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Contraceptives: Our Choices, Their Choices

Forum for Women's Health

India has been the first country in the world to have a national family planning programme. When the programme began in 1952, the stated aims and objectives were, towards helping the overall development of individuals and families. Through this, was sought to be achieved, a check on the increasing population. Over a period of time, however, the interests of the families and of the women and men therein, have been repeatedly ignored and the programme has emerged in a true sense as a population control programme.

The emphasis was always said to be, on women's health and welfare. Yet time and again it has been brought to light that the way the, whole programme functions, well-being of women is the last concern. Controlling population growth rate, seems to be, the major objective for all family planning related activities. There is no other explanation, for the widespread use of targets for various contraceptive methods, for the direct and indirect coercion, that women face, every time they try to use the public health care system. This had been adequately documented in various places [1].

Non government organisations, especially women's groups, have played an important role in bringing these biases of the programme to light, while exerting pressure on the government through campaigns and legal actions, for changing the thrust of the programme. As a result, of late, there seems to be some acceptance, even by the administration responsible of the coercive functioning of the program. Albeit, it is argued to be, only a problem of implementation. In fact, more and more, the State and its agencies seem to be talking, in terms of giving women choice, meeting their 'unmet need' for contraception and providing for more to choose from. There is talk of a 'population policy with a human face' which would treat individuals, especially women with dignity and grant them their rights.

In actual practice, however, this concern is not visible. We hear of policies that would do away with targets for individual methods. The sterilisation camps, the pressure to accept a contraceptive method, as a precondition, for any kind of assistance from any government service, targets for health workers for promotion of the programme, all of these continue. Besides, there are newer

ways of indirect coercion - that would do away with targets for individual methods. The sterilisation camps, the pressure to accept a contraceptive method, as a precondition, for any kind of assistance from any government service, targets for health workers for promotion of the programme, all of these continue. Besides, there are newer ways of indirect coercion - reduction in duration of maternity leave or no maternity leave for the third delivery, cancellation of abortion leave, enactment of laws preventing people with more than three children from contesting elections, and so on.

Under the garb of concern for the health and well being of women the programme continues, with its basic philosophy of controlling population growth, through controlling number of births. This too, is sought to be achieved through contraceptive technologies. A technological quick-fix solution, is being presented as, 'the' solution for the 'problem of uncontrolled growth of population'. So although the policies keep talking of overall development, `development is the best contraceptive', and so on, the actual programme never reflects this.

From time to time, a particular contraceptive method has been selected and (popularize & or used through cajoling and coercion. New developments in contraceptive technology, are stated to be the reasons, for the shift in the method, that is promoted by the official family planning programme. A critical analysis of the methods provided, however, indicate that the selection is guided, more by the concerns of reducing births, than the choice and overall health benefits, to the users. The emphasis has been on getting more effective methods, many a times at the cost of safety of the users health.

When the programme began, for example, the stress was on barrier methods like. diaphragms, jellies and foam tablets or on other methods like the rhythm method. In the '60s the emphasis shifted to more unsafe methods like the IUDs and this qualitative shift was achieved, through cash incentives for users, for doctors and for motivators. At the same time, the distribution of barrier methods was discontinued at the family planning centres thus reducing their demand and use. Today, no government centre provides diaphragms and cervical caps and women 'prefer' IUDs and other methods over these.

In the '70s, the stress shifted to sterilizations. Men were targeted for vasectomies. This was the period of national emergency in India, which has left indelible impressions on Indian minds, of the cruel and coercive mass sterilizations. This coercion, was one of the major 'reasons for the fall of the government and the governments that have come since, have been avoiding popularising vasectomies. At the side time, the development of so-called easier techniques, for performing tubectomy at around this time, has resulted in, putting the burden of

sterilisation on women. We have the situation today, when the use of the safer procedure of vasectomy, is reducing day-by-day and tubectomies are being performed on younger women, without the precautions and knowledge to avoid complications.

Since sterilisation is accepted after four children, rather than two that the official programme advocates, it was realised that sterilizations, do not help to control births, to the desired number, the stress in the 80s and the 90s is once again on spacing methods. Effectiveness of the contraceptive in preventing conception, is the most important criteria and to achieve it, the user's intervention in the use of a method is being reduced. The focus is hence on provider controlled methods, and naturally, for the convenience of the provider, the method then has to be long acting.

It is not just a coincidence, that the research and development in contraceptives, has also moved along the same lines, to put forth a whole range of new methods, that, fit into this category of methods that are long acting, provider controlled and effective. Examples of these are the hormonal injectables, implants, vaginal rings and also absolutely new approaches like the anti-fertility vaccines.

As a group, we have been active in the area of science, and reproductive technology in particular, and have been closely following clinical trials, as well as, analysing overall designs of trials and understanding and direction of research. We find most research, directed towards development of tools of population control, and then marketing and popularising them. These modern methods, can never be methods for birth control and contraception.

Birth control has to be in the hands of the user, to be used as and when she wants to. Further, it should not intervene, with the overall functioning of the body. A woman is fertile, only for, at most, four days in a menstrual cycle. For that fertility of two to four days, bombarding her body continuously with chemicals, every day, is the most harmful and in a sense inefficient way of achieving birth control.

This, however, is not the understanding of contraception, that modern science and technology share. The free quest for knowledge that science is supposed to be, is not actually so, in practice. Firstly, the funding for the research and development, come mainly from global agencies and governments that believe in population control through controlling births. This undoubtedly influences the direction of the research. Besides this, it is also true that the paradigm within which scientific developments take place, is also influenced by the prevailing, dominant ideology.

It is these influences and biases, that affect and mould the direction of research and development of contraceptives, that we wish to explore in this article, through looking at the clinical trials for contraceptives. We would, in particular, stress the way in which trials are being carried out in India, the unstated biases inherent in the design of the trials, the changing nature of the trials, for introduction of new methods and comment on the understanding itself, which guides this direction of the research.

Informed Consent

We begin with looking at direct experiences of women, with development of new contraceptives, which is through their participation in clinical trials. The issue that has been discussed many a time, especially in the Indian context, is that of informed consent for trials or the lack of it. Although agreed upon on paper and reiterated time and again, in reality, nothing is informed to the woman undergoing the trial. Usually, women who come to the centre, for their basic needs, are recruited for the trials. Even the fact, that it is a trial, in which something with unknown effects are, being tested is not revealed. In such a situation, there is no question of giving any information about the possible good or bad effects, of the method being tested or providing opportunities for looking for contra-indications which must be looked into, to begin with.

From the experience of the Net-en trials in Hyderabad [2] way back in 1985, to the testimonies of women on whom Norplant [3] and vaccines [4] have been tried, to the ongoing trials with even an abortificient like RU-486 [5], this has been a common observation. Our latest experience has been with the six capsule Norplant trials being conducted in almost thirty centres in India.

The study has been designed to gauge acceptability for Norplant over existing methods like the condom, pills and the IUD. All four methods are offered to the woman coming to the centre and she has to make a 'choice' from these. An objective statement of facts is apparently made about the possible effects of all these methods and the woman is given the freedom to choose.

Women coming to the centre, have information from other women, about experiences with the pill, IUD and the condom. They know nothing about Norplant because this method has not been in use. Yet, the counselling or information that is given to her about this new method, is just the following:

"These rods are of Norplant. It is a new method whose trial (the English word is used with no other explanation) is going on. With a small operation these rods will be inserted under the skin in your arm. It will work for five years and give you contraceptive protection. After five years you have to get it removed. Come

to us we will do it whenever you want. It has the same medicine as the pill. There are not many problems with it (This cautious tone could well be because we were present). Only there may be some intermittent spotting for the first six to seven months, after which, everything will be fine. [6]

When it is known that Norplant causes extreme menstrual irregularities in the form of excessive bleeding or even amenorrhoea, and many women have discontinued its use because of this, is this enough information? On the one hand Norplant-2 and the six capsule Norplant were considered equivalent and, on the other, the findings of the phase III trials with Norplant-2 were not being shared.

The women were being told this much, asked to go home, think about it, consult with their husbands and come back. Is this enough for any woman to make her decision? When an altogether new method is being offered should there not be more sharing of information than this brief incomplete introduction? What is also totally shrouded in the approach, is the fact that each centre had a target for the number of Norplant users that they had to enrol in a one year period, while, there were no such numbers for the other methods. Would this not influence the so-called 'choice' given to women? Obviously, the researchers could push the method on those, whom they think, are fit for inclusion in the trial.

Whenever questioned on this count, most researchers have some standard baseless arguments, to put forward. While researchers claim, that anyway women cannot understand scientific information, the same women were found to be very curious and desirous of knowing details. In fact, they do ask questions of the doctors too, but are given half-truths as answers or not told anything at all.

We believe that women's supposed inability to understand, is hardly a reason, for not providing them the information. The participation in the trial is based on informed consent. So information is mandatory. How the study is conducted, is more important, than merely completing it. If we do not want to invest energies into explanations to 'illiterate, stupid women', then, either we do away with the studies or take women, who are 'literate and who have understanding, as subjects for the trials. Why is it that all trials are being conducted on women, who come from the poorer sections of society and are usually very vulnerable to the health care providers primarily responsible for conducting the trials?

Subjectivity-some accepted and unaccepted norms

The second reason given again in keeping with the 'stupid women' image, is that the trials have to be conducted in an objective manner, and, they do not want women's subjective responses to mess up the neat and clean 'scientific' study. This is a problem shared by all scientists, doing research with human subjects. In

clinical trials, subjectivity is demanded of the person, who is participating in the trial and so information on the trials and trial products, are never given to the subjects. The 'scientific' reason given by the researchers is that if the women are told about the possible side effects, they would turn hypochondriac and start imagining all of them, preventing any objective evaluation of the same.

Not knowing how the contraceptive works, many a times a lot of ill effects of the contraceptives, are not assigned to them and hence are not reported during the trials. At the same time, a lot of complaints of women are still attributed to the assumption that 'the woman is complaining unnecessarily'. Here no effort, is made to get rid of the subjectivity of the researcher.

The researcher has a given list of complaints to look for and chooses to ignore others that might be reported. There is an impression about how the contraceptive method works, and only those aspects that fit into this understanding are looked into. When this is the case, and no openness is shown towards the fact that the basic understanding itself is incomplete, the trials could miss out on a number of crucial ill effects and problems with the method.

This is not just conjecture but has been proven from time to time. For example, the use of IUDs began in, the mid '60s. Inspite of the fact that doctors fitted in the IUD's, they never noticed the high incidence of reproductive tract infections among women. It was women and feminist researchers who brought this fact to light, as late as in the '90s. The doctors never intended to and hence could never notice these infections, although they were widespread.

In essence, it means that, an objective clinical study as conducted today means, that which negates the subjective experience of the subject, but overlooks and negates the influences of the subjectivity of the researchers, who have designed the trial or are actually carrying them out. In our opinion, there is no way to get rid of subjectivity. The issue is of recognising the subjectivity and stating clearly the vantage-point from which observations and deductions are made.

For example, in the latest trial with Norplant where acceptability is being tested, it should be essential that the researchers share that they are testing a new device and so women were making a choice from amongst three known methods and one unknown one. Since in a span of one year, one hundred women had to be inserted a Norplant, it was possible that the harmful effects of the method would be underplayed to get the required target. Unless these subjective conditions are shared or taken into account while analysing the results, can we say that the acceptability study was an objective one?

The whole as necessarily made of the parts

The basis for adopting this stance of objectivity comes, mainly, from the prevailing understanding of science, which is the reductionist approach. Looking at the whole, as a conglomeration of the parts is the method applied to all matter living and non-living. With this approach, the body is looked at, as made up of the various organs and the active interdependence of the organs is overlooked. In case of contraceptives, it is assumed, that the intervention is at the level of certain organs alone and only those, usually the reproductive organs, are studied.

For example, in case of Norplant, since it is assumed that it affects the hormonal cycle related to reproduction, only those effects are studied. Norplant continuously disrupts the hormonal cycle totally for a long period of five years. Yet, after discontinuation, the only thing studied in the follow up is the return of fertility. The assumption is that if Norplant was used to control or restrict fertility, the only thing that has to be checked is the return of fertility. No other system is, supposedly, affected by exposure to the drug. The study nowhere has the provision to see what could be the long-term effect on the overall health of the woman exposed to the chemical for such a long period.

Even in case of the reproductive organs, only their ability to reproduce is considered important. The long term effect on the future the only thing that has to be checked is the return of fertility. No other system is, supposedly, affected by exposure to the drug. The study nowhere has the provision to see what could be the long term effect on the overall health of the woman exposed to the chemical for such a long period.

Even in case of the reproductive organs, only their ability to reproduce is considered important. The long-term effect on the future progeny, their reproductive abilities, is not even thought of. And this is true, in the case of all long-acting systemic methods. If, at all, the progeny is studied, it is to the extent of determining a normal birth. The effects of drugs like DES, given to pregnant women are visible even today in the disabled, cancer prone, infertile DES daughters. Yet, the lesson is not fully learnt.

The frontier area of research in contraceptives in India, has been the research in immunological contraceptives or the anti-fertility vaccine. These methods are based on a reductionist under-standing of the immune system. The vaccine is supposed to identify one chemical, required for the process of reproduction and naturally produced in the body as the antigen. The vaccine, helps the body create antibodies against this antigen.

It is assumed that the vaccine would act only against the chosen antigen and not against other molecules, that may be present and even be similar in structure. The proponents of this method of contraception also share some arrogance that this process of generating antibodies against self-molecules, would be restricted to only the specific antigens and not become an overall problem of the immune system. All of these seem to be premature assumptions, about the way in which a human body would and should respond, because, in actuality the body functions in much more complex ways, than these models of the body can simulate.

The pace at, which new contraceptives are being introduced, does not at all take into account the health and general well being of the users, who are invariably women, in this patriarchal society, that sees reproduction to be solely women's responsibility. The effects on women's health, if acknowledged, are condoned on the grounds that women want contraception or ought to use some contraceptive or the other, and effects on the health are the 'costs' to be paid for these needs.

For acceptance of any new technology, a cost benefit analysis is the basis, meaning the costs to be paid, have to be weighed against the possible benefits, and a decision has then to be arrived at. This is done, but, without questioning the basic definitions, of what are the costs to be paid and what are the benefits to be achieved. The political questions, of who has to pay the costs for whose benefit, are not even raised. Justification for the analysis is sought and obtained from the most effective tool of modern science-statistics, which not only hides the human aspect, but also makes everything appear to be objective, factual and honest.

The Game of Numbers

This game is again played at two levels. One, is the clear cut case of hiding data or presenting them in such a way, that the picture appears to be rosier than what it actually is. The second, is the accepted method of finding averages, that hide the stories of suffering and agony of individuals or also help to reduce the actual extent of the trials. We would give examples, from the trials for long acting contraceptives being carried out in India.

The injectable Depo Provera has undergone the initial clinical trials in India in the '70s and in the early '80s. One of the studies was a WHO multicentred, multinational study in which two centres from India-Bombay and Chandigarh were included [7]. This was one of the few studies in which the contraceptive was not being supplied by the company. About 1700 women from ten centres all over the world were given either Depo or Net-en, once in three months and the effects observed. In Bombay 38 women were given Net-en and 36 women Depo while in Chandigarh 97 women were given Net-en and 99 were given Depo.

The results of the study in Chandigarh, were anomalous. What has been striking, is the way in which the analysis was carried out. A total of 24 pregnancies were reported, in women using Net-en. Of these, six were in Chandigarh and seven in Bangkok although the number of women participating in the trial from these centres was not in the same proportion. Chandigarh, also had the highest discontinuation rate for medical reasons. At the end of the first year in Chandigarh 60 per cent of all women on Net-en and 82 per cent of all those on Depo, dropped out of the trial.

The discontinuation rates, because of amenorrhoea and bleeding irregularities, were much higher in Chandigarh than in all the other centres, including Bombay. We give the results in the table below. No reason could be found by the researchers for these queer findings. Instead of trying to find out the cause, the way out was found by reporting of the results excluding the Chandigarh data from the calculation of all averages.

Discontinuation due to	**For Depo**		**For Net-en**	
	Chandigarh	**Other Centres**	**Chandigarh**	**Other Centres**
Bleeding irregularity	46.7	5.7	52.5	5.0
Amenorrhoea	69.4	5.2	40.4	0.9

Can there be a more preposterous way of handling data? Can this in any way be considered to be anything other than wilful manipulation of data? And this is done in a WHO study! The other result from the study is that since effectivity for Net-en is not very satisfactory when an injection is given once in three months, it should be given once in two months. In spite of the large drop out rate and other problems reported for both the injectables, they are both considered to be well tolerated. The tolerance of women in Chandigarh is wilfully ignored.

Another recent example of such bungling is from the phase II clinical trials of the anti-fertility vaccine carried out in New Delhi. The data reported in the scientific paper says that of 162 women interviewed for the trial 148 completed the schedule of three primary injections. It is possible that the rest took one or two of the injections. What kind of follow-up was given to them is not clear. The paper further goes on to state, that while all women made antibodies to HCG, 119 (80 per cent) generated titres that were clearly greater than 50 ng/ml.

Of these 119 women, one woman got pregnant, while twenty six women with antibody titre concentrations varying from 5 to 35 ng/ml, also got pregnant. Even though such a large number of women did not generate sufficient antibodies required for effective contraception, this study claims to prove, that a

birth control vaccine is feasible. Dr. Talwar, the researcher in charge wants to go ahead with the phase III trials of the same vaccine in spite of such a report. He claims that the vaccine is effective because there was only one pregnancy in the 119 women.

Menstrual irregularities, is an often, reported complaint by all women exposed to long acting hormonal injections or implants. In the Norplant-2 phase III trial, 17 per cent women got their implants removed, because of problems related to menstruation [9]. Even amongst those who continued, the problem was quite serious.

The severity of the complaint to individual women, does not get reflected in the objective, numerical averages, calculated to determine menstrual disturbances.
A quaterly observation of each woman was done. If the woman menstruated two to four times in these three months, had cycles of 22-35 days duration, bled for 10-20 days and maybe had some spotting for a total of about 10 days in that period, it was assumed that she did not suffer from menstrual disturbance. This is based on some apparent standard definition of what should be considered as disturbance, in the menstrual cycle.

It seems very exhaustive and considerate, until, one looks carefully at the experience of an individual woman, that gets hidden under these neat, specific numbers. A woman who has a regular cycle of 30 days and bleeds about 5 days during each menstrual period is considered to be 'normal' by these criteria. If, with the Norplant, her period changes in such a way that she has her period after 35 days, bleeds about 10 days each time and maybe even spotting for few days (something she never had before), she would still be normal and 'scientific' decision would be, that Norplant does not affect her menstrual cycle or that she does not suffer from menstrual disturbances due to Norplant!

Shouldn't the analysis be such that it looks at the changes in the menstrual patterns of individual women and then determine the occurrence of disturbance? Is this not use of statistics in such a way that it would help prove, that implants did not adversely affect the health of women?

Another problem in the study design itself, is in the norms set for selection of the sample size. In the phase III trials for a contraceptive, it is necessary that the observations be made for twenty thousand menstrual cycles. This could be achieved, by studying two thousand women for ten menstrual cycles or two hundred women for hundred menstrual cycle or whatever be the combination. This appears to be large number, until one realises that the criteria- has remained the same for all contraceptives including those, that are supposed to work continuously for five years. In case of Norplant-a contraceptive, which works for

sixty months, this would mean a study with about three hundred and forty women for five years.

Here, the number is much smaller, but we presume that the study is carried out for the full period for which it is supposed to be used. In actuality, however, one thousand four hundred and sixty six women were involved and a total of twenty thousand six hundred sixty nine menstrual cycles were studied. This meant that, the results were based on trials in which, women were observed for only a period of one year or two years.

It is quite obvious that for testing of long-acting contraceptives, studying 20,000 menstrual cycles, is not at all sufficient. It, in fact, presumes that there would be no special effects on the body, inspite of the long-term, continuous exposure to that contraceptive. Only such a mis-conception, can justify a design of a trial in which, a five year contraceptive is actually tested only for at most two years.

The arrogance that the contraceptive would affect only to the extent that the scientist presumes it would affect, is one of the reasons. The other is, that there is a great need, for both those developing the contraceptive and those who fund the research, that the studies be completed favourably with minimum costs and as soon as possible. To facilitate this process, the guidelines for research on hormonal contraceptives itself were changed, way back in 1987 by the WHO

Changing Nature of Research

A special meeting called to discuss the guidelines for research, came up with two specific suggestions. Both of these were said to be based on the observation that, the trials conducted until then, were not in a position to give a clear and definite picture of the possible side effects of particular contraceptives. There were questions raised, about the reliability of animal trials and about the lack of any kind of surveillance after a contraceptive was introduced and used, by a fairly large number of women.

The animal trials were claimed to be misleading, because, they did not explicitly give an indication about the effect on the human body. The issue had come up in the case of Depo Provera. The study, done with beagle dogs, had indicated a high incidence of breast cancer after exposure to Depo. Based on this, when questions were raised about the safety of Depo, the reasoning put forward was, that in any case beagle dogs did not exactly give the full picture as far as human beings went.

The special committee appointed by WHO went ahead to say that there was no need to waste time and energy on annual trials and the process of development

of hormonal contraceptives, could be hastened, by reducing the stress on animal trials. All these years, what had been the basis for convincing women about the safety of chemicals being introduced into their body, suddenly became unreliable and unnecessary.

The other thing that is said, is that no clinical trial can be large enough to be able to point out the possible ill-effects of any contraceptive. It has been accepted that continued use of hormonal contraceptives has brought to light many health problems for women. Hence, now the researchers say, that once the drug has been widely in use, it is important that a constant surveillance be kept. This suggestion appears very much, to be talking into account, women's health problems, yet the implications for women on the whole are far from beneficial. This is evident from the situation of injectables in India.

As the animal trials for Depo were not considered to be stating the facts about the injectable, Depo was cleared for use in the U.S. This clearance was also supported by a study, sponsored by the WHO, regarding occurrence of cancer in Depo users. An analysis of that study is also necessary, before accepting the results. The clearance given by U.S. FDA (Food and Drug Administration), however, paved the way for approval by other countries and that does seem to be one of the reasons for the clearance in India.

In 1993 the Indian government made available hormonal injectables in the market. It was clearly stated that these injectables would not be brought into the family planning centres but would be sold by the drug stores. This was the first contraceptive that had got such a clearance in India. Despite trials for the contraceptive being incomplete, the injectable is available in the market today. A tradition of testing contraceptives within the Indian situation has been abandoned to make way for this long acting method.

The license to the drug is also conditional. It is said that a post marketing surveillance has to be conducted. The details of this surveillance or this study, which is to be continued post-release into the market, have not been disclosed to the general public. There is no statement of this condition in the package insert with the injection.

Whatever information we have been able to gather from the principal investigator of this study is as follows. There are some identified centres all over the country. According to this source, ten women from each of these centres will be regularly injected with Depo every three months and then they will be followed through for a period of one and a half years [10].

The centres are regular OPDs in general hospitals and also community outreach centres of large NG0s like the Family Planning Association of India. Centres like these, are going to provide Depo free of cost. How does this become a post marketing surveillance, is beyond our understanding and in any case the number of women included in the study in this way would never be large enough or any different from the usual phase III trials. The only thing that seemed to be different is that they said, they would try and see to it that the selection of women would be done very judiciously and only women 'appropriate for Depo' would be chosen for the study.

In our opinion, the need to take into account all the ill effects of the long acting contraceptives, is very much there. Yet, we do not think that these changes in the research protocol help, in anyway, in that process. As we see in the case of the introduction of the injectables, it in fact, makes things more dangerous for women from the third world, who are more vulnerable to being targeted for long acting contraceptives through coercive State-run or NGO-run population control programmes.

The Direction of Research

That brings us to the final issue involved in the introduction of 'new contraceptives, which is the direction in which research is presently being conducted. Today, recognising the problems with hormonal contraceptive methods and the chaos that they create, in the menstrual cycles of women, resulting in the discontinuance of use of methods, all efforts are being directed towards methods like the anti-fertility vaccines, which would intervene in the immune system of the body.

The proponents of the vaccine, wanting to show that the AFVs are a better option over existing hormonal methods, claim a major advantage to be, that the AFVs do not disturb or disrupt the menstrual cycle. This statement, in itself, is a misguiding one, because it does not disclose the other part of the statement that it involves another very sensitive system of the body the immune system. It is also not true that all vaccines would not affect the menstrual cycle.

It does cause systemic changes, because, although most of the vaccines do not affect the hormonal system, they do act through manipulation of the immune system-a much less understood and a much more complex system of the body. It, is ridiculous on the part of eminent scientists, to claim its safety, by saying that the AFVs do not interfere with the menstrual cycle. A method that works on the basis of 'fooling' the immune system to misread its characteristic proteins cannot anyway be claimed to be safe and less problematic.

In this worldview, there is a reductionist approach to the human body on the whole. This cartesian approach to human physiology is old and many limitations of it have come to light over the years. The whole body physiology is a complex and interdependent mesh of various systems and a tampering in one does have an effect on the other. The hormonal system of women has been tampered with extensively, through the population control programmes, over the last 35 years. Without acknowledging the harm that has been done to women, through the hormone cycle interventions, now this new system is unjustifiably being brought under attack.

Further, AFVs work through inducing auto-immunity of some kind. What could be its impact on the spread of AIDS and in the situation of a changing disease pattern all over the world is not something that can be assessed. It is also well known, that women are more prone to auto immune diseases. Inspite of this the researchers going ahead with the AFV research want us to be assured about the 'no risk aspect of AFV because 'there is no scientific evidence to indicate whether an AFV, per se, would increase or reduce the risk of HIV infection, except the obvious fact that it is a non-barrier method.

With the popularity of immunisations, the proponents of the anti fertility vaccine feel that the acceptability of this contraceptive method would be larger. Since their interests lie in reducing births, they look upon this as an advantage with the AFV. However, looking at the coercive nature of the family planning programmes, in fact, this is what provides the potential for abuse. People's vulnerability and lack of information could result in their being administered the vaccine, without their knowledge or even under the guise of any other disease vaccine. In a country, where women are sterilised or inserted with IUDs without their knowledge and permission, this is not far fetched.

It is for this reason that women's groups have come up with a position that the AFVs offer no advantage over all existing methods. Further, since they can be dangerous for the people who are exposed to them, the demand has been that the research on these vaccines itself should be stopped. Until now, issues raised were confined to the way in which research was being done and the design of the trials, but, this is the first time that the time has come to question the direction of research and the priorities within it.

The Alternatives

Whenever such demands are made, the people making the demand are charged as being anti progress of any kind and also interfering in the noble pursuit of acquisition of knowledge, by scientists. We believe, however, that as users we have suffered the consequences of this unchecked development, for too long. We

are definitely not against progress and acquisition of knowledge. But, we do feel that it is time to redefine what we mean by progress and what is the knowledge that would help us, as users of contraceptive technology.

In this situation, we do not feel that participating in the ethics committees and so on (the tasks put forward by the international research bodies) will solve the problem. These invitations are, in fact, one more gimmick that population control promoters are using to misguide people, under a garb of being scientific, objective and pro-people. They would just help to some extent as checks on the implementation. Beyond this, however, there are flaws in the whole model itself and we need to question that as such. Critiquing the existing way in which trials are designed and implemented is essential and needs to be done collectively by as many people and groups as possible.

Besides, this we see a ray of hope in the efforts, however small they may be, made by women's groups all over the country, while running fertility awareness or self-help programmes or in the various other alternatives evolved or experimented with. In the efforts made by women themselves to question scientists, researchers and health policy planners while giving their preferences for the kind of birth control method that they would like.

A birth control method, that would empower and strengthen women, while, at the same time result in greater co-operation and understanding in the man woman relationship itself. A method that would be in the hands of the user, to be used with discretion and knowledge, and which would automatically involve the male partner as well. Research has to be in directions that would promote these concepts. Then, the whole understanding, direction and analysis would change and so also then would the trial designs and procedures.

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