CONTRACEPTIVE RESEARCH IN INDIA

Testing on Women

kusha

Field trials to determine the efficacy and safety of a particular contraceptive are very often carried out in a dubious manner in the third world on woman from the deprived sections of society. Research institutes are either coerced or tempted by international funding agencies (sometimes through the government) and are used as laboratories to test out potentially dangerous contraceptives The author relates her experiences in a contraceptive testing unit (CTU) located in the working class area of central Bombay. Inspite of visible side effects, contraceptives ranging from diaphragms to hormonal implants to injectable contraceptives as well as new drugs to induce abortion (MTP) were tested on women in exchange for a modest monetary incentive.

Introduction

Family welfare programmes have to be committed to the emanicipation of women and their being accepted as equal partners in decision making in all spheres of developmental activities. International women's year has created a widespread awareness of the inequalities between men and women. It threw light on the steady decline of women in the labour force, and on the poor participation of women in socio-economic and political activities. The report on the status of women brought out the urgeney of providing facilities for training women and to provide an opportunity for their access to sources including tools and skills so that they could enhance their contribution to their family and to society.

In the field of family planning, it is important to understand the acceptability of a particular contraceptive, reasons for choosing one method over the other and assess what makes women and men continue or discontinue using a method of their choice. It is also important that family planning education is given to both men and women emphasising the inter-relationship between family planning and the status of women, since it is a recognised fact that the status of women directly influences the acceptance of family planning. At the same time the availability of family planning education directly contributes to the status of women by conferring on her a basic human right to choose.

The term 'family planning' was changed to 'family welfare' on this basis and entirely on the premise that when an eligible couple is contacted for family planning, it is the 'couple' who equally share the responsibility of deciding the type of contraceptive they will use, the number of children they will have and when to have them. What is generally happening in reality in the field of family welfare is just the opposite. The ideal contraceptive, acceptable to all people from different strata of society, at the same time being harmless, effective, easy to use, easily available and cheap simply does not exist, at present. What is more disturbing is that research towards attaining this ideal is also not given priority.

Goverment Policies

The initial approach of setting up clinics in different parts of the country and waiting for people to accept fertility regulating methods (FRM) was based on the several so-called (KAP) studies which indicated family planning acceptance. However, the policies of the government changed from time to time due to pressures from foreign government and non-government agencies mostly from the west since these agencies provided money and aid in kind. Later, the approach was changed to family planning extension programmes wherein family planning workers moved in the community and set up depots to distribute condoms. However targets were not fulfilled and once again the approach was changed. Family planning was then integrated with maternal and child welfare programmes and in 1966 post-partum programmes were launched.

These changes of approach were only made on the basis of whether targets were being met or not. For instance at first the number of conventional contraceptive users was considered; the number of IUD users was counted without any consideration of the removal rate after IUD, insertion and so on. The same was true with pill users and the extent of bogus sterilisation is only too well known. The KAP studies were mostly useless because the ethos, needs or priorities of the people was not considered.

Added to this in several states the government in its enthusiasm to achieve targets bungled their programmes by coercing people to accept IUDs or sterilisation operations.

The state governments got away with this callous approach to meet targets as far as women were concerned. Women were made to suffer humiliations, indignities and often serious physical side-effects, but the strategy boomeranged on the government when men were forcibly sterilised. A government was toppled! Even then this patriarchial male-dominated society did not care to understand what suffering women had been made to undergo for so many years. If women complained they we e told to bear the side-effects. Now during the past few years, probably to pacify the male ego and to stay in power, the government's stress is once again on women—catch them anywhere, in hospitals after delivery or in abortion and child welfare clinics. Women have to accept any contraceptive that suits the authorities.

Review of literature

Dr. D. N. Kakar has done a study of women using either the pill, IUD, or injectables Kakar, 1984). The study throws light on several factors responsible for a method being continued or discontinued. It is strange why a similar study was not done on the use of condoms. It is because men cannot be bothered to accept the responsibility of using this method ? Though Dr. Kakar's book deals only with women's contraceptives, it sheds light on several important factors which are directly connected with physical problems faced by women due to contraceptive usage and male attitudes to contraception. In several case studies it was pointed out that women discontinued contraceptives because of side-effects such as spotting or intermenstrual bleeding. Several women said that they needed much greater medical attention when these side effects took place. They needed reassurance and understanding from their husbands but were instead treated with a certain coldness Dr. Kakar asks, "how many husbands would be genuinely concerned about providing comfort to their wives without being able to derive sexual gratification ? " It is usually the woman who bears the brunt of physical discomfort and at the same time takes the responsibility of avoiding a pregnancy.

Annual reports of the Indian government and many of the western offices of population have shed light on the amount of foreign aid in the nature of cash and kind. The main contributor to the population control fund and even to the concerned UN body is the USA. The UN has set up a special division on biomedical research and over 100 million had been spent by 1972. The division has clinically tested 45 different drugs and six different devices on 45,000 persons — mainly women of the third world. Among those who have been funding the population activities in the third world countries in cash or kind either through the government or through private agencies are US, UK, Netherlands, Japan, Germany, Canada, Norway and Denmark. In India, WHO and Ford Foundation are the major contributors for research in contraceptives. IPPF, Pathfinders and Population Councils are other important donors. By 1980 over 7,500 subjects, mainly women in Bombay alone were involved in some of the trials in contraceptive testing.

Historical background of a contracptive unit

The family planning unit of the government of India was started in 1954. It had three main objectives - (i) testing of contraceptives for their efficacy, safety and acceptibility; (ii) conducting research in reproduction and fertility control; and (iii) developing newer contraceptives. In 19.6, the FP unit was reorganised as a contraceptive testing unit (CTU). The first clinic was set up in the industrial area of central Bombay. Located in the premises of the mother and children welfare society, the health of mothers and children formed an integral part of its work from its very inception. The social workers' attitude then was to educate women and men of the community in every facet of health. Stress was laid on the overall education of people through organising the community around the clinic. Men, women and children came to the clinic not only for FP methods but for all their socio-economic and other personal problems. Some of the activities started at the clinic were (1) Education of men and women and children through exhibitions, group talks not only on FP but also in health care, antenatal care, post natal care, women's movement and nutrition education. Women and girls were given sex education. (2) The entire community was screened for TB by taking mini x-rays and treated or referred for admission to a hospital. (3) To get the entire community involved in the welfare activities, health day, 'makar-shankranth' day, children's day, women's day and so on were celebrated. (4) Women were encouraged to speak in meetings and debates, their mahila mandal was set up and skits and songs were staged by the women themselves. Competitions in essay writing, painting, were held. Classes in first aid, nutrition and adult education were conducted. (5) Efforts were made to help women continue education and to

secure jobs. (6) Even separate clinics were conducted for ANC and PNC as well as for babies. Sterility being a major problem of the community, sterility clinics were also conducted.

Research activities

Between 1958 and 1962 it was found that older women with large families were the only ones who were attracted to the clinics. As welfare activities increased and as more welfare clinics were set up in different parts of the industrial area in central Bombay a larger number of younger women began to attend the clinics. Foam tablets, spermicide jellies and diaphragms were the conventional contraceptives available at that time. Each woman attending the clinic had to undergo a test for PAP smear and colposcopy examination to rule out cancer and other gynaecological complaints before contraceptives were given to her. Field trials on foam tablets were conducted. Several foam tablets like Contab and Planitab, were tested. The CTU developed a "24-hour CAP test", to assess the harmlessness of foam tablets and contraceptive jellies Several batches of foam tablets and contraceptive jellies received under a code number were tested by this method which was standardised and recognised internationally. When several jellies were disqualified, there was a hue and cry by the pharmaceutical companies manufacturing these jellies. They pressurised the CTU to abandon the test but the CTU was firm and this rigid stand taken by the unit prevented the release of these sub-standard contraceptive jellies into the Indian market.

By now there were six clinics, three being in industrial areas, two attached to hospitals in Bombay and one in a rural area attached to a PHC In the first year of their existence the community had accepted these clinics truly as family welfare centres. There was an excellent rapport between the research staff and the family members. Those who participated in research trials knew fully well the implications involved. With the arrival of IUDs and later the hormonal pills welfare activities were curtailed. The government started thinking in terms of cost benefit for the entire FP issue. No funds were released for activities which were meant for the welfare and education of the people.

Women were offered money for participating in research. The health of women did not remain the prime consideration of these centres. Several types of IUDs were tried. Now with education, younger women had started attending FP clinics for spacing their children. Eminent gynaecologists based in Bombay made some modifications in these IUDs. Comparative studies with different types and sizes of IUDs were conducted to find out the ones that had minimal side-effects and low failure rates. Copper T and Lippes loop are the outcome of this research and both are now extensively used by women all over the world.

In 1958 and 1959 Dr. Gregory Pincus introduced hormonal contraceptives. The CTU at that time was asked to introduce in their field trials 10 milligram doses of this hormonal contraceptive. This move was resisted by the social workers as they did not want to endanger the health of Indian women. During the sixties and seventies, the government accepted lower doses of hormonal contraceptives for trials in our country. Then began the exploitation of women in contraceptive research.

In the field of research, the funding authorities selected their own research scientists, institutes and private agencies to carry out the research in what they believed was the important area. Policy decisions were also in their hands. What we see today, therefore, is that contraceptive research is being conducted in the area of "someone else's" choice. No research is being done to evolve safer mechanical barrier methods, neither to improve the efficacy of the older methods nor to evolve indigenous safe methods The mode of administration of hormonal drugs, the dose and the content have varied. But they still remain the dreadful hormones tampering with the woman's body. Listed below are some of the contraceptives, in which research trials were conducted :

Foam tablets : These are used by women just prior to coitus A wet tablet is inserted in the vagina releasing foam which acts as a screen against penetration of sperms which are killed by the chemical action. The women's cervix and vaginal walls could be affected, resulting in irritation, burning and white discharge for many. Efficacy is around 40 per cent.

Diaphragm and jellies - or jelly alone : Spermicidal jelly is applied to the diaphragm and inserted in the vagina within an hour before coitus. The diaphragm acts as a mechanical barrier and the jelly destroys the sperms. Efficacy is good, but this method requires privacy and facility for washing. As above, the cervical canal and the vaginal walls are affected and may cause irritation, burning and white discharge.

Intra-uterine devices (IUD) : There are several types and sizes of these devices— the

important ones being the Lippes' loop, maxguli coil, CuT, CuY, Sonawala and Merchant's devices, and others. All these are inserted within four to seven days of menstrual flow. Being a foreign body inside the uterus, changes in endometrium and release of chemicals occurs resulting in cramps, irregular bleeding, perforations, white discharge and abdominal pains. Some women also complained of headache due to copper devices (Interestingly when a Lippes loop was inserted headaches disappeared) Unnoticed expulsion is another problem. Perforation with IUDs are well known and the whole of the abdominal cavity could be affected.

Oral pills : Hormal steroids are the basis of each pill. The woman has to swallow one pill a day for each day of the month (with a gap of seven days or otherwise depending on the type of steroids). There have been three-a-month pills too. These gave woman a severe bout of vomitting, giddiness and headaches. Women complained of headaches, nausea, giddiness, dizziness, weight gain, weight loss, rise in blood pressure, continuous bleeding or intermenstrual spotting. Pills have adverse effects on liver function, immune response of the body and cause vitamin B complex deficiency. The oral pills either inhibit ovulation or bring about changes in cervical mucous prevailing pregnancy. Drop out rates are very high.

Injectables : There are two types of injectables, injection Depoprovera and injection NET-EN. Both are known for their adverse effects. These are given to women either once a month, once in three months or once in six months depending on the dose of steroids. Those women who were given 300 mgs (once in six months) after delivery continued to have bleeding severe or moderate to spotting daily for over four to five months. Woman developed prolonged ammenorrhea (absence of menstrual flow). The drop-out rate was very high. Although injection Depoprovera was withdrawn by the government on hearing of the dangerous effects private agencies even today are promoting these through their outlets in India as well as in many other third world countries. Once the injection is given it cannot be withdrawn and the woman has to suffer as long as the effects of the injection persist in her body.

Implants : These are silastic subcutenous implants introduced in women's thighs. The hormones are slowly released into the blood stream and act to prevent conception. Those tried in the CTU clinics were supposed to protect women from pregnancy for eight months but the majority of subjects become pregnant within six months. Side-effects are same as those of hormones. Women had to undergo minor surgery for removal of empty implants which would get embedded in the muscles.

Vaginal rings : These are inserted in the vagina on the fifth day of the menstrual period. It is removed only at the next menstrual period. The vaginal rings are absolutely useless for the majority of women who have no proper toilet facilities. But they were being tried for the prestige of an individual scientist. The vaginal ring caused irritation, burning in the vagina and white discharge. It would also slip off and get lost.

Nasal spray : This drug is dangerous and useless for the majority of our women. It could affect the nasal cavity, thalamus, brain and even the heart as the woman is expceted to spray the drug daily through her nose in definite quantities. Poor malnourished women were cajoled into participating in this trial.

In all the hormonal drug trials women were required to give blood samples at definite intervals to assess the release of hormones in the blood stream. As many as 80 blood samples were collected in some of the trials. At least 10 to 15 blood samples required to be given by each woman participting in each of these trials. Not one lady medical officer has ever raised her voice in protest against this exploitation of poor women. Medical officers are more aware of the hazards a malnourished woman on these trials had to undergo. Yes, women were paid for participating in these trials. But that did not mean that these women had been bought that they could be used as guinea pigs. Are the women doctors so inhuman as not to understand the gravity of the situation ? The health of poor woman is being sacrificed for others — mainly for those funding nations and agencies and in order that the elite may know if a contraceptive might be dangerous or not. Few middle class or upper class women will agree to participate in such trials.

Research in male contraceptives

Mention has to be made of Dr. Padma Vasudevan who has used her knowledge in polymers for evolving a new method of contraception for use by men. Condoms and vasectomy operations are so far the only two methods for men, condoms being the most harmless and the easiest to use.

Dr. Kothari of the KEM Hospital has also conducted some research on developing intravas device (IVCD). But Nothing has been heard of this research for some time now. Nasal sprays were also to have been tried out on men. It is reliably learnt that although men were being approached for trials, not a single man could be enrolled for this trial inspite of being offered VIP treatment. Men apparently could never be bothered with any such trivial contraceptive research trials !

Birth control methods under trial

(a) Morning after pills : Trials with 'Morning After' pills are in progress. These are hormonal pills to be swallowed by women the day after coitus. It is too early to say what the side-effects it may have. Women on this trial are also required to give a number of blood samples.

(b) Pellets : These are expected to arrive soon for trials on Indian woman. It is not yet known as to which part of the woman's body will be tampered with this time.

(c) Vaccines : These are also expected to make their way into India. These vaccines will affect the outer covering of the ovum making it impossible for sperms to penetrate and for fertilisation to occur.

(d) Prostaglandins for abortion: When a woman desiring abortion (MTP) goes to a hospital she cannot choose the method by which she will be aborted. Even though there are safe methods which could be improved by research, a drug prostaglandin is being tested. This drug not only gives the women severe camps, abdominal pain, vomitting and diarrhoea but in some cases was the cause of incomplete abortion. Women under the trial programme suffered tremendously. This is another case where advances in science are also being used against women. Amniocentesis was a method developed to help detect an abnormal foetus yet it is now being used extensively for sex determination of the foetus which has in turn led to sex selective abortions.

From the CTO Records

Women of India, mainly from the weaker section of society, are being subjected to all kinds of inhuman treatments at home and even in places where they expect help and service. The following are a few instances recorded in the clinic which illustrate the attitude of husbands towards the wife vis a-vis her reproductive responsibilities.

Case 1 : During the late 1950s, the early years of the FP programmes, foam tablets as contraceptives were being offered to women. A mother of five children accepted this method after consulting her husband. A packet of 12 tables used to be issued whenever she wanted the stock. Once, a clinic staff removed one tablet from the pack to test the foaming capacity of the tablet and issued 11

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Campaign Against Long Acting Contraceptives

The government has decided to allow family planning institutions and private gynaecologists and obstetricians to import the injectable contraceptive, Norethisterone enantale (or NET-EN). The ICMR has been conducting studies on the drug for some time now under the WHO multicentric trial programme. The report of the study has not yet been made public and components of the study have not been completed as yet. NET-EN is a synthetic progestogen, similar to Depo Provera which has been the centre of a raging controversy among experts regarding its safety and suitability for women. Several women's groups, people's science groups and people's health groups have come together to protest against the introduction of NET-EN or any other long-acting contraceptive, such as Depo-Provera or contraceptive implants. The demands of the campaign are : Ban NET-EN; Ban all injectable contraceptives; All exports of the ICMR and other studies should be made available to the public; A public inquiry and debate must be instituted before such controversial contraceptives and drugs are introduced into the country. The campaign group's first action was a demonstration at the closed-door experts' meet convened by the Family Planning Association of India ostensibly to help make the decision on whether or not to use NET-EN and/or Depo Provera. The demonstrators distributed pamphlets and stated their demands to the assembly. Sympathetic participants later disclosed that discussions had centred around how best to use the injectables and not whether or not.

For further information on the campaign, please write to Women's Centre, Yasmeen Apartments, Yeshwant Nagar, Santacruz (E), Bombay. So far the following groups have decided to participate in the campaign—Women's Centre, Forum Against Oppression of Women, Medico Friend Circle, Committee for Protection of Democratic Rights, Shramik Mukti Morcha, Kashtakari Sanghatana, Yuva Sangharsh Vahini and others.

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The FP programme was prompted in the main by a fear of population size, that is, by (correct or incorrect) considerations of macro population policy. It being unrealistic to expect that family planning decisions should reflect population policy norms rather than individual life experiences, people were quite dishonestly sought to be converted with the message that the small family norm was good for them; proposition that was simply not correct. Considerable evidence was available even in the late sixties that a large family norm may be more suitable in certain situations (for instance in poor, labour intensive agrarian economies and where poorer classes are subject to heavy depletion in children ever born). Some of this sort of understanding did creep into the programme rhetoric from time to time, but made no real difference, as the real moving force behind the programme was never the happiness of individul families

As far as the macro understanding goes, it is not difficult to see through it at all. The argument that over population eats up the gains of developments is not a new one. Not only does it divert attention from more fundamental questions like models of development or distribution of resources; one also senses behind it a fear of people, people of certain nations, certain races and certain classes. It is another manifestation of the old Malthusian bogey that the poor are responsible for their own poverty because of their large numbers.

Birth control, which was all that family planning ever meant in India, can be advocated on many grounds. But certainly it cannot be advocated as a uniform prescription for all, without any regard for human dignity or individual liberty. The events of 1977 amply illustrated that the people would not buy an irrelevant product, however sophisticated the packaging. The tragedy is that no real lessons appear to have been learnt.

ilina sen
CMSS Office Rajhara (Kanday) Durg MP 491228

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tablets. That night the wife received severe beating from the husband. He suspected that his wife had used one foam tablet with another man.

Case 2 : Having got fed up with her husband forcing her to undergo repeated abortions a woman quietly got an IUD inserted. The husband got suspicious and forced his wife to get it removed. Inspite of removing the device, she was thereafter maltreated and beaten up often. After a few months inspite of her being pregnant she was thrown out of the house in the middle of the night, the reason being that she had not taken her husband's permission to get the IUD inserted.

Case 3 : There was a case of a doctor's wife who had to undergo repeated abortions each time after a 'sex determination test' revealed a female foetus.

Case 4 : Women have to bear the burden of looking after the family and also take the responsibility of contraception. There were several instances when a woman could not be offered any method immediately as she required treatment for some gynaecological complaint. The period of treatment was always short — a month or two in each case. Her husband would be asked to use a condom or refrain himself till she was alright. But in most cases the women would conceive during this period and either continue with an unwanted pregnancy or be forced to undergo an abortion.

Any one who has worked in FP clinics has come across women belonging to various religious groups who demand oral pills to postpone their menstrual periods so that they could participate fully in religious and social functions or even go for an outing. If given a chance, women can decide how they would like to utilise scientific discoveries.

Conclusion

In conclusion, the poor women of the third world countries like India get exploited not only by the government, the research institutes, private individuals in the field of contraceptive research but also by men who care very little about their health and their comforts. Research on birth control measures which could be used by men has not been undertaken with any degree of seriousness.

For instance although the condom is really a harmless and effective method for men, no serious studies have been conducted on its being accepted or rejected by men. Women just leave condoms behind at the hospitals if they are distributed knowing fully well that husbands will not use them. The statistics on condoms are based not on the numbers used but on the total number issued. There is no proper follow-up nor any serious effort to promote this harmless contraceptive. Is it because it is to be used by men ?

Reference

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