long-acting and hazardous contraceptive methods. Therefore, we would have liked to see some evidence that the scientists were cognizant of the social context of the ultimate application of the technologies they are developing.

We have expressed out concern that research criteria used are not centered around people's health, wellbeing and reproductive self-determination. As could be seen from the opening session to the conference, the prime aim was - and still is - the development of mass-fertility control methods for population control. We urge scientists involved in basic and applied research to take social responsibility and consider the full consequences of their research. We hope that they will take up the challenge and have the courage the stop this research!!

For further information, contact: *31 October, 1998*

Women's Global Network For Reproductive Rights, NZ Voorburgwal 32, 1012 RZ, Amsterdam, The Netherlands.
Forum For Women's Health, 5 Bhavana Apartments, Opp. Golden Tobacco, Santa Cruz (West), Mumbai -400 056.
Saheli Women's Resource Centre, Unit Above Shop Nos. 105-108, Defence Colony Flyover Market, New Delhi 110 024.

A CALL TO ALL SCIENTISTS

AT THE INTERNATIONAL CONGRESSES OF IMMUNOLOGY NEW DELHI, 27 OCTOBER- 6 NOVEMBER, 1998

We demand an immediate halt

to the unethical research and development of Anti-Fertility Vaccines because of high health hazards and the potential for abuse.

The anti-people, particularly anti-women, policies of population control and drive for profiteering cannot determine the direction of contraceptive research.

Scientific goals cannot be pursued at the cost of the health and well-being of women and men.

आह्वान

दिल्ली में आयोजित अंतरर्राष्ट्रीय इम्यूनॉलॉजी सम्मेलनों (27 अक्टूबर से 6 नवम्बर 1998) में एकत्रित वैज्ञानिकों को हम आह्वान करते हैं:

गर्भ-निरोधक टीकों की अनैतिक रिसर्च व उनके विकास पर तुरन्त प्रतिबन्ध लगाया जाए क्योंकि:-

वे स्वास्थ्य के लिए हानिकारक हैं।

उनके दुरूपयोग को नकारा नहीं जा सकता।

जनसंख्या नियन्त्रण की जन-विरोधी और नारी-विरोधी नीतियाँ और मुनाफाखोरी की आकांक्षा रिसर्च की दिशा तय नहीं कर सकती।

वैज्ञानक लक्ष्यों की पूर्ति के लिए जन-स्वास्थ्य की कुर्बानी नहीं की जा सकती।

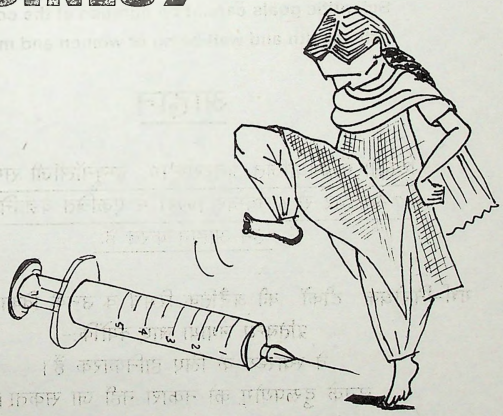
For more information contact:

Forum For Women's Health
5 Bhavana Apartments, Opp. Golden Tobacco
Santa Cruz (West), Mumbai -400 056

Saheli Women's Resource Centre
Unit Above Shop Nos. 105-108
Defence Colony Flyover Market, New Delhi 110 024

STOP

RESEARCH ON ANTI-FERTILITY VACCINES!



गर्भ-निरोधक टीकों पर रोक लगाओ!

WH-3.

Caution on two contraceptives

Women's groups and activists warn that two injectable contraceptives that will possibly be included in the national family planning programme may not be completely safe.

T.K. RAJALAKSHMI

FEARS about the inclusion of certain injectable contraceptives in the national family planning programme have been raised yet again following the Supreme Court's ruling on August 14 in a case filed by Stree Shakti Sanghatana, Saheli and others in 1986 pleading for a stay on the Phase IV clinical trials of Net-en (Norethisterone Enanthanate) and its entry into the programme. Without making a direct reference to a case filed in 1993 against hazardous drugs by the Drug Action Forum, the court assured women's organisations and health activists that neither Net-en nor Depo-Provera (Depo Medroxy Progesterone Acetate), another contraceptive against which a case is pending in court, be permitted for mass use for now. During hearings, the court had asked the Drug Technical Advisory Board (DTAB) to examine its sub-committee's August 1995 recommendations that "the use of Depo-Provera should be restricted to women who would be aware of all the implications of its use".

While the report pertaining to Depo-Provera was reproduced in the affidavit filed by the government this year, the Union Ministry of Health and Family Welfare proposed to include Net-en in the family planning programme even in places where facilities for follow-up and counselling were not available. Women's and health groups fear that both the injectables would come to be used even in places where the infrastructure does not exist.

Depo-Provera and Net-en, both synthetic derivatives of progesterone, suppress ovulation, make cervical mucous inhospitable to sperm and make the lining of the uterus unsuitable for implantation. Depo-Provera is a three-monthly injectable developed by Upjohn of the United States, while Net-En is a product of Schering AG of Germany.

What has raised the hackles of women's groups and health activists is the manner in which Depo-Provera found its way into the Indian market in 1994 without the mandatory Phase III trials. It was sold across the counter against a medical prescription. According to Schedule Y of the Drugs and Cosmetics Act, "if the drug is already approved and marketed, Phase III trials as required under item 7 of Appendix I are usually required". Since Depo-Provera was already approved in the United States, what remained was the Phase III trials. Item 7 on Appendix I, which is about confirmatory trials, states: "The purpose of these trials is to obtain sufficient evidence about the efficacy and safety of the drug in a larger number of patients generally in comparison with a standard drug or a placebo. These trials may be carried out by clinicians in the therapeutic areas concerned, having facilities appropriate to the protocol. If the drug is already approved/marketed in other countries, Phase III data should generally be obtained on at least 100 patients distributed over three or four centres primarily to confirm the efficacy and safety of the drug in Indian patients when used as recommended in the product monograph for the claims made."

Dr. C. Sathyamala, an epidemiologist trained at the London School of Hygiene and Tropical Medicine, says the Drugs Controller of India made post-marketing surveillance (PMS) conditional for the sale of Depo-Provera, thereby substituting Phase III trials. In her book *An Epidemiological Review of the Injectable Contraceptive Depo-Provera*, published by Medico Friends Circle and Forum For Women's Health, she points out that Upjohn used Chiang Mai, a remote rural area in Thailand, as its "testing ground" for Depo-Provera. Sathyamala feels that the unlettered women of Chiang Mai were perhaps not informed that they were taking part in clinical trials and that no protection, legal or otherwise, would have been given to them. It is felt that similar tactics may have been deployed in the PMS conducted between June 1994 and December 1997 among Indian women by Professor Rustom P. Soonawala, obstetrician and gynaecologist and Consultant. The PMS study covering 1,079 women was conducted at 10 centres to observe the side-effects and acceptability of Depo-Provera 150 mg. A report submitted in 1999 concluded that no failure of contraception was reported during the survey and no drug-related adversity was found. It said that, "neither pregnancies nor deaths were reported during the study" and that "the results indicate that Depo-Provera 150 mg is a safe and effective contraceptive, and that sufficient pre-treatment counselling on the expected hormonal effects would greatly increase the acceptability of this method of contraception." Interestingly, two of the three authors of the report are from Pharmacia and Upjohn.

During the course of the study, some women were reported to have discontinued the contraceptive. The reasons attributed for this were "non-serious medical

S. THANTHONI

Baldfaced, boldfaced or barefaced lies?

meant "confident", a sense that soon turned into "impudent", as confidence so often does. Not until 1884 did the Italian printer Giambattista Bodoni use *boldface* to describe a darkly thick, or bold, typeface, which looks like this and is easily distinguished from lightface type.

From *bare* and *bold* to *bald*: The etymology of *baldfaced* should interest angry animal rights advocates. All the early uses referred to animals: in 1648, "a *bawld-fac'd* heighfer"; in 1677, "a sorrel Mare... *bald-faced*"; and in 1861, "our *bald-faced* hornet." And of course, the symbol of America was "the *bald* eagle."

In its original sense, *bald* did not mean "hairless, shiny-pated, cueball-like, suedeheaded." It meant "white". The top of our symbolic eagle's head is not featherless; the last time I patted one, its head and neck were covered with smooth white feathers.

In the 13th century, the *balled coot* was a water bird with a white mark on its forehead, lingering in the lingo today in the simile *bald as a coot*. *Baldfaced whiskey* was a 19th-century Americanism for pale, raw liquor, and a *boiled*, *biled* or *bald-faced* shirt was a cowboy's go-to-meetin' white shirt. The Celtic *bal* meant "a white mark", and the Sanskrit *bhala*, "forehead", from the Indo-European *bhel*, "white, shining." Had enough? At bottom, it's white. That's why horses with white markings on their noses are often called Old *Baldy*, same as the snow-covered mountain.

In current use, then, *baldfaced lie* is the most popular because it sounds most resounding; *barefaced lie* continues to run strong with no connotation of any pursuit of the hirsute; and *boldfaced lie* sounds like a printer's error. In every case, kill the hyphen.

"WE can sell all the *woof tickets* we want," the Washington Wizards' basketball forward, Juwan Howard, said, but "it's about performance out there... We've got to get it together." A reader asks: "Any idea what Juwan Howard is talking about?"

As early as 1985, Clarence Page of *The Chicago Tribune* defined *selling woof tickets* as "an invitation to fight". In 1996, Jane Kennedy of *The San Francisco Examiner* called it "telling lies". In *The Atlanta Journal and Constitution*, Betty Parham and Gerrie Ferris wrote in 1992, "Although its origin is uncertain, '*woof ticket*' is a somewhat dated phrase that refers to an outrageous or exaggerated boast meant to intimidate or impress the listener."

Woof is a Black English pronunciation of "wolf". According to Geneva Smitherman's 1994 *Black Talk*, a *woof ticket* is "a verbal threat, which one *sells* to somebody; may or may not be real. Often used as a strategy to make another person back down and surrender to what that person perceives as a superior power."

Tom McIntyre, Professor of Special Education at Hunter College in New York, noted nearly a decade ago: "*Woofing* is especially effective against those who are unfamiliar with it and don't realise that it is most often 'all show and no go.'... The menacing behaviour can usually be defused and eliminated by informed, tactful action." He advised teachers to "look secure and self-assured while you withdraw." In the context of the basketball star Howard's remarks, *woof tickets* are not to be bought; on the contrary, he uses the phrase to show that performance, and not intimidating attitude, is needed to "get it together."

THERE'S a word that pops up every four or eight years: *interregnum*.

The Latin means "between reigns." The *interregnum*, or *interregencie*, originally meant the interval that a throne or position of leadership was vacant, as between the death or removal of one sovereign and the accession of the next. This invited trouble, as in the Cromwell era.

William Blackstone, in his 1765 *Commentaries*, held that in England "the king is made a corporation to prevent in general the possibility of an *interregnum* or vacancy of the throne." The word now means "an intermission in the order of succession" and, more generally, "a breach of continuity." Specifically, in the United States, it means "the period between the election of a new President and his inauguration."

But it is not limited to political power: The breakfast-table autocrat Oliver Wendell Holmes wrote, "Between the last dandelion and violet... and the first spring blossom... there is a frozen *interregnum* in the vegetable world."

The word, lest we forget, is spelled with two *r*'s. It received a special play during the transition from Jimmy Carter to Ronald Reagan, which wags called the *interreaganum*.

THE book-publishing industry has its own new term for a variation of a release date: *laydown*. "This review copy is being sent to you," Knopf Publicity notifies me, "with the understanding that you will not run your review before Tuesday, July 18 – which is the National *Laydown* Date for bookstores all across the country. (Official Publication Date is July 25.)"

A *laydown date* is the day that a book officially goes on sale. It is used especially when the publisher wants to restrict any sale or revelation of the news in a book before it leaks. The *publication date* is a week or month after that, giving reviewers time to noodle the book around and buyers the feeling that they are getting the jump on their neighbours.

Laydown without the *date* means "distribution": *Publishers Weekly* (where's the apostrophe?) wrote recently about a Beatles book that "hits the stores with a worldwide *laydown* of 1.5 million copies." The noun has a sinister use among arms merchants (an obliterating strike is a *nuclear laydown*) and can also be found in the lexicon of graphic artists, construction workers and railroaders. But its most prevalent use is in gambling, as the adjective in a *laydown hand*.

In poker, it's the "showdown", when all hands are laid open for all players to determine the winner. In bridge, a *laydown hand* is a winning hand placed face up on the table all at once, rather than being played out. This bridge meaning has been extended to a general "sure thing." A Boston economist told *The New York Times*, "The Fed has more reason to tighten than not – but it's not a *laydown*."

Some of us who respect reasonable embargoes resist marketing manipulation. Let's say I go to a bookstore, the bookseller sells me a book and I spot a news story in it. Would I feel free to use it in a column no matter what its *laydown date* or publication date? You bet I would; that's a *laydown*.

New York Times Service

events", which, interestingly, included irregular bleeding, in some cases heavy, amenorrhea (absence of menstruation), urinary tract infection, abdominal pain, bloating abdomen, post-coital bleeding, weight gain, abdominal cramps and even viral hepatitis. Women's and health groups were disturbed by the conclusion that was reached that the symptoms were non-serious.

In fact, at a workshop convened by the Institute for Research in Reproduction in Mumbai in December 1998 to review the status of the available injectable contraceptives in the Asian region *vis-a-vis* India and to discuss the inclusion or otherwise of such contraceptives in the national family planning programme, the consensus was that the injectables had side-effects.

Women's and health groups cautioned the government against their inclusion in any form in the family planning programme. Concerned about the "deliberate misrepresentation of information", they urged the government to disallow the use of such hazardous drugs as the existing health infrastructure was not capable of providing the necessary follow-up for such long-acting contraceptives. Further, the non-accountability of pharmaceutical companies, coupled with evidence to the contrary about their efficacy, they said, provided the grounds for a ban on all injectables.

Interestingly, Depo-Provera is more commonly used in developing countries. In developed countries it is not an item of "popular choice".

At a health camp for women. Women's groups oppose providing easy access to injectable-type contraceptives in the name of choice.

ORIGINALLY introduced in 1967, Depo-Provera was publicised in India in 1994 by a leading advertising group, which proclaimed it to be the world's most widely used and widely available and largest used preparation of its kind, and that it had been successfully used by over 30 million women in 90-odd countries. Sathyamala says that, even if one concedes that Depo-Provera is the "largest used" preparation, its overall use is low and that except in South Africa it does not appear to be an important contraceptive of choice even in countries with no restriction on its use. There is a stark difference in the share of injectables used among the black and white populations of South Africa. Some 41 per cent of the contraceptive users preferred injectables. A break-up of this figure revealed that persons using injectables constituted only 3 per cent of the 79 per cent of white women, who used modern methods, while users of injectables formed 27 per cent of the 49 per cent of the black women who used modern methods. Quoting various studies and papers, Sathyamala writes that in developed countries, where Depo-Provera is registered as a drug, it is prescribed primarily to mentally challenged women, women with a problem of drug addiction, indigenous populations such as native Americans in the U.S. and Maoris in New Zealand, sexually active adolescents, coloured women and women from low-income groups.

According to Sathyamala, Depo-Provera is a long-term, systemic, invasive contraceptive, which acts at multiple levels. Its potency and the ease with which it can be used have been cited as reasons for its promotion in sections with high birth rates and low "motivation" levels. By not taking the women's experience seriously, it is more than likely that important morbidities are being left out, she argues. When a woman reports a symptom while being on Depo-Provera, the general tendency seems to be to "reassure" her that the reported symptom is not associated with the use of the contraceptive.

Women's groups, such as the All India Democratic Women's Association, Sama and Jagori, and health forums such as the Medico Friends Circle and the Forum for Women's Health, maintain that Depo-Provera has been indicted for causing a climacteric-like syndrome (premature menopause), irreversible atrophy of the ovaries and endometrium (inner lining of the uterus) leading to sterility, deaths due to spontaneous formation of clots inside blood vessels (thromboembolism), a 10-fold increase in the birth of Down's Syndrome babies and increased infant deaths. There are heightened chances of breast and cervical cancer as well. Activists of the organisation have accused Upjohn of suppressing and/or underplaying the life-threatening implications of the injectables and in the process misleading the medical community as well as the Drugs Controller of India. Studies on Depo-Provera have been funded by Upjohn or directly carried out by its bio-statistical division. The dissenting groups feel that given the large body of scientific information on the injectable, the conduct of another study that was part of a PMS was nothing but an attempt to mislead and misinform the authorities.

The introduction of the injectables cannot be seen in isolation of the government's population policy. The activists argue that while the National Democratic Alliance government appears to have given up coercive methods of population control, State governments were doing exactly the opposite. While a Bill to debar people with more than two children from contesting elections was still on the national agenda, Haryana and Delhi have passed a legislation debarring persons with more than two children from contesting the local body elections. In Maharashtra, the third child is excluded from the benefit of the Public Distribution System. In Uttar Pradesh, Rajasthan and Madhya Pradesh, the disincentives include the denial of access to government schemes.

Evidently, these disincentives could push women and their families into accepting what they perceive as safe and long-acting contraceptive methods. Women's groups are not against family planning and contraception, but they oppose the easy access to injectable-type contraceptives in the name of choice, while the truth is that for the majority of Indian women, informed choice about anything, leave alone contraceptives, is a chimera. ■

Thrust on biotechnology

Tamil Nadu unveils a comprehensive biotechnology policy in order to take advantage of the emerging industrial activity in this sector.

ASHA KRISHNAKUMAR

WITH 5,000 species of flowering plants, 22,500 sq km of forest cover and a coastline of 1,000 km, Tamil Nadu is exceptionally rich in biodiversity. This kind of wealth, rarely occurring in a State, needs to be put to sustainable use, especially since the market for biotechnology products in the country is expected to double to Rs.15,000 crores in the next five years. By putting in place an exhaustive biotechnology policy, Tamil Nadu has become one of the first States to take advantage of this anticipated growth. The landmark policy, which provides a comprehensive scientific plan to put to use the State's natural resources to promote the biotechnology industry, was unveiled by Chief Minister M. Karunanidhi on September 12.

The policy comes with a firm commitment by the State government on financial and procedural matters in order to enable its speedy implementation. Karunanidhi said: "The idea is to provide a policy framework as well as suitable implementation structures to convert the bioresources of the State into economic wealth in ecologically and socially sustainable manner." He said that the growing demand for biotechnology products and the State's potential to tap the market for them had encouraged the government to announce the policy. The policy, based on the recommendations of a committee appointed by the government under the chairmanship of the agricultural scientist Dr. M.S. Swaminathan, focusses on product development in the four segments of technology – medicine, agriculture, environment and industry.

The State's biotechnology enterprise would involve

* the setting up of a biotechnology incubator park near Chennai to develop and commercialise products and patents;
* the establishment of a medicinal plants park near Madurai to focus on sourcing raw materials in a sustainable manner and offer value addition to scientifically tested herbal and traditional medicines;
* continuing government's support to the women's biotechnology park at Kelambakkam, near Chennai, which would concentrate on microenterprise and traditional biotechnology products;
* the starting of a marine park at Mandapam in Ramanathapuram district to devise ecologically sustainable methods to conserve sea weeds and plankton; and
* the opening of a Bioinformatics and Genomics Centre at the Tidel Park in Chennai in order to exploit the germplasm base and the vast pool of talented bioinformatics scientists and low-cost software skills in the State.

Tamil Nadu is committed to encouraging biotechnology entities, consisting of research organisations, service providers, knowledge workers and companies, which will commercialise the new products and processes, and to creating a network to facilitate the transfer of information and knowledge among the various entities.

According to the policy document, schemes are being worked out to protect and develop various biosphere reserves, such as the Gulf of Mannar off Rameswaram, the Pichavaram mangroves in Nagapattinam district and Muthupettai in Tiruvarur district. The Global Environment Facility has announced an assistance of $7.85 million to protect the Gulf of Mannar.

Industrial activity has so far been confined largely to first generation biotechnology enterprises such as fermentation of antibiotics. To broaden the industrial base, a large number of plant tissue culture units are being set up, besides promoting the production of food and industrial enzymes, classical fermentation products (antibiotics and immunomodulators), bioenergy and biopolymers, and other such activities.

According to the policy document, all efforts are directed towards the creation of a critical mass of industrial activity in biotechnology. A two-pronged strategy

S. THANTHONI

At a facility involved in the process of developing transgenic plants, at the M.S. Swaminathan Research Foundation, Chennai.

WH-3.

Clinical use of Depo-Provera for contraception

Andrew M Kaunitz, MD FACOG
Associate Professor, Department of Obstetrics and Gynecology
University of Florida Health Science Center, Jacksonville, Florida, USA

Since it was first developed for contraceptive use in the early 1960s by The Upjohn Company[1], Depo-Provera has been the subject of intensive study and review by academic medical investigators, government authorities, international health organizations including the World Health Organization (WHO), and The Upjohn Company itself. Clinical experience with Depo-Provera, which has accumulated over several decades, has exceeded 3 million women-months[2], and over 1000 scientific papers have been published[3].

Initiation of contraception with Depo-Provera

Timing of the first injection. The ideal time to initiate contraception is within 5 days of the beginning of menses. This ensures that the woman is not already pregnant, and prevents ovulation during the first month of use[4].

Dose and injection site. Depo-Provera is supplied as an aqueous suspension of microcrystals, which should be administered by deep intramuscular injection into the gluteal or deltoid muscle, using a 21–23 gauge needle. The vial should be shaken vigorously just prior to use, to ensure that a uniform suspension is administered. After injection, there is an initial peak in the blood concentration of the drug[5], but the low solubility of the microcrystals at the injection site results in prolonged circulating levels of the active progestagen: pharmacologically active levels persist for 3–4 months after injection. Doses of Depo-Provera ranging from 50 to 400 mg/ml are marketed in the USA and elsewhere. Pharmacokinetic comparison suggests that the higher dose preparations are associated with reduced drug bioavailability[6]; therefore, 150 mg/ml should be used for contraceptive purposes.

Clinical trials with Depo-Provera

Depo-Provera, 150 mg every 3 months, has been demonstrated to be an extremely effective contraceptive. Taking the mean of all available studies, the 'typical' failure rate is 0.3%[7]. The shortest reported period before return to fertility, whether measured by time to conception, time to ovulation, or serum levels of the drug, appears to be 4 months after the last injection. The recommended dosing frequency for Depo-Provera is every 3 months. Thus, a conservative estimate of the 'grace period' for women seeking continued contraceptive effectiveness suggests that pregnancy should be excluded before reinjecting women who are more than 2 weeks late for their Depo-Provera injection.

Depo-Provera, 150 mg every 3 months by deep muscular injection, is an extremely effective contraceptive

The contraceptive efficacy of Depo-Provera has been evaluated in five large, controlled, multicenter studies conducted from the mid-1960s to the late 1980s. Two of these studies were sponsored by The Upjohn Company and three were conducted by the WHO. The major demographic features of these studies are highlighted in Table 1. All studies were open, because blinding and the use of

Table 1
Demographic features of the multicenter studies of Depo-Provera

Reference	Study design	Drug and dose
18	Multicenter, open study in healthy women of demonstrated fertility	Depo-Provera, 150 mg in 3 ml
Unpublished	Multicenter, open study in healthy women of demonstrated fertility, with history of reasonably regular menstrual cycles	Depo-Provera, 50 mg in 3 ml Depo-Provera, 150 mg in 1 ml
8	Multicenter, randomized, open, concurrent-control study in healthy women	Depo-Provera, 150 mg in 1 ml Depo-Provera, 100 mg in 1 ml
10	Multicenter, randomized, open, parallel-group, active-controlled, study in healthy, non-breast feeding women	Depo-Provera, 150 mg in 1 ml
9	Multicenter, randomized, open, parallel-group, active-controlled, study in healthy, non-breast feeding women of demonstrated fertility	Depo-Provera, 150 mg in 1 ml

* Pearl Index.
** Life table method.
† WHO authors calculated the pregnancy rate by life table analysis, but they refer to units of the Pearl Index (per 100 woman-years).

concurrent control treatments was considered neither practical nor ethical.

Demographics and baseline characteristics. The contraceptive effectiveness of Depo-Provera, 150 mg every 3 months, was assessed in 7240 women: 4200 women in the Upjohn-sponsored studies and 3040 women in the WHO-

Dose regimen	Number of subjects	Patient-months experience	Study duration	Pregnancy rate
First injection between 3rd and 7th day of the menstrual cycle in non-postpartum patients, and at least 4 weeks after delivery in postpartum patients, following injections every 3 months	3905	82,384	Median: 13 months	15 (0.22/100 woman-years)*
Every 3 months	155	2003	Median: 13 months	0 (0.0)
	140	1841		0 (0.0)
First injection within first 5 days of menstrual cycle; following injections every 3 months (± 7 days)	607	5429	59% patients completed 1 year (both groups)	0 (0.0)
	609	5507		2 (0.44/100 woman-years)*
Every 3 months	1587	20,550	NA	3 (0.1/100 women after 12 months)**
Every 84 days (±5 days)	846	4782	NA	4 (0.7/100 woman-years)†

All drugs were administered in aqueous solution by intramuscular injection.
NA = not available

sponsored studies. In addition, 609 women were treated with Depo-Provera, 100 mg every 3 months. Thus, the contraceptive efficacy of Depo-Provera was assessed in a total of 7849 women, representing 122,496 patient-months of experience.

The racial distribution, between non-white and white women, was approximately equal in the Upjohn-sponsored studies, but racial distributions for the WHO-sponsored studies are unavailable. The methods used to report age statistics varied in different studies, but the mean or median subject age appears to have ranged from 23 years to 28 years. Similarly, statistics on parity were also reported differently, but the mean or median parity appears to have ranged from 2 to 4.

Pregnancy rates

All studies reported the 'use effectiveness' of Depo-Provera, which takes into account all pregnancies that occur while a woman is still using the method[7]. Failure rates were based on the number of pregnancies that occurred in women who were receiving Depo-Provera. Both 'method failures' (pregnancies occurring while the woman was using the method correctly) and 'patient failures' (pregnancies occurring while the woman was using the method incorrectly) were included in the calculations, but women who were pregnant on admission to the study were not included.

There is a wide body of scientific evidence demonstrating the contraceptive efficacy of Depo-Provera

Table 2 summarizes the failure rates in each of the five studies. Failure rates for Depo-Provera, 150 mg every 3 months, ranged from 0 (no pregnancies reported) to 0.22 pregnancies/100 woman-years, calculated by the Pearl Index, and from 0 to 0.7 pregnancies/100 women/year, calculated by life table analysis (though the WHO authors expressed the rate per 100 woman-years). In 86,228 patient-months of experience with Depo-Provera in the Upjohn-sponsored studies, 15 pregnancies were reported, representing a failure rate of 0.2/100 woman-years of use. In 36,268 patient-months of experience with Depo-Provera in the WHO-sponsored studies, 9 pregnancies were reported, 2 of which were in women receiving Depo-Provera, 100 mg every 3 months. Thus, in the Upjohn and WHO studies combined, there were only 24 pregnancies among 7849 women using Depo-Provera for 122,496 patient-months.

The first WHO study compared Depo-Provera at doses of 150 mg and 100 mg, each given once every 3 months[8]. Results suggested that the lower dose was less effective than the higher dose. Trials using Depo-Provera at doses of 250–500mg, administered once every 6 months, produced unacceptably high rates of pregnancy and therefore excluded the use of these higher dose, less frequently administered regimens.

In the second WHO study, Depo-Provera was compared with another injectable contraceptive, norethisterone enanthate (NET-EN)[9]. The failure rates for Depo-Provera, 150 mg every 3 months, were lower than for NET-EN, 200 mg, administered either every 60 days or every 60 days for the first 6 months and every 84 days thereafter.

The third WHO study was scheduled to run for 2 years, but was terminated after 1 year because the failure rate for NET-EN, 200 mg every 84 days, exceeded the maximum allowable rate of 2%[10]. The 12-month gross pregnancy rate for

Table 2
Failure rates in the multicenter studies of Depo-Provera

Reference	Dose regimen	Number of subjects	Number of pregnancies	Failure rate Life table analysis*	Failure rate Pearl Index**
Upjohn-sponsored studies					
18	150 mg in 3 ml every 3 months	3905	15	0.32	0.22
Unpublished	150 mg (50 mg in 3 ml) every 3 months	155	0	0.0	0.0
	150 mg in 1 ml every 3 months	140	0	0.0	0.0
WHO-sponsored studies					
8	150 mg in 1 ml every 3 months	607	0	0.0	0.0
	100 mg in 1 ml every 3 months	609	2	0.4	0.44
10	150 mg in 1 ml every 3 months	1587	3	0.1	Not done
9	150 mg in 1 ml every 84 days	846	4	0.7†	Not done

* Pregnancies/100 women after 12 months.
** Pregnancies/100 woman-years.
† Calculated by life-table analysis; however, the WHO authors expressed the rate in units of 'woman-years'.

Depo-Provera, 150 mg every 84 days, was estimated to be 0.7 ± 0.4/100 woman-years. The rates were calculated by life table analysis, but were expressed in units of 'woman-years'. Although this rate was higher than those reported in other trials of Depo-Provera at the same dose, it was significantly lower than the rate for NET-EN (3.6 ± 0.7/100 woman-years).

When the results of these five studies are compared with historic control data, it is clear that Depo-Provera, 150 mg every 3 months, provides users with highly effective contraception. Its use effectiveness is higher than that of oral contraceptives (OC), and comparable to that of implants[2,3] and surgical sterilization[7] (Figure 1).

Other studies of Depo-Provera's contraceptive efficacy. Another Upjohn-sponsored study examined the contraceptive efficacy of Depo-Provera, 150 mg once every 3 months[11]. This study comprised 100 healthy, postpartum women some of whom used Depo-Provera for up to 3 years. During the course of this study, no pregnancies were reported. Three other studies of Depo-Provera, 150 mg every 84 or 90 days, also reported results that were in close agreement with the results of the Upjohn-sponsored studies[12-14].

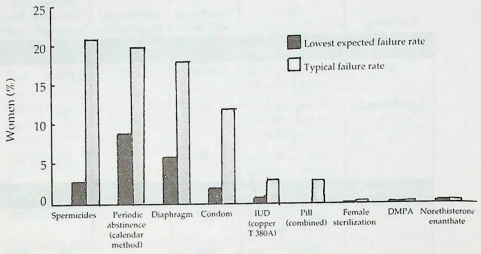


Figure 1
Contraceptive failure rates: percentage of women experiencing an accidental pregnancy in the first year of use (after Trussell and Kost[1])

Patient acceptance and continuation rates

Continuation rates reflect patient acceptance of this approach to contraception. Twelve-month continuation rates were determined by subtracting the discontinuation rate for all reasons (except protocol completion) from 100% and in the Upjohn and WHO multicenter trials, rates for Depo-Provera ranged from 49% to 71%. The rates reported for Depo-Provera were similar to those reported for NET-EN and indicate that, among women enrolled in a clinical trial, over half would continue using Depo-Provera after 12 months. Those who discontinued use did so in order to conceive, for medical or personal reasons, or because of contraceptive failure or side-effects.

Comparison with historic data on continuation rates for other reversible contraceptive methods suggest that Depo-Provera is well accepted in a variety of patient populations. Studies in Nigeria[15] and Thailand[16] reported 12-month continuation rates of 46.7% and 59.1%, respectively. The Thailand study also found a strong correlation between the desire not to have any more children and higher continuation rates: rates for those who did not desire any more children were about 50% higher than for those who did.

Return to fertility

Injectable contraceptives have not permanently affected fertility in the populations studied[17]; pharmacokinetic studies have correlated the return of ovulatory cycles with the decrease in serum levels of Depo-Provera. However, because return to fertility is commonly delayed beyond the end of the last 3-month injection period, some have thought that Depo-Provera causes irreversible suppression of ovulation. Unfortunately, these concerns have led some clinicians and family planning programs to prohibit the use of Depo-Provera in adolescent and nulliparous women.

Return to fertility following Depo-Provera use has been assessed in a number of ways. Several investigators have followed patients who discontinued Depo-Provera in order to conceive, and measured the time from the last

injection to conception. Other investigators have measured the time from last injection to first ovulation, using physiologic markers of ovulation.

Time from last injection to conception. In the first Upjohn-sponsored study (reference 18, Table 1), 193 (5%) of the 3905 women discontinued the study in an attempt to conceive. Out of 188 of these women, 114 (60.6%) became pregnant (based on chance, 89% would have been expected to conceive[9]) and 74 (39.4%) were either lost to follow-up or decided not to become pregnant[14]. Of the 114 who became pregnant and for whom data were available, 78 (68.4%) conceived within 12 months, and 95 (83.3%) within 15 months of their last injection: the median time from last injection to conception was 10 months, with a range of 4–31 months (Figure 2)[20]. When these findings were adjusted to reflect the 3-month period in which the drug was still active, the expected 12-month conception rate after discontinuing Depo-Provera was 82.8%, which was similar to that reported for OCs (87.0%) and intrauterine devices (IUD; 86.8%)[20].

Pardthaisong[21,22] compared the rates of return to fertility in a group of 796 Thai women using Depo-Provera, 150 mg every 3 months, with the rates for 437 OC users and 125 IUD users, all of whom discontinued their contraceptive method to become pregnant. The women were followed for up to 4 years after they discontinued use. Former Depo-Provera users had a longer median time to conception (10 months from the date of the last injection) than either former OC users (3 months) or IUD users (4.5 months). However, almost 70% of former Depo-Provera users had conceived within the first 12 months of discontinuation and over 90% had conceived within 24 months. Within 3 years of discontinuing contraception, fertility rates were similar in all groups.

These observations have important implications regarding patient counselling before Depo-Provera is initiated, because candidates need to be alerted to the possibility of a prolonged duration of contraception. Nevertheless, as

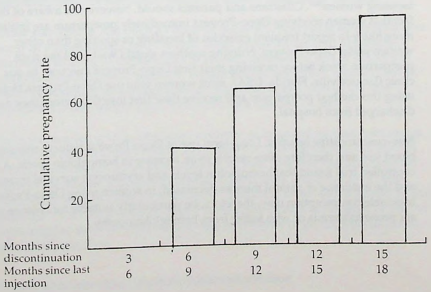


Figure 2
Fertility as determined by the pregnancy rate after discontinuation of Depo-Provera (after Schwallie and Mohberg[20])

Depo-Provera does not have any permanent impact on fertility, it is an appropriate choice for appropriately evaluated and counselled adolescent and nulliparous women interested in long-term contraception.

Duration of use. Neither age nor duration of Depo-Provera use appears to affect significantly the time to return of fertility[19,21]. In the Schwallie and Mohberg study (1974)[19], the average duration of infertility following the last injection was independent of patients' age or duration of Depo-Provera therapy. Comparable results regarding duration of Depo-Provera use were reported by Pardthaisong (1984)[21]. In that study, age also did not appear to affect the return of fertility until 5 months after Depo-Provera discontinuation; thereafter, fertility returned sooner in women under 25 years of age than in those aged 30–40 years[21]. This result is not unexpected, as fecundity declines with age – the proportion of women aged 15–24 years with impaired fecundity has been reported to be 4.8%, compared with 12.1% among women aged 35–44 years[23].

Data from Schwallie and Mohberg indicate that women with lower final body weights conceived sooner that those with higher body weights.

Benefits of Depo-Provera

The benefits of Depo-Provera include convenience, privacy and a reduction in menstrual blood flow

Contraceptive benefits. Depo-Provera is an appropriate contraceptive choice for many women and is particularly appealing to those who prefer the convenience of an injection once every 3 months to taking tablets daily or the use of barrier methods. Unlike non-degradable implants, such as Norplant, which must be surgically removed by a trained healthcare worker, Depo-Provera contraception can be discontinued by the woman herself; all that is required is a decision not to return for the next injection. If privacy is important, Depo-Provera offers several advantages, as no storing of contraceptive supplies is needed and no one other than the healthcare providers has any means of determining that injectable contraception is being used.

Depo-Provera can be used immediately postpartum[11,24] and has not been associated with problems of infant nutrition or development when used by lactating women[25,26]. Clinicians and patients should, however, be aware of the fact that women receiving Depo-Provera immediately postpartum are initially more likely to report frequent episodes of bleeding or spotting than other women using Depo-Provera. Nursing mothers should wait until the sixth postpartum week before receiving their first Depo-Provera injection. In our clinic (Jacksonville, Florida, USA), most women who use Depo-Provera begin using this method postpartum and receive their first injection before they are discharged from hospital.

Non-contraceptive benefits. Long-term use of Depo-Provera reduces menstrual blood loss and therefore often results in an increase in hemoglobin levels. A well controlled trial found that hemoglobin levels and erythrocyte survival increased, and the incidence of painful menses decreased, in women using Depo-Provera[27]. Injectable contraception may, therefore, be particularly suitable for women who are prone to anemia or who suffer from hemoglobinopathy.

Side-effects of Depo-Provera

Menstrual changes. The most commonly reported side-effect is a change in the menstrual bleeding pattern, which occurs in almost all women using Depo-Provera. Episodes of unpredictable, irregular bleeding and spotting, lasting 7 days or more, are common during the first few months of use. With increasing duration of use, the frequency and length of episodes of bleeding and spotting decrease, and amenorrhea becomes more common. Approximately 50% of women using Depo-Provera for 1 year report amenorrhea.

Menstrual changes are the most common cause of dissatisfaction with and discontinuation of Depo-Provera. This can, however, be markedly reduced by appropriate selection and education of users, as well as by supportive follow-up measures. Women who are uncomfortable, for whatever reason, with the menstrual changes that inevitably accompany the use of injectable contraception, should be counselled to choose alternative methods. In many cases, however, concerns about menstrual changes result from anxiety about pregnancy or gynecologic disease. Thus, well informed and supportive healthcare providers, who give easy access to follow-up counselling and evaluation, can do much to promote women's satisfaction and contraceptive continuation. In the author's experience, many women using Depo-Provera view amenorrhea as one of the favorable aspects of their contraceptive choice.

Patient education and support do much to promote acceptance of the menstrual changes that accompany injectable contraception

Medical intervention for irregular bleeding is seldom necessary for women using Depo-Provera. In cases of reported heavy or persistent abnormal bleeding, gynecologic evaluation to exclude unrelated conditions, such as vaginitis, cervicitis or cervical lesions, is appropriate. Treatment with oral estrogen (e.g. conjugated estrogen, 1.25–2.5 mg/day for 10–21 days) will minimize or eliminate the bleeding[28] but it often recurs after discontinuing estrogen. However, even in women reporting continuous, heavy, vaginal bleeding, anemia is uncommon and, if not present, counselling and reassurance of the woman is more appropriate than estrogen therapy. An alternative type of contraception, rather than medical or surgical intervention is the solution for women who are persistently dissatisfied with the menstrual changes. Dilatation and curettage has little role in the management of menstrual changes in women using Depo Provera.

Other side-effects. Although a variety of minor and reversible side-effects may occur in women using Depo-Provera, major problems are rare. Headache, dizziness, bloating of the abdomen or breasts, depression, loss of libido, and alopecia are occasionally reported. Weight gain is commonly reported and in study populations, an average gain of 5.4 pounds after 1 year of use was reported. Further weight gains with continued use may occur*.

As in women using OCs, laboratory evidence of impaired glucose tolerance is sometimes seen in Depo-Provera users, but overt glucose intolerance seldom occurs. Women with a history of diabetes should, however, be monitored for signs of the disease. Changes in hepatic transaminase levels have not been reported in women using Depo-Provera[29], including those with a history of viral hepatitis[30]. Very high doses of Depo-Provera may induce cushingoid facies, but contraceptive doses do not produce clinical evidence of glucocorticoid excess or adrenal suppression.

* Please refer to package insert for further information.

Patient selection

The contraceptive efficacy of Depo-Provera has not been found to be affected by the patient's weight or the use of concurrent medications. Women who are taking antibiotics or anticonvulsant medications, however, require careful observation.

Appropriate candidates for Depo-Provera. Depo-Provera may be an ideal contraceptive for women seeking a highly effective method of birth control but who have experienced problems with other reversible methods. This includes women who have difficulty in remembering to take pills, who prefer the convenience of injections, or who experience side-effects, such as nausea, when using OCs. Others may select Depo-Provera because medical factors preclude the use of oral or intrauterine contraception, or because Depo-Provera offers

Table 3
Medical conditions and special situations in women that make the use of Depo-Provera contraception appropriate

- Postpartum
- Conditions in which the use of estrogen-containing contraceptives may be inadvisable:
  - migraine headaches
  - hypertension
  - systemic lupus erythematosus
  - valvular heart disease
  - age greater than 35 years, combined with smoking
- Conditions in which Depo-Provera may offer additional non-contraceptive benefits:
  - menorrhagia/leiomyomata uteri
  - endometriosis/dysmenorrhea
  - hemoglobinopathy
- Concomitant use of anticonvulsants or antibiotics that may reduce oral or implantable contraceptive efficacy:
  - phenytoin
  - phenobarbital
  - carbamazepine
  - primidone
  - rifampin
- Conditions in which poor compliance with other contraceptive methods may occur:
  - psychosis
  - mental retardation
  - intravenous drug abuse
  - adolescence
- Conditions in which pregnancy poses specific fetal risks:
  - use of teratogenic medications such as isotretinoin, oral anticoagulants and valproic acid
  - human immunodeficiency virus infection/AIDS

non-contraceptive benefits to their condition. In some women, use of concomitant medications may reduce the efficacy of oral or implantable contraception and others are at risk of non-compliance when using oral or barrier contraception. Finally, pregnancy poses specific fetal risks in some women. Examples of conditions and situations that place women in these groups are listed in Table 3.

Inappropriate candidates for Depo-Provera. Depo-Provera is not suitable for women who may want to become pregnant in the next 1–2 years, who are not prepared to accept menstrual changes or amenorrhea, or who are unwilling or unable to receive injections every 3 months. Contraindications also include undiagnosed vaginal bleeding, urinary tract bleeding, breast pathology and pregnancy.

References

1. Richard BW, Lasagna L. Drug regulation in the USA and the UK: the Depo-Provera story. *Ann Intern Med* 1987; 106: 886–91.
2. Liskin L, Blackburn R, Ghani R. Hormonal contraception: new long-acting methods. *Popul Rep* 1987; 15: 58–87.
3. Mishell DR. Long-acting contraceptive steroids, postcoital contraceptives and antiprogestins. In: *Infertility, Contraception, and Reproductive Endocrinology.* (Mishell DR Jr, Davajan V, Lobo RA, eds). Boston: Blackwell Scientific Publications, 1991; 872–94.
4. Siriwongse T, Snidvongs W, Tantayaporn P, Leepipatpaiboon S. Effect of depo-medroxyprogesterone acetate on serum progesterone levels when administered on various cycle days. *Contraception* 1982; 26:487.
5. Ortiz A, Hiroi M, Stanczyk FZ, Goebelsmann U, Mishell DR Jr. Serum medroxyprogesterone acetate (MPA) concentrations and ovarian function following intramuscular injection of Depo-MPA. *J Clin Endocrinol Metab* 1977; 44: 34–8.
6. Wright CE, Antal EJ, Gillespie WR, Albert KS. Effect of injection volume on the bio-availability of sterile medroxyprogesterone acetate suspension. *Clin Pharmacol* 1983; 2: 435–8.
7. Trussell J, Kost K. Contraceptive failure in the USA: a critical review of the literature. *Stud Fam Plan* 1987; 18: 237–83.
8. WHO Task Force on Long-Acting Systemic Agents for Fertility Regulation, Special Programme of Research, Development, and Research Training in Human Reproduction. A multicentered phase III comparative clinical trial of depot-medroxyprogesterone acetate given in three-monthly doses of 100 mg or 150 mg: 1. Contraceptive efficacy and side effects. *Contraception* 1986; 34: 22–35.
9. WHO Expanded Programme of Research, Development, and Research Training in Human Reproduction, Task Force on Long-Acting Systemic Agents for the Regulation of Fertility. Multinational comparative clinical evaluation of two long-acting injectable contraceptive steroids: norethisterone enanthate and medroxyprogesterone acetate. 1. Use-effectiveness. *Contraception* 1977; 15: 513–33.
10. WHO Task Force on Long-Acting Systemic Agents for Fertility Regulation, Special Programme of Research, Development, and Research Training in Human Reproduction. Multinational comparative clinical trial of long-acting injectable contraceptives: norethisterone enanthate given in two dosage regimens and depot-medroxyprogesterone acetate. A final report. *Contraception* 1983; 28: 1–20.
11. Mishell DR, El-Habashy MA, Good RG, Moyer DL. Contraception with an injectable progestin: a study of its use in postpartum women. *Am J Obstet Gynecol* 1968; 101: 1046–53.
12. Salem HT, Salah M, Aly MY, Thabet AI, Shaaban MN, Fathalla MF. Acceptability of injectable contraceptives in Assiut, Egypt. *Contraception* 1988; 38: 697–710.
13. Castle WM, Sapire KE, Howard KA. Efficacy and acceptability of injectable medroxyprogesterone. A comparison of 3-monthly and 6-monthly regimens. *S Afr Med J* 1978; 53: 843–5.
14. Chinvanthananond P, Samransamruajkit S. New regimen of injectable contraceptives. *J Med Assoc Thai* 1987; 70: 198–203.

15. Fakeye O. Contraception with subdermal levonorgestrel implants as an alternative to surgical contraception in Ilorin, Nigeria. *Int J Gynecol Obstet* 1991; 35: 331–6.

16. Narkavonnakit T, Bennett T, Balakrishan TR. Continuation of injectable contraceptives in Thailand. *Stud Fam Plan* 1982; 13: 99–105.

17. Fotherby K, Howard G. Return of fertility in women discontinuing injectable contraceptives. *J Obstet Gynecol* 1986; 6(suppl 2): S110–S115.

18. Schwallie PC, Assenzo JR. Contraceptive use-efficacy study utilizing medroxyprogesterone acetate as an intramuscular injection once every 90 days. *Fertil Steril* 1973; 24: 331–9.

19. Schwallie PC, Mohberg NR. Medroxyprogesterone acetate: an injectable contraceptive. *Adv Planned Parenthood* 1974, 12: 36–44.

20. Schwallie PC, Assenzo JR. The effect of depo medroxyprogesterone acetate on pituitary and ovarian function, and the return of fertility following its discontinuation: a review. *Contraception* 1977; 10: 181–202

21. Pardthaisong T. Return of fertility after use of the injectable contraceptive Depo-Provera: up-dated data analysis. *J Biosoc Sci* 1984; 16: 23–34.

22. Pardthaisong T, Gray RH, McDaniel EB. Return of fertility after discontinuation of depot medroxyprogesterone acetate and intrauterine devices in Northern Thailand. *Lancet* 1980; i: 509–12.

23. Mosher WD, Pratt WF. Fecundity and infertility in the USA, 1965–88. *Adv Data* 1990; 192: 1–12.

24. Jones JR, Lonky S. Use of injectable contraceptive immediately post partum. *NY State J Med* 1971; 71: 2279–82.

25. Karim M, Ammar R, Mahgoub SE, Ganzhoury BE, Fikri F, Abdou I. Injected progestogen and lactation. *Br Med J* 1971; 1: 200–3.

26. Jimenez J, Ochoa M, Soler MP, Portales P. Long-term follow-up of children breast-fed by mothers receiving depot-medroxyprogesterone acetate. *Contraception* 1984; 30: 523–33.

27. De Ceulaer K, Gruber LA, Hayes R, Sargent GT. Medroxyprogesterone acetate and homozygote sickle-cell disease. *Lancet* 1982; ii: 229–31.

28. Speroff L, Glass RH, Kase NG. Dysfunctional uterine bleeding. In: *Clinical gynecologic endocrinology and infertility*. 4th ed. Baltimore: Williams & Wilkins, 1989: 265–82.

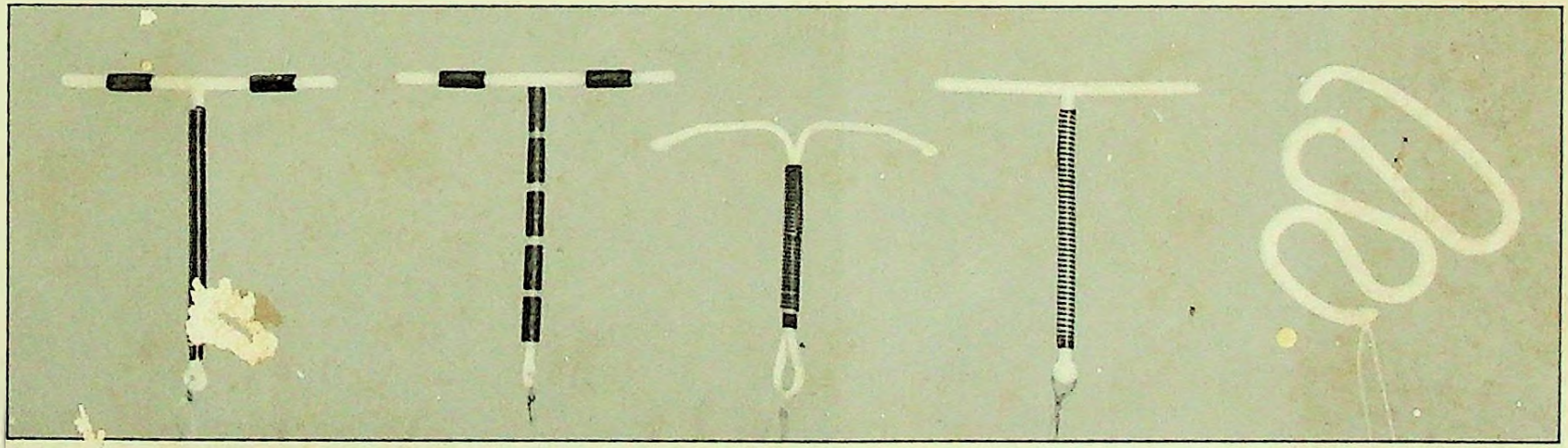
29. Tankeyoon M, Dusitsin N, Poshyachinda V, Larsson-Cohn U. A study of glucose tolerance, serum transaminase and lipids in women using depot-medroxyprogesterone acetate and a combination-type oral contraceptive. *Contraception* 1976; 14: 199–214.

30. Mark I. Medroxyprogesterone acetate as a contraceptive for female drug addicts. *Scand J Soc Med* 1983; 11: 75–80.

31. Emans SJ, Grace E, Woods ER *et al.* Adolescents' compliance with oral contraceptives. *JAMA* 1987; 257: 3377.

WH-3.

FIVE INTRAUTERINE DEVICES FOR PUBLIC PROGRAMS



THE POPULATION COUNCIL

THE POPULATION COUNCIL has played a major role in developing and evaluating intrauterine devices (IUDs). As a result of the Council's work, five IUDs are now available to governments and nonprofit agencies in developing countries at prices well below those quoted commercially. The five IUDs are:

the Copper T 380
the Copper T 220
the Nova T
the Copper T 200
the Lippes Loop

Three versions of the Copper T—the 380 (Model TCu 380A), the 220, and the Nova T—appear to be among the world's most effective IUDs, having annual pregnancy rates near 1 per 100 users. Under conditions that prevail in many developing countries, the use-effectiveness offered by these new IUDs is expected to be equal or superior to that provided by oral contraceptives. Based on current evidence, these three IUDs can be used by women without needing to be replaced for at least 15 years.

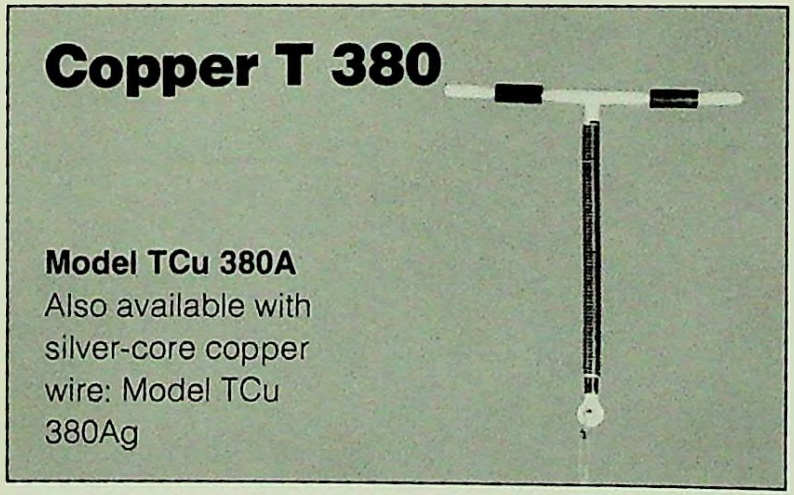
These devices are now being made available to public sector programs at low cost in both bulk-packaged and individually packaged forms. This booklet provides information about them and where and how they can be obtained.

The Population Council's long involvement in IUD development has helped to make available other IUDs as well at low cost to public sector programs. Two of these IUDs—the Copper T 200 and the Lippes Loop—are also described in this booklet for programs that may wish to use them.

Copper-bearing IUDs have gained widespread use since their development in the early 1970s. Various types of copper-bearing IUDs have been approved by regulatory agencies in both developed and developing countries. Based on clinical studies, field experience, and on the results of toxicological and teratological investigations, Copper T IUDs appear as safe as nonmedicated IUDs.

Details of the investigations carried out by the Population Council, as well as manufacturing and packaging procedures and specifications, are available to public agencies from the Population Council upon request.

IUDS AVAILABLE AT LOW COST TO THE PUBLIC SECTOR



The Copper T 380 consists of a plastic T with copper collars on its horizontal arms and tightly wound copper wire on the vertical stem. Total surface area of the copper is 380 sq. mm. The Copper T 380 is the most effective IUD ever developed by the Population Council, with an annual pregnancy rate below 1 per 100 users per year. In Population Council studies, this de-

Two-Year Comparison of the Copper T 380 and Copper T 200 among Parous Women

Two-year rates per 100 women	Device		Statistically significant difference
	Copper T 380	Copper T 200	
Pregnancy	0.8	5.4	Yes
Expulsion	9.2	6.9	No
Removals for bleeding & pain	22.8	20.1	No
Removals for other medical reasons	4.7	4.0	No
Continuation of use	50.5	49.9	No

Source: Sivin and Stern, 1979.

vice exhibited a *cumulative* pregnancy rate of only 1.9 per 100 users at the end of four years of use.

In its other performance characteristics, the Copper T 380 is very similar to the Copper T 200.

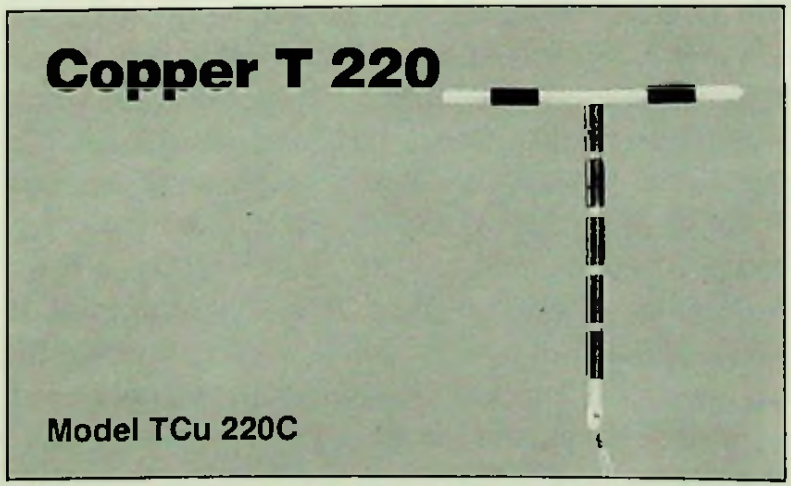
Because Copper T devices are smaller than most nonmedicated devices such as the Lippes Loops C and D, they are somewhat easier to insert and are better tolerated by women who have never borne a child. Among such women, rates of removal for bleeding and pain have been higher for the Copper T 380 than those observed for the Copper T 200.

There are no important differences between the Copper T 380 and either the Copper T 200 or the Lippes Loop regarding rates of uterine perforation, ectopic pregnancy, or pelvic inflammatory disease.

Part of the contraceptive effectiveness of all copper IUDs comes from the minute quantities of copper that slowly dissolve in the uterine environment. Since this causes the copper wire to become depleted, the Copper T 380 should be replaced with a new device after six years. The Copper T 380 is also made with a copper wire containing a core of silver (Model TCu 380Ag). Because the silver core prevents the wire from developing breaks as the copper dissolves, theoretically the effective lifetime of this device is extended by at least 10 years for a total of at least 16 years of effective use. Programs wishing to select the silver-core copper wire should specify this preference when purchasing the device.

The Copper T 380 is manufactured with a plastic ball at the bottom of the vertical stem; the ball is intended to guard against cervical penetrations.

The Population Council is preparing a formal request to the US Food and Drug Administration for approval of the Copper T 380 with silver-core wire (Model TCu 380Ag).



This Copper T device consists of a plastic T surrounded by seven solid copper collars: two on the horizontal arms and five on the vertical stem. The Copper T 220 is much more effective than either the Copper T 200 or Lippes Loop D, and it is nearly as effective as the Copper T 380.

In addition to being more effective, the Copper T 220 is expelled less frequently and has had lower removal rates for bleeding and pain than the Loop D.

Two-Year Comparison of the Copper T 220 and Lippes Loop D among Parous Women

Two-year rates per 100 women	Device		Statistically significant difference
	Copper T 220	Lippes Loop D	
Pregnancy	1.2	3.3	Yes
Expulsion	6.6	10.0	Yes
Removals for bleeding & pain	8.8	12.9	Yes
Continuation of use	70.2	66.6	No

Source: Snell and Stark, 1979

There are no major differences in the rates of uterine perforation or pelvic inflammatory disease between the Copper T 220 and either the Lippes Loop D or Copper T 200. In the United States, the ectopic pregnancy rate observed with a Copper T 220 has been marginally higher than that of other copper IUDs or nonmedicated devices. In European studies of the Copper T 220, the rate has been similar to that reported for nonmedicated devices.

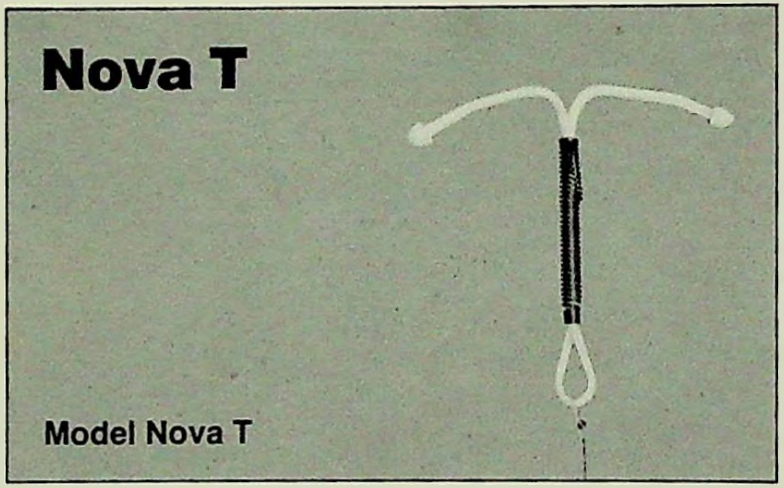
Based on the rate of copper loss, the Copper T 220 is expected to remain fully effective for the reproductive life of the user. At present, clinical studies to determine the effective lifetime of this device extend to six years.

The Population Council is not seeking US Food and Drug Administration approval for the Copper T 220 device in view of the greater effectiveness of the Copper T 380 device. However, because of the positive results obtained with the Copper T 220 in clinical trials conducted by both the World Health Organization and the Population Council, it is available to public programs that desire to use it.

Two-Year Comparison of the Copper T 220 and Copper T 200 among Parous Women

Two-year rates per 100 women	Device		Statistically significant difference
	Copper T 220	Copper T 200	
Pregnancy	2.2	6.0	Yes
Expulsion	6.0	7.1	No
Removals for bleeding & pain	15.9	15.2	No
Removals for other medical reasons	6.8	5.4	No
Continuation of use	58.5	54.6	No

Source: World Health Organization, 1979



Developed and tested in Scandinavia, this device utilizes a modified plastic T with silver-core copper wire on the vertical stem; total copper surface area is 200 sq. mm. Plastic knobs on the ends of the horizontal arms and a small loop on the vertical stem are designed to minimize uterine penetrations.

The Nova T appears to offer higher effectiveness than the Copper T 200.

The Nova T and the Copper T 200 exhibit similar clinical performance with respect to expulsion rates and removals for medical reasons.

Two-Year Comparison of the Nova T and Copper T 200 among Parous and Nulliparous Women

Two-year rates per 100 women	Device		Statistically significant difference
	Nova T	Copper T 200	
Pregnancy	1.4	3.6	Yes
Expulsion	6.9	5.4	No
Removals for bleeding & pain	17.4	15.5	No
Removals for other medical reasons	6.0	5.8	No
Continuation of use	60.2	63.6	No

Source: Allonen et al., in preparation.

The Nova T is made with silver-core copper wire, which prevents the copper from fragmenting as it dissolves. Theoretically, the effective lifetime of this Nova T device should be about 15 years.

Approval of the Nova T by the US Food and Drug Administration has not been requested. The device is available in most Scandinavian countries, and is approved by their regulatory agencies.

INSERTION OF COPPER T IUDS FOLLOWING CHILDBIRTH OR ABORTION

Most IUD insertions are performed several months after delivery or termination of pregnancy. IUDs also can be inserted immediately following childbirth, but they exhibit much higher expulsion rates under such conditions.

IUDs can be inserted immediately after a therapeutic abortion. Copper T devices appear to be superior to the Lippes Loop under such circumstances:

Two-Year Comparison of the Copper T 220 and Lippes Loop D Inserted Immediately Following Therapeutic Abortion

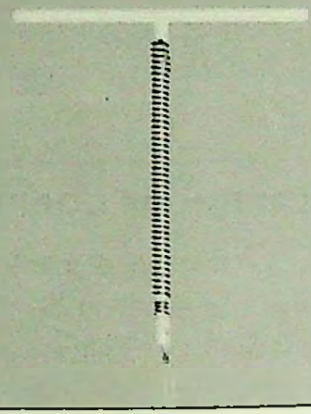
Two-year rates per 100 women	Device		Statistically significant difference
	Copper T 220	Lippes Loop D	
Pregnancy	2.0	4.7	Yes
Expulsion	3.9	9.3	Yes
Removals for bleeding & pain	11.2	14.8	No
Continuation of use	71.6	63.4	Yes

Source: World Health Organization. 1979.

Copper T 200

Model TCu 200B
Also available with silver-core copper wire: Model TCu 200B-Ag

Model TCu 200
Also available with silver-core copper wire: Model TCu 200Ag



The Copper T 200, the earliest Copper T, consists of a plastic T with a coil of copper wire 200 sq. mm. in surface area wrapped around its vertical stem.

Like other Copper Ts, the device is easy to insert in women who have never borne a child, and is better tolerated by such women than the larger nonmedicated plastic devices. Comparative studies of the Copper T 200 and Lippes Loop D show little difference in effectiveness between the two devices. But menstrual blood loss is significantly less with the Copper T 200.

There are no important differences between the Copper T 200 and Lippes Loop regarding rates for uterine perforations, ectopic pregnancies, or pelvic inflammatory disease.

The Copper T 200 made with copper wire should be replaced with a new device every three to four years. The Copper T 200 is now available with copper wire containing a core of silver, which prevents the wire from fragmenting as the copper dissolves. Theoretically, the silver-core wire should add at least 10 years of effectiveness to the device. Programs wishing to select the silver-core copper wire should specify this preference when purchasing the device.

The Copper T 200, Model TCu 200B, has been approved by the US Food and Drug Administration. This device is manufactured with a plastic ball at the bottom of the vertical stem. The ball does not significantly influence performance of the device, but may offer protection against possible cervical penetrations. The Copper T 200 is also available without the ball (Model TCu 200). Both models also can be obtained with silver-core copper wire (Models TCu 200B-Ag and TCu 200Ag, respectively).

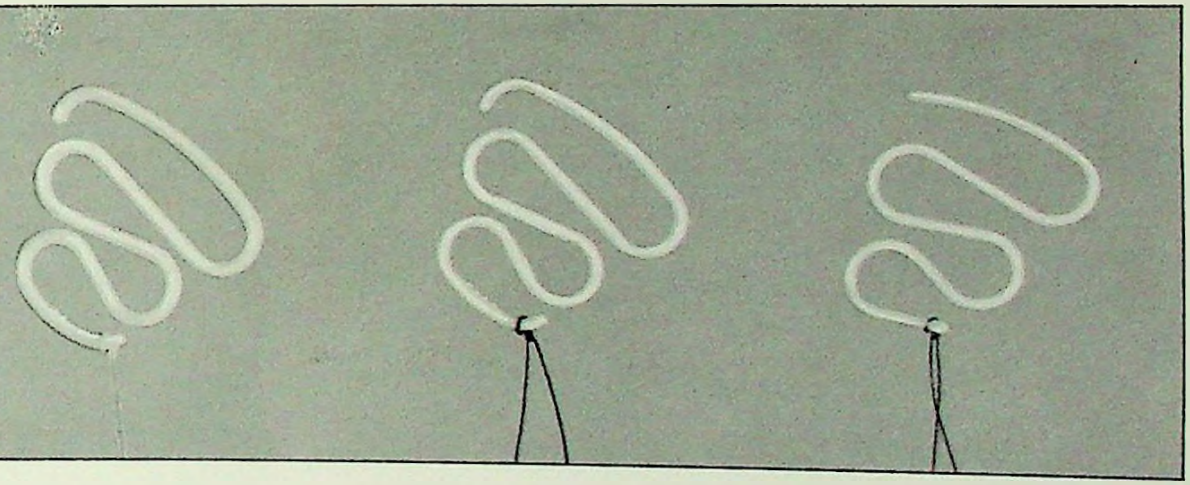
IUD SHELF LIFE

Unless directly exposed to light, freezing temperatures, or extremely high temperatures, Lippes Loops and Copper T IUDs can be stored without deterioration for many years, since the plastic and copper are very stable

In an accelerated stability study, Copper T 200 devices were rigorously analyzed and tested after being stored in the dark at 50°C and low humidity for 36 months. No important physical changes in the devices were detected.

Nor does prolonged storage appear to affect the sterility of individually packaged devices. Full sterility was retained after three years of storage at 37°C and 80% relative humidity or 50°C and variable humidity. Based on this research, individually packaged, presterilized Copper Ts should remain sterile for many years of storage as long as the plastic pouch remains sealed and no moisture enters the pouch. The cardboard shipping boxes are not waterproof, however, and should be stored in dry places away from any direct contact with water.

Lippes Loop



Models D, B, and A
Model C is the same size as Model D, with flattened inner curves

This nonmedicated plastic device is used throughout the world. Four models—A, B, C, and D—are available. Loop D is considered the standard against which the performance of other devices is measured. Loop C is the same size but more flexible, and is recommended for insertion in women who have had the Loop D removed because of excessive bleeding or pain. Loop B is smaller in size, and is recommended for women with small uteri who have had a previous pregnancy or for women who have had a miscarriage. Loop A is the smallest size, and is recommended for women who have never had children.

Although some newer intrauterine devices have proved to be more effective, Lippes Loop models C and D provide excellent protection and exhibit high continuation rates among women age 35 and over. The effective lifetime of Lippes Loop devices is probably in excess of 15 years. Because it is made of nonmedicated plastic, the device has not required US Food and Drug Administration approval.

HOW PUBLIC PROGRAMS CAN OBTAIN THESE IUDS

The Population Council does not sell or supply the IUDs described in this announcement, but it has ensured that supply channels are available. Public health and family planning programs in developing countries can obtain these IUDs in two ways: through commodity grants from international assistance organizations or by direct purchase from manufacturers.

COMMODITY GRANTS

Some international assistance organizations provide contraceptive commodities to public programs upon request. Programs should direct inquiries to such agencies:

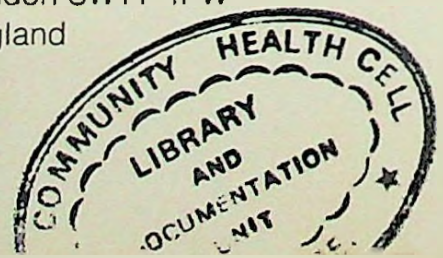
The Agency for International Development (USAID) supplies Lippes Loops and USFDA-approved copper IUDs. Inquiries should be made to the AID mission representative attached to the local US embassy.

Family Planning International Assistance (FPIA) supplies IUDs to some family planning programs. Contact the regional directors of FPIA in Nairobi, Manila, Dacca, or Bogota or write to:

Chief Operating Officer
Family Planning International Assistance
810 Seventh Avenue
New York, New York 10019
USA

The International Planned Parenthood Federation (IPPF) is able to supply IUDs to some family planning programs. Write to:

Dr. Carl Wahren, Secretary-General
International Planned Parenthood Federation
18-20 Lower Regent Street
London SW1Y 4PW
England



The Pathfinder Fund supplies IUDs to some family planning programs. Contact the regional representatives of the Pathfinder Fund in Jakarta, Dacca, Bogota, Santiago de Chile, Salvador (Brazil), Cairo, or Nairobi or write to:

Mr. Howard Gray, Executive Director
The Pathfinder Fund
1330 Boylston Street
Chestnut Hill, Boston, Massachusetts 02167
USA

The United Nations Fund for Population Activities (UNFPA) considers requests for IUDs from governments or other agencies having local government approval. Write to:

Mr. Dennis Badham
United Nations Fund for Population Activities
485 Lexington Avenue
New York, New York 10017
USA

PURCHASE FROM MANUFACTURERS

As a result of agreements with the Population Council, the manufacturers listed below will sell the intrauterine devices described in this announcement at reduced cost to public governmental programs and nonprofit institutions that supply devices free of charge or at nominal cost to women in developing countries. (Profit-making organizations do not qualify for purchase at these reduced prices.)

Supplier	IUDs Offered	
	Type of IUD	Model Number
Biotec Laboratories Prolongacion Sanctorum 5 Naucalpan, Edo, de Mexico Att: Lic. Benigno Estrado	Copper T 220	TCu 220C
Finishing Enterprises, Inc. (Formerly Hallmark Plastics, Inc.) 908 Niagara Falls Boulevard North Tonawanda, New York 14120 Att: Mr. Paul Bronnenkant	Lippes Loop Copper T 200	A, B, C, D TCu 200B
Niagara Hallmark Devices 4536 Portage Road Niagara Falls, Ontario, Canada Att: Mr. Paul Bronnenkant	Copper T 380 Copper T 220 Copper T 200	TCu 380A TCu 380Ag TCu 220C TCu 200 TCu 200Ag TCu 200B TCu 200B-Ag
Ortho Pharmaceutical Corporation Route 202 Raritan, New Jersey 08869 Att: Mr. D. K. Wemlinger	Lippes Loop	A, B, C, D
Ortho Pharmaceutical (Canada) Ltd. 19 Green Belt Drive Don Mills Ontario M3C 1L9, Canada Att: Mr. Eric Milledge	Lippes Loop Copper T 200	A, B, C, D TCu 200
Outokumpu Oy Box 60 SF-28201 Pori 10 Finland	Copper T 380 Nova T Copper T 200	TCu 380Ag Nova T TCu 200 TCu 200Ag TCu 200B TCu 200B-Ag
Pharmaceutical Plant Leiras P.O. Box 415 SF 20101 Turku, Finland Att: Mrs. Soili Jarvela	Copper T 380 Nova T Copper T 200	TCu 380Ag Nova T TCu 200 TCu 200Ag TCu 200B TCu 200B-Ag
Schering AG P.O. Box 650311 D-1 Berlin 65 West Germany Att: Mr. Degen	Copper T 200	TCu 200

USE OF BULK-PACKAGED IUDS

IUDs may be packaged in two ways: either in bulk as nonsterile lots, or individually, as complete, presterilized units, with inserters. Bulk packaging is cheaper, and bulk-packaged IUDs can be transported and stored more readily. IUDs packaged as complete, presterilized units are more convenient for immediate use, however, since they eliminate the need for sterilization procedures prior to insertion. In comparative field trials, no significant difference in rate of removal of devices because of pelvic infection was detected between bulk-packaged units (Lippes Loop) or individually packaged, presterilized units (TCu 200).

Clinic personnel using bulk-packaged IUDs should be trained in appropriate sterilization procedures and the proper technique for loading and assembling of the sterilized components prior to insertion. Before insertion, all components—IUD, inserter tube, movable flange, and plunger—should be submerged completely in an antimicrobial solution (such as one part of benzalkonium chloride, Zephiran®, in 750 parts water) for at least 30 minutes. Prolonged submersion of copper IUDs will result in some discoloration of the copper but this will not affect the performance of the IUD. Solutions containing iodine are not recommended for sterilization of copper IUDs because of their oxidizing properties. Iodine solutions may be used for sterilizing Lippes Loops, however.

If inserters are to be reused, they should be thoroughly cleansed in water immediately after the insertion procedure and then replaced in the antimicrobial solution. Because the shape of the insertion tube may become distorted after repeated use, no more than five insertions are recommended for each tube. The plungers and movable flanges may be reused many times without distortion.

One-Year Termination Rates for Pelvic Infection, Copper T 200 and Lippes Loop D among Parous Women

Country	Individually packaged, presterilized Copper T 200	Bulk-packaged Lippes Loop D
Colombia	0.5	0.5
Iran	1.7	0.8
Korea	0.8	1.2
Philippines	1.5	0.5
Thailand	0.3	0.7

Source: Sivin, 1976, 1975.

Lippes Loops and Copper T devices are available in unsterilized bulk lots or as individual, presterilized units. The individually packaged IUDs come with an inserter in each package, along with instructions and information on use of the IUD. The instructions are usually printed in English, but some suppliers can provide printing in different languages, usually at added cost. Bulk-packaged unsterilized inserters are available for use with bulk-packaged IUDs.

Prices vary somewhat from manufacturer to manufacturer. Also, they depend on the size of the order and the type of packaging, labeling, and shipment required. Not all manufacturers offer all IUDs. Furthermore, delivery, packaging, labeling, and other supply matters vary from manufacturer to manufacturer.

The approximate price of inserters suitable for the various IUDs is US$0.10 each.

Programs interested in purchasing IUDs are advised to request information about availability, cost, terms, storage instructions, and other aspects of supply directly from the manufacturers listed above and to select the supplier that best meets their needs.

Approximate Prices in US Dollars for Single IUD (August, 1979)

Device	Individually prepackaged sterile units with inserter	Bulk-packaged (without inserter, unsterilized)
Copper T 380	$0.80-1.20	$0.35
Copper T 220	$0.85-1.20	$0.50
Nova T	$1.20	not yet determined
Copper T 200	$0.65-1.20	$0.20
Lippes Loop	$5.00	$0.08-0.16

SOURCES

Allonen, H., Luukkainen, T., Nielsen, N C., Nygren, K.-G. and T. Pyorala. "Two year rates for Nova T," paper in preparation.

Jain, A.K. "Safety and effectiveness of intrauterine devices," *Contraception*, 11, no. 3, 1975.

Jain, A.K. and I. Sivin. "Lifetable analysis of IUDs: Problems and recommendations," *Studies in Family Planning*, 8, no. 2, 1977.

Luukkainen, T., Nielsen, N.C., Nygren, K.-G., Pyorala, T. and A. Kosonen. "Randomized comparison of clinical performance of two copper releasing IUDs. Nova T and Copper T 200 in Denmark, Finland and Sweden." *Contraception*, 19, no. 1, 1979.

Roy, S., Casagrande, J., Cooper, D.L. and D.R. Mishell, Jr. "Comparison of three different models of the Copper T intrauterine device," *American Journal of Obstetrics and Gynecology*, 134, no. 5, P. 568-574, 1979.

Sivin, I. "A comparison of the Copper T 200 and the Lippes Loop in four countries," *Studies in Family Planning*, 7, no. 4, 1976.

Sivin, I. Interoffice memorandum, 23 May 1975.

Sivin, I. and J. Stern. "Long acting more effective copper T IUDs," *Studies in Family Planning*, 10, no. 10, 1979.

Tatum, H.J. "Comparative experience with newer models of the Copper T in the U.S.," *Analysis of Intrauterine Contraception*, Segal, S.J. and F. Hefnawi, eds. North Holland/American Elsevier, 1975.

Tatum, H.J. "Intrauterine contraception," *American Journal of Obstetrics and Gynecology*, 112, P. 1000-1023, 1972.

Thiery, M., Van der Pas, H., Van Kets, H., Boogers, W., Haspels, A. and J.J. Amy. "Four years' experience with the TCu 220C, a long-acting multisleeved copper intrauterine device," *Advances in Planned Parenthood*, XIV, no. 1, 1979.

Tietze, C. and S. Lewit. "Comparison of the Copper T and Loop D: A research report," *Studies in Family Planning*, 3, no. 11, 1972.

Tietze, C. and S. Lewit. "Evaluation of intrauterine devices: Ninth progress report of the Cooperative Statistical Program," *Studies in Family Planning*, 1, no. 55, 1970.

World Health Organization HRP/79.1 Rev. 1, 1979.

Zipper, J., Medel, M., Goldsmith, A. and D.C. Edelman. "Six year continuation rates for Cu T 200 users." *Journal of Reproductive Medicine*, 18, no. 2, 1977.

This booklet is intended as a brief overview of currently available data and is not intended to serve as a full presentation of all the safety, efficacy, and other data concerning these IUDs. More detailed technical information is available and may be specifically requested from:

The Population Council
Center for Biomedical Research
The Rockefeller University
1188 York Avenue
New York, New York 10021

THE POPULATION COUNCIL
One Dag Hammarskjold Plaza
New York, New York 10017

Printed in the U.S.A.