

Population Policy and its Implications for Women

(Special focus on injectables)

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Saheli Women's Resource Centre
N E W D E L H I

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CONTENTS

1.	Why the concern now?	Saheli Collective
2.	The case against NET-EN	Saheli Collective
3.	Guidelines for the use of NET-EN	Government of India
X 4.	Feasibility of introducing ICs into PVCs	Information Service VHAI
X 5.	F.P.P. & Violation of human rights.	Ganesh/Venkatramani
6.	Ethical consideration in human research	Excerpts
7.	A Feminist understanding of contraceptives (Excerpts)	Manisha Gupte
8.	Some ideas on what needs to be done	Saheli Collective
9.	<u>Annexures</u>	
	I. Phases of trial	
	II. The tragedy of DES	Saheli Collective
	III. Usage & History of NET-EN	Saheli Collective
	IV. List of centres where Phase III & IV trials of NET-EN were/are being conducted.	ICMR.

WHY THE CONCERN NOW?

India prides itself as the first country in the world to have a national programme of family welfare and planning. It became an integral part of economic planning right from the first Five Year Plan, 1951-56. In the beginning a 'clinic approach' was adopted i.e. services were provided to those who sought them on their own. When this did not reduce birth rate to a targeted level, the clinic approach was changed into the 'extension approach'. Here, female health workers were recruited to actively canvass for the adoption of contraceptives by married couples. Incentives in the form of cash rewards were used and the health workers in the government service were pressurized by the target system to 'motivate' couples. Utilization of force to compel people to adopt F.P., methods reached an unprecedented height in 1976-77 (during the emergency). The end result of this period was the overthrow of the ruling party of the time. Because of this, the pressure was let off to an extent during the sixth Five Year Plan and no overt force was used on the people. However, from the policies and programmes outlined in the current five year plan (seventh Plan Period), it is clear the effort is to reduce birth rate at all costs, reminiscent of the period of the emergency.

In this plan period, the emphasis of the government is to be on

- a) long-acting invasive methods of contraception
- b) speedy introduction of contraceptives approved in other countries without conducting the necessary clinical trials in India.
- c) use of social marketing techniques to push contraceptives.

From this it seems that the national goal of population control is likely to overrule all considerations of the health of women, who are the primary targets of these methods and policies.

IMPLICATIONS OF EMPHASISING LONG-ACTING INVASIVE CONTRACEPTIVES

The methods of preventing pregnancy can be broadly classified into 4 categories :

- 1) methods that do not interfere with the reproductive

system-abstinence, withdrawal, rhythm, mucus method (natural methods) and condom, diaphragm, cervical cap (barrier methods).

- 2) methods that prevent conception by acting locally on the reproductive organs -- intra-uterine contraceptive device (Copper T, Lippe's loop).
- 3) methods that prevent conception by acting on the entire reproductive system -- oral pills, injectables, subcutaneous dermal implants etc.
- 4) methods that surgically and permanently block conception -- vasectomy, tubectomy.

The first three categories are considered spacing methods which are used to control the interval between two successive births while the fourth category are terminal methods.

Since all methods of contraception are designed to prevent/block/disrupt the normal reproductive process in healthy individuals, safety and effectiveness are the two most important criteria for evaluating a contraceptive. Considerations such as control over reproduction and contraception, potential for abuse, and health service implications also need to be taken into account. These considerations will have to be applied to each of the spacing methods available.

Safety

In contrast to therapeutic agents used to treat physical and mental illness, contraceptive agents are directed to interfere with normal body processes in individuals in good health.

- * they are used potentially over long periods of time
- * require a rapid and complete reversibility of action
- * are employed on a continuous basis by considerably larger number of women
- * are frequently administered with less supervision than any other therapeutic agent.

Another consideration is that interference with the reproductive process may theoretically at least affect the health of future generations and the future fertility of the woman herself.

Because of the above factors, all effects other than the contraceptive effect, experienced by the use of a contraceptive assume far greater significance. Unlike therapeutic agents which could potentially leave the user in an overall state of better health, complications due to contraceptives can potentially leave the user in a comparative state of illhealth.

The harmful effects of the three categories of spacing methods depends on the level at which they act, i.e. the level at which they disrupt the reproductive process.

Natural and barrier methods do not interfere with the reproductive system as such, and therefore there is no question as to their not being safe.

IUCD's act locally and the problems due to their use are generally limited to the reproductive organs i.e. pelvic inflammatory disease, excessive menstrual bleeding and sometimes septic abortions and ectopic pregnancies. Invasive methods (those that enter the blood stream) such as oral pills and injectables act systemically. They act not just on the reproductive organs but on the other organs also which are not involved with reproduction. Thus oral pills can affect the clotting mechanism leading to the formation of blood clots in the viens, which can result in myocardial infarction (heart attack).

It is obvious that the systemically acting invasive contraceptive agents are far more hazardous than the locally acting, natural or barrier method.

Effectiveness

It is generally argued that invasive methods have much lower failure rates than the other spacing methods.

For every contraceptive method there are two kinds of effectiveness : theoretical effectiveness and use effectiveness.

Theoretical effectiveness refers to the anti-fertility action of the contraceptive agent under ideal conditions without errors or omission in technique. Theoretical effectiveness can vary from population to population because of disease pattern, height, weight, etc. Use effectiveness reflects the level of protection

achieved by a population using the method in a given place, time, and under given conditions. Use effectiveness also varies from population to population because of social and cultural factors. To a considerable extent use effectiveness is determined by continuation of use and consistent practice of method adopted by the user. In turn, continuation and regularity of use reflect, among other things, the frequency of "side effects" experienced with the method.

In order to promote invasive methods of contraception, generally their theoretical effectiveness is compared with the use effectiveness of barrier methods. For instance, condom with spermicidal agent has similar theoretical and use effectiveness as the oral pill. However, the oral pill is pushed on the argument that its theoretical effectiveness is greater than the use effectiveness of condoms with spermicidal agent. This is a gross misrepresentation of facts.

Approximate number of pregnancies during the first year of use per 100 non-sterile women

Method	Theoretical effectiveness	Use effectiveness (average experience)
Oral contraceptive (Pill)	0.34	4-10
Condom + Spermicidal agent	less than 1.0	5
IUCD	1-3	5

Contraceptive technology, 1976-77.

With regard to injectable contraceptives, till now only their theoretical effectiveness is known. Their use effectiveness remains to be seen. However, since frequency of side effects influences continuation rates, and continuation rates determine use effectiveness; it is possible to predict their use effectiveness on the basis of information we already have. In India, continuation rates with the injectable NET-EN have been found to be considerably lower (31.4) than with IUCD (52.6 for Copper T) by the end of two years.

As with this injectable, complications due to other invasive methods will be higher than with other spacing methods. Therefore continuation rates due to complications and lack of health facilities are likely to be lower, thereby making them less effective in practice.

Thus, both from the point of view of safety and effectiveness, invasive methods are not likely to offer any advantage to the user.

Why then this emphasis on invasive methods?

This is where the social and cultural aspects of reproduction and its control, and health service implications come into play.

Control over reproduction and contraception

Unless left completely to the choice and desire of users, people have to be motivated to use contraceptives, and more importantly, to continue using them. This is where long-acting invasive methods offer a particular advantage. Unlike the pill which needs to be taken daily, and thus requires daily motivation on the part of the user, or the condom which also requires constant motivation, long-acting invasive methods offer the potential of protecting the user for much longer periods of time after just one shot of motivation. For example, one injection can protect a user for two months or more. This same logic applies in the desire to produce sub-dermal implants which, once inserted, can protect the user for two years or more. IUD's, once inserted, can also protect a user for 2-3 years. However, IUD's can be pulled out by the user herself if she so desires, whereas long-acting invasive methods do not leave this control in the hands of the user. A woman can decide not to take another injection but can do nothing about the injection and its effects for the duration of its action i.e. 2 months or more. Similarly, implants can be removed surgically, but only by a medical practitioner. Instead of the user having the power to decide when to discontinue a method, the power now shifts into the hands of the medical and F.P. practitioners.

Potential for abuse

Invasive methods also carry a high potential for abuse. While nobody can force a person to use a condom, swallow a pill or

keep an IUD in place, an injection can be given to a woman without her knowledge of receiving a contraceptive. Just the way IUD's are known to have been inserted into women after undergoing abortion or delivery, without their knowledge, subdermal implants, or vaginal rings can also be inserted without the knowledge of the woman, when she is in the hands of the health and F.P. system.

Implications for health services

Long-acting methods are also propagated on the grounds that they are beneficial in countries with poor health services. The logic is that long-acting methods require less contact with the health and F.P. services since one time motivation offers long term protection. In terms of 'fitting' the user with a contraceptive this logic holds true, however, breaks down completely when we consider that long-acting methods create far more complications and therefore create the need for greater medical supervision and better health services.

The particular characteristics of long-acting invasive methods therefore create advantages for the government and the F.P. programme, but not for the woman herself. To focus on the ease and comfort of taking one injection and relaxing for 2 months, or taking an implant and being worry-free for 2 years, is to overshadow the crucial issues of safety and effectiveness.

IMPLICATIONS OF INTRODUCING CONTRACEPTIVE AGENTS WHICH HAVE BEEN FOUND SAFE AND EFFECTIVE ELSEWHERE, WITHOUT CONDUCTING CLINICAL TRIALS IN INDIA.

Every new drug or contraceptive agent goes through a series of animal and human trials before it is approved for marketing. These tests are done to determine the efficacy, dosage, short-term/long-term effects and effect on progeny, of the drug or contraceptive agent. When all these factors have been established, operational research studies are conducted to see how the contraceptive is accepted in a normal service delivery situation. Logistical problems of supply, requirement of health services and training requirements of health and F.P. personnel to deliver the contraceptive are also studied. (see phases of trials in annexure).

It is mandatory for a drug company to conduct animal and human studies to establish safety and efficacy before applying for permission to market a drug or contraceptive agent. Countries wishing to use the drug or contraceptive agent in their own country make their decision on the basis of this data. However, clinical trials on humans (phase I,II,III) are also conducted in each country, depending on the drug regulations in that country.

Some countries may conduct all the phases of human trials while other countries may conduct only phase III and then go on to operational research. The reasons for conducting clinical trials in the country are :

- a) The physiological norms of the people (height, weight etc.) differ significantly from one part of the globe to the other, with the result that dosage alterations are sometimes necessary.
- b) In India, a great majority of people have had tropical diseases with the result that the functioning of liver or spleen is affected which, in turn, may alter the pattern of bio-transformation of these drugs in the liver.
- c) Finally, we know that there is what is called as the 'genetic variability of enzymes' which affects drug responses. In recent years it has been realized that drugs may affect the rates of enzyme formation. The activity of drug inactivating enzymes in human liver is also known to be under hereditary control.

(source : ICMR Technical Report Series No. 12.)

The new recommendation of approving contraceptive agents on the basis of results found elsewhere, and only conducting operational research studies in the country is therefore a dangerous trend. While such a policy would no doubt expedite the introduction of new contraceptive agents, it will leave Indian women open to all kinds of unforeseen harmful effects of these contraceptives, with little help provided by the inadequate health services in

the country. A country like ours also does not have any mechanism for conducting post-marketing surveillance to document and monitor unforeseen effects. Further, once the drug is in the market, the Indian drug regulatory authority is not powerful enough to withstand the multinational and national drug lobby and withdraw a hazardous drug or contraceptive from the market. (The history of high-fixed-dose oestrogen-progesterone combination drugs is a classic example where even though the Drug Controller banned these combination drugs, the drug companies were able to get a stay order against the ban. These drugs are still sold in the country over the counter).

IMPLICATIONS OF ADOPTING SOCIAL MARKETING TECHNIQUES TO PROMOTE CONTRACEPTIVE USE.

The government is at great pains to make us (and the world) believe that our F.P. programme is a voluntary programme, a people's movement, based on the *cafeteria* approach. In this context using social marketing techniques appears to be no more dangerous or harmful than using high pressured advertising to sell a variety of soaps.

The government and F.P. planners also counter arguments against the promotion of hazardous contraceptives by stating that there is no harm in including them in the "contraceptive cafeteria". After all different users may find different contraceptives more acceptable.

However, this approach requires certain preconditions which do not exist in our country. To choose freely women need :

- unbiased information regarding the advantages and disadvantages of the different contraceptives.
- the freedom to choose a contraceptive best suited to them
- constant supply of all contraceptives.

It is a well known fact that voluntary acceptance of a contraceptive method is a myth in our country. Reliant on medical and F.P. personnel for their information about contraceptives, women are usually given incomplete and/or biased information. The F.P. worker may not be aware of the complications and risks associated with a method. Because of the targets each worker has to meet, they may hesitate to give information even if they have it,

thinking that women may get unnecessarily put off. Often motivators recommend their own favourite method. Contraceptives are also recommended on the basis of what is available with that particular motivator, or the contraceptive which is being tested. For instance, barrier methods like cervical cap and diaphragm are not available in the country.

Government propaganda, in the form of leaflets and pamphlets, is no less biased and social marketing techniques are not going to help the user in any way. Advertising has never been associated with complete and accurate information, and using non-conventional outlets for sale of contraceptives ensures less information rather than more information. The experience of Bangladesh is a clear indicator of what will ensue. A few years ago, Bangladesh adopted an inundation programme using social marketing techniques to promote oral contraceptives. These pills were to be distributed through unconventional outlets such as paan and cigarette shops as well as through family planning workers. Funded by USAID, the programme turned out to be expensive for both the women and the funders. Instead of reducing fertility this programme ended up by increasing the fertility rate by more than 10% (a common occurrence if women miss one or more pills in the cycle). Another consequence was that many women continued to take the pill even after they had become pregnant because the pill often masked the indications of pregnancy. As the pill often produces symptoms similar to pregnancy, the village women confused the symptoms of pregnancy with the effects of the pill. Even USAID's trained family planning workers could not answer most of the basic questions about the pill. After 3 years of experience with the inundation programme, these workers could not say how many days after the onset of menstruation a woman should start taking the pill; did not know what advice to give to a woman who missed taking the pill on five consecutive days; and could not say what type of side effects might be anticipated by women on the pill.

When combined with the fact that long-acting invasive methods tend to leave women with less control over contraceptive choice, and that contraceptive availability is determined by a complex relationship between drug companies, AID agencies and the government, it is obvious that social marketing is not going to

be in the interests of women. They will only be the victims of high doses of subtle pressure to conform to the behaviour desired by the F.P. planners and the government.

CONCLUSION

The new trends in the F.P. policy pose a serious threat to the health and personal liberty of women, who are the targets of F.P.

We need to understand and expose the implications underlying these policies. We also need to raise the following questions:

- 1) Is it justifiable to introduce hazardous invasive hormonal contraceptive methods to prevent a normal physiological phenomena such as pregnancy?
- 2) Is it justifiable to pose contraception as an answer to the lack of adequate obstetrical facilities, nutrition and other basic requirements which cause the majority of morbidity and mortality in women in the reproductive age group?
- 3) Is it justifiable to snatch away from Indian women the little control they have over their fertility by promoting methods of contraception that are designed to place control in the hands of F.P. experts?
- 4) While it is necessary to conduct trials on human beings to test new contraceptives, is it justifiable to recruit persons who are not in a position to give informed consent in the true sense?

The writ petition filed in the Supreme Court on April 7, 1986 against the introduction of NET-EN into the mass Family Planning programme, is intended to make the research institutions and F.P. experts answerable to these questions. However, the debate cannot and should not remain confined to the four walls of the court room. A true change in the F.P. policy which will be favourable to women can only be achieved if the debate is carried out in all feminist, health and human rights forums.

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S A H E L I

WOMEN'S RESOURCE CENTRE

SEMINAR ON POPULATION POLICY AND
ITS IMPLICATIONS FOR WOMEN

WORKING PAPER

ON

POPULATION POLICY AND VIOLATION OF HUMAN RIGHTS

By

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POPULATION POLICY AND HUMAN RIGHTS:

SOME REFRACTIONS

Population dynamics is multi-dimensional. Where population policy is directed towards reducing the birth-rate and limiting family size, as in India, the traditional and blinkered vision has been and continues to be that these dimensions comprehend only the methods of population control and/or the allied desiderata of nutrition, health and family welfare. In part, this approach stems from an alarmist view, reminiscent of Malthusian Theory of Demographic Trends which show rapid population increase from decade to decade at every census. In some measure, the approach appears to be conditioned by thoughts analogous to Keynesian economic theory of State control through money and taxation. For the rest, and more recently, this vision is coloured by a roseate dream of technological marvels accelerating India's progress to plenty and prosperity in the 21st century. Neither Malthusian Theory nor Keynesian analogy nor Ersatz brains are of validity or adequate for solving the population problem. It is the man behind the machine who must pause to think first. In this sphere as in several others- one must hasten slowly. Where population planning is concerned, culture shock cannot be administered as if it were Electro Convulsive Therapy on the premise that the entire populace is mentally retarded.

2. For too long now, our planners and policy makers have ignored or disregarded the constitutional and

2. legal dimension of population policy and control.

Given the avowed population policy, if regulation of population necessarily involves control of fertility, then any State action or executive measure taken to effectuate such policy or accomplish such control must be subject to constitutional parameters. The fundamental rights and the Directive Principles of State Policy read in the light of the preamble of our Constitution, broadly define the limits of permissible modus operandi available to the State. The relevant constitutional principle expounded by the Supreme Court in the context is that it is not the object of State action (however laudable or desirable such action may be) but the direct effect of such action on the citizen and his fundamental rights that must be seen. Thus, if a given administrative act contravenes or infringes or even constitutes an imminent threat to the citizen's guaranteed rights, such act would be unconstitutional, notwithstanding the fact that it was done pursuant to a laudable policy or for the intended benefit of the citizen.

3. In the present context, merely because control of fertility or newly discovered but incompletely tested and researched - methods of achieving such control have not acquired the necessary social dimension, acceptance or awareness, neither these factors nor the constitutional parameters can be neglected in framing population policy or implementing it.

As a necessary corollary, if newly devised fertility control methods are introduced (e.g. Injectable Contraceptive, Subdermal Implants) and administered to women without apprising them of the short term side effects and the potential but unknown and untested long term deleterious effects on women and their progeny and without obtaining their fully informed consent, the use of such methods is a clear invasion of womens' biological integrity and hence their fundamental rights. Barely a decade ago, enforced sterilization of men blatantly invaded their fundamental body rights. Today, the State is more insidiously invading the reproductive system of women by luring them to be guinea pigs for testing injectable contraceptives. This State action is as reprehensible as it is unconstitutional. It affects the woman's autonomy or, as the Courts have some times expressed it, her " right to self-determination".

4. The root cause is a problem of perception. , The State's vision is confined to one medium, namely, that of fertility and hence population control. But there is another medium - that of constitutional and legal rights - through which also that vision must travel. We must focus on these refractions. For a proper appreciation of the issue, we must by turn look at generally accepted international norms, specific conventions regarding medical ethics related law and bio-medical research and experimentation, n

the professed population policy of Government and the mandates of our Constitution. India is a signatory or party to all the relevant international norms, international charters, covenants, conventions and declarations. The basic documents in international relevant law to our context are the United Nations Charter and the Universal Declaration of Human Rights adopted by the General Assembly of the United Nations. Other international conventions and covenants, some dealing specifically with the rights of women and children, elaborate the basic theme.

UNITED NATIONS CHARTER

5. The United Nations Charter reaffirmed " faith in fundamental human rights, in the dignity and worth of the human person, in the equal rights of men and women".

UNIVERSAL DECLARATION OF HUMAN RIGHTS

6. This Declaration was adopted on 10th December, 1948 by the General Assembly of the United Nations and it reiterates the principles of the United Nations Charter. Article 1 recognises that all human beings are born free and equal in dignity and rights and that they are endowed with reason and conscience. Article 2 entitles everyone to all the rights and freedoms set forth in the Declaration. Article 3 provides that everyone has the right to life, liberty and security of person while Article 4 provides in part that no one shall be subjected to degrading treatment.

Article 8 declares that everyone has the right to an effective remedy by the competent national tribunals for acts violating the fundamental rights granted him by the constitution or by law. Article 12 enjoins that no one shall be subjected to arbitrary interference with his privacy and family while Article 16 recognises that men and women of full age have the right to marry and to found a family. Article 25 postulates that everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services.

CONVENTION ON THE ELIMINATION OF ALL FORMS OF DISCRIMINATION AGAINST WOMEN (Adopted by the United Nations General Assembly on 18th December, 1979)

7. In its preamble, the Convention considered that discrimination against women is incompatible with human dignity and the welfare of society and constitutes an obstacle to the full realization of the potentialities of women and hampers the growth of the prosperity of society and the family. Article 1 defines the term "discrimination against women" to mean any distinction, exclusion or restriction made on the basis of sex which has the effect or purpose of impairing or nullifying the recognition, enjoyment or exercise by women, irrespective of their marital status, on a basis of equality of men and women, of human rights and fundamental freedoms in the political, economic, social, ... cultural, civil or any other field.

Article 5 mandates the States Parties to take all appropriate measures:

- (a) To modify the social and cultural patterns of conduct of men and women, with a view to achieving the elimination of prejudices and customary and all other practices which are based on the idea of the inferiority or the superiority of either of the sexes or on stereotyped roles for men and women;
- (b) To ensure that family education includes a proper understanding of maternity as a social function and the recognition of the common responsibility of men and women in the upbringing and development of their children, it being understood that the interest of the children is the primordial consideration in all cases.

Article 10(h) requires States Parties to take all appropriate measures to eliminate discrimination against women in order to ensure to them equal rights with men in the field of education and in particular to ensure, on a basis of equality of men and women " access to specific educational information to help to ensure the health and well-being of families, including information and advice on family planning". (Emphasis supplied)

Article 11(1)(f) contains like mandates in the field of employment including in particular " the right to protection of health and to safety in working conditions, including the safeguarding of the function of reproduction". (emphasis supplied). Article 11(3) provides that protective legislation relating to matters covered in that article shall be reviewed periodically in the light of scientific and technological knowledge and shall be revised, repealed or extended as necessary. Article 12 contains like provisions in the field of health care in order to ensure " access to health care services, including those related to family planning". (emphasis supplied). Article 14

specifically requires States Parties to take into account the particular problems faced by rural women and the significant roles which rural women play in the economic survival of their families, including their work in the non-monetized sectors of the economy, and to take all appropriate measures to ensure the application of the provisions of the Convention to women in rural areas. The article further requires States Parties to eliminate discrimination against women in rural areas in order to ensure that they participate in and benefit from rural development and, in particular, to ensure to such women the right " to have access to adequate health care facilities, including information, counselling and services in family planning," (emphasis supplied). Article 16 likewise calls for elimination of discrimination against women in all matters relating to marriage and family relations and to ensure to women, among other things " the same rights to decide freely and responsibly on the number and spacing of their children and to have access to information, education and means to enable them to exercise these rights". (emphasis supplied).

DECLARATION OF THE RIGHTS OF THE CHILD
(Adopted by the U.N. General Assembly on
20th November, 1959).

8. Prior to this Declaration, the need for special safeguards for the child had been stated in the Geneva Declarations of the Rights of the Child of 1924 and recognised in the Universal Declaration

of Human Rights and in the statutes of specialized agencies and international organisations concerned with the welfare of children. Since "the child by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection, before as well as after birth", and "mankind owes to the child the best it has to give", the General Assembly set-forth relevant principles in the Declaration. Accordingly, Principle 2 provides that the child shall enjoy special protection, and shall be given opportunities and facilities, by law and by other means, to enable him to develop physically, mentally, morally, spiritually and socially in a healthy and normal manner and in conditions of freedom and dignity. Principle 4 adds that the child shall be entitled to grow and develop in health; to this end, special care and protection shall be provided both to him and his mother, including adequate pre-natal and post-natal care.

INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL
AND CULTURAL RIGHTS (Adopted by the U.N.
General Assembly on 16th December, 1966)

9. Article 10 to the Covenant recognises that
"The widest possible protection and assistance should be accorded to the family, which is the natural and fundamental group unit of society, particularly for its establishment"^a Article 12 recognises the right ~~of~~ of everyone to the enjoyment of the highest attainable standard of physical and mental health and, to
achieve the full realization of this right,

requires the States Parties to take steps " for the reduction of the stillbirth -rate and of infant mortality and for the healthy development of the child".

SPECIFIC CONVENTIONS

The first formation of principles
10. In the sphere of bio-medical research to be observed in order to satisfy moral, ethical and legal concepts seems to be the Nuremberg Code. It is worthwhile reproducing these principles in full:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as the subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made, and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability or death to the experimental subject.
11. The World Medical Association has also produced certain important statements or declarations of which one most relevant here is the Declaration of Helsinki, 1975. The Association prepared the following recommendations as a guide to every doctor in bio-medical research involving human subjects, but stated that Doctors are not relieved from criminal, civil and ethical responsibilities under the law of their own countries. The WMA formulation of principles also deserve to be read in full and are reproduced hereunder:

Basic principles

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.
3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with the medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.
4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interest of the subject must always prevail over the interests of science and society.
6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
7. Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Doctors should cease any investigation if the hazards are found to outweigh the potential benefits.
8. In publication of the results of his or her research, the doctor is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The doctor should then obtain the subject's freely-given informed consent, preferably in writing.
10. When obtaining informed consent for the research project the doctor should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a doctor who is not engaged in the investigation and who is completely independent of this official relationship.
11. In the case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.
12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II Medical Research Combined with Professional Care (Clinical Research)

1. In the treatment of the sick person, the doctor must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, re-establishing health or alleviating suffering.
2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.
3. In any medical study, every patient-including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method.
4. The refusal of the patient to participate in a study must never interfere with the doctor-patient relationship.

5. If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee.(1.2).
6. The doctor can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. Non-Therapeutic Biomedical Research Involving Human Subjects (Non-clinical Biomedical Research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom biomedical research is being carried out.
2. The subjects should be volunteers - either healthy persons or patients for whom the experimental design is not related to the patient's illness.
3. The investigator or the investigating team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.
4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

12. The full text of the Declaration and other Codes is to be found in the B.M.A. Handbook on Medical Ethics. It has been pointed out that even these formulations require to be supplemented with a view to greater precision and specificity since some of the statements of principle appear to lend themselves to ambiguity. On this aspect see generally Mason and McCall Smith - Law and Medical Ethics - Butterworths London 1983; Carolyn Faulder - ^{The} Whose Body Is It? Troubling Issue of Informed Consent, Virago Press, London 1985. The study of principles as contained in the above Codes and Declarations followed by a perusal of the

population policy as framed in the Seventh Five Year Plan 1985 to 1990 Volume II would reveal the hiatus between precept and practice.

GOVERNMENT'S POPULATION POLICY

13. The current statement of the Government of India's Population Policy and Control is to be found in the Seventh Five Year Plan 1985-1990 Volume II Chapterx 11, 13, 14 and 17 read together, as also in the recent restatement of the 20-Point Programme. (See e.g. the Hindustan Times issue dated August 21, 1986). Point No. 9 of the restatement reads: "Two child norm ; Objectives: To bring about voluntary acceptance of the two child norm; to promote responsible parenthood; to reduce infant mortality and to expand maternity and child care facilities." Point No. 12 reads: "Equality for women: Objectives: To raise the status of women; to enhance awareness of the problems of women; to create mass consciousness about women's rights; to implement a national programme of training and employment for women; to enable women to participate with equality in socio-economic development, and nation building; and to rouse public opinion against dowry and ensure effective implementation of anti-dowry legislation". The Population Policy as set out in the Seventh Five Year Plan however, glosses over crucial issues and in certain respects even militates against the tenor and professed objectives of the revised 20-Point Programme, not to mention the ethical codes and legal principles mentioned above. Accordingly, we may briefly analyse the contents of the Plan Document.

Medical research which covers a broad spectrum of discipline is carried ^{out} principally under the auspices of the Indian Council of Medical Research (ICMR) (p. 272 para 11.17). Qualitative improvements are required in health and family planning services. Supplies and logistics require greater attention, education and training programmes need to be made more need based and community oriented and, since management and supervision are vulnerable areas, the management information systems need to be developed (p. 272 para 11.19 (iv)). One of the programme thrusts in the Plan period therefore, is to further strengthen the 3-tier system of centres:
/ sub-centres, primary health centres (PHC) and community health centres (CHC) would be further strengthened by converting the existing maternity and child health (MCH) centres and rural dispensaries into PHCs and sub-district hospitals into CHCs and by setting up new functional units wherever necessary. (p.273 para 11.20 (ii)). One of the high priority areas is in the field of family planning. On this point, it is stated:

" In the field of family planning, the focus would be on increasing the availability and improving the acceptability of the existing methods of contraception and on the phased introduction of longacting injectables and subdermal implants in the field of spacing methods. Operational research for development of integrated package of MCH, family planning and nutritional services through evaluation of appropriate modules would also be accorded priority, in addition to studies to improve the system of delivery of primary health care. Efforts would be intensified to develop an immunological agent for fertility control" (p. 277 para 11.42 (b)).

The Plan thus tacitly concedes the lack of acceptability of even the existing methods of contraception. At the

same time, it insidiously introduces " long acting injectables and subdermal implants in the field of spacing methods", as if these were entirely normal and accepted and without giving a clue to the controversy surrounding their use. In a somewhat more assertive vein, while speaking on research and technology development, the Plan states:

" Research related to new methods of family planning which have been found efficacious and safe for their introduction into the national programme would be completed expeditiously, e.g. long-acting injectables and subdermal implants will be introduced progressively in the Seventh Plan. The methods which have been found safe and effective elsewhere and have been approved by the competent authorities abroad may be introduced in the programme on a pilot basis as an operation research scheme, and then gradually expanded in the programme." (P. 285 para 11.85).
(emphasis supplied)

There is no warrant for the statement that long-acting injectables and s-ubdermal implants have been found efficacious and safe. This statement in the plan is entirely misleading. Unobtrusively the Plan adds that the new methods intended to be used are those which have been found safe and effective elsewhere and have been approved by the competent authorities abroad. This is a clear abdication by the Government of India of its constitutional and scientific responsibilities and a classic case of blind transfer of technology. Although the ICMR has thus abdicated its responsibilities and these controversial contraceptives have actually already been introduced, yet the ICMR " would continue to play a pivotal and co-ordinating role in medical research" (P. 277 para 11.43).

14. The Plan proudly claims that " India was the first country in the world to have a Government level programme of

family welfare and planning. It became an integral part of economic planning right from the First Five Year Plan - 1951-1956 ... However, the programme received a set back during the years 1977-1979 ..." (P. 279 para 11.56). The reasons for this "set back" are well-known, namely, the infamous enforced vasectomy operations of the emergency era. With the above quoted one sentence, however, the entire traumatic episode is glossed over in the Plan. Nothing daunted, while recognising the Sixth Plan emphasis that the family planning and welfare programme "must rise above all controversies and should be accorded high priority" and be the responsibility of Government as a whole", the present Plan solemnly asserts that "targets for family planning particularly sterilization are being achieved by special drives and camps" (P. 280 para 11.60, p.282 para 11.74).

15. The plan claims that experience has shown that involvement of women's groups and youth groups in some common, social and economic activities is quite useful in promoting the family welfare programme (p.282-283 para 11.79(ix)). The practice has been to the contrary. When these same women's groups including reputed specialists represented against the use of Net Oen neither the Drugs Controller of India nor the Indian Council of Medical Research cared to reply. All data and explanation was withheld and, therefore, these groups were constrained to approach the Supreme Court for redress. Nearly four months including the time granted to the Government of India, the I.C.M.R.

and the Drugs Controller, to file their counter affidavits have elapsed and still no reply is forthcoming.

16. The Plan recognises that the Constitution of India provides for equal rights and privileges for men and women and makes special provisions for women to help them improve their status in society (P.321, para 14.1). It also admits: "The health problem of women in society is another crucial area not given the required attention ... Nutritional surveys have indicated high rates of inadequacies among females compared to males... Statistics from Primary Health Centres show that adult women do not generally take treatment from them. Maternal mortality continues to be very high. A ^{number of} studies have indicated that a large number of children suffer from mal nutrition to which the mothers' poor health contributes to a great extent. Anaemia among rural women is estimated to be as high as 60 to 80 percent leading to low birth weight among babies (P.321, para 14.2). Perhaps on the prevalence of anaemia alone, the use of long-acting injectables and subdermal implants is wholly unwarranted. But these matters are unimportant to our planners.

17. While speaking on medical research, linkages, infra-structure development etc., the Plan says "The development of any new drug/device takes an unduly long time - almost 7 to 10 years. Efforts would be made to shorten this time by reducing the

pre-clinical toxicology period and by moving into programme introduction phase when the interim results show promising trends. This would be done without sacrificing safety and ethics. (P. 379 para 17.274). Clearly, neither the ICMR nor Government can be bothered about conducting its own biomedical research and tests. Doubtless, that is why the anxiety to rely entirely on methods accorded approval by people beyond our shores ^{who} but/would know precious little about epidemiological, nutritional and other allied factors in our country. Ethics and safety have already been sacrificed the drop out rate in the ICMR's own phase-III and Phase- IV trials and the misleading manner of advertisement of the injectable contraceptives without a word of - caution on its side effects and unknown long term deleterious effects are sufficient to prove this point.

CONSTITUTIONAL AND LEGAL PRINCIPLES

18. Article 21 of our Constitution provides that no person shall be deprived of his life or personal liberty except according to procedure established by law. The connotation of the expression "life" is now well settled by decisions of the Supreme Court. It does not mean mere animal existence but a life of dignity and subsumes the ancillary rights to food, clothing and shelter. The Supreme Court has also laid down that relevant Directive Principles would, as a matter of constitutional interpretation, be read into the concerned fundamental right to effectuate that right and give it full

meaning and content. Article 39(e) and (f) provide that the State shall, in particular, direct its policy towards securing, among other things, that the health and strength of workers, men and women and the tender age of children are not abused and that children are given opportunities and facilities to develop in a healthy manner and in conditions of freedom and dignity. Today, when carcinogenicity, return of fertility and effect of progeny resulting from the use of injectable contraceptives such as Net Oen, are still unresearched and unknown and given the impatience of Government and the ICMR to push through the use of such drugs/device in family planning, it is difficult to see how these constitutional protections will obtain in practice. In the case of a similar hormonal drug as Net Oen: "The DES nightmare is only now approaching its dreadful climax as the sons and daughters of the women who were exposed, try to cope with their fate. Diethylstilbestrol is a non-steroid sex hormone which was mistakenly administered to 'nearly six million women between 1943 and 1959' in the drive for bigger and better babies; even without considering the four in each thousand DES daughters who will have vaginal or cervical cancer before the age of 30, the consequences for their sons are disastrous..."

Germaine Greer: Sex and Destiny, The Politics of Human Fertility. Picador 1984 p.142.

19. At this juncture, it may be useful to refer to the wellknown thalidomide case (also popularly known as Sunday Times case) for certain assertions which were

which were made by the Sunday Times newspaper concerning the controversy. The drug Thalidomide was described as a sedative for, in particular, expectant mothers. Women who took the drug during pregnancy subsequently gave birth to children suffering from severe deformities. The newspaper published one article on the matter and then threatened to publish another. The unpublished article formed the subject matter of an injunction application filed by the Attorney General to restrain publication. The said unpublished article opened with the suggestion that the manner of marketing thalidomide in Britain left a lot to be desired. It stated that the Drug Company which manufactured and marketed the drug under licence from the original German manufacturers

- ' ---relied heavily on the German tests and had not completed full trials of its own before marketing the drug;
- failed to uncover in its research into medical and scientific literature the fact that a drug related to thalidomide could cause monster births;
- before marketing the drug did no animal tests to determine the drug's effect on the foetus;
- accelerated the marketing of the drug for commercial reasons. Were not deflected by a warning from one of its own staff that thalidomide was far more dangerous than had been supposed;
- were not deflected by the discovery that thalidomide could damage the nervous system, in itself a hint that it might damage the foetus;
- continued to advertise the drug as safe for pregnant women up to a month from when it was withdrawn. (emphasis in original).

20. It is submitted that in the case of injectable contraceptive Net Oen, the Government, the IC^{MR} and the

Drugs Controller of India are open to very similar criticisms atleast in so far as they seek to rely on the tests conducted "elsewhere and ...approved by the competent authorities abroad" and have not completed full trials in India before sanctioning use, marketing and distribution of Net Oen. The ICMR's own data would warrant further such conclusions being drawn similar to those raised in the Thalidomide case. The sequelae of DES lay dormant for 10 years. It is reasonable to assume that Net Oen may have a similar dormant period before its long term effects on its acceptors and progeny are known. It would be wholly untenable to await such potential catastrophe instead of averting it.

21. Article 47 of our Constitution provides that the State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of drugs which are injurious to health. Since the phase- III and phase-IV trials conducted by the ICMR themselves show short term deleterious effects of Net Oen, the State has a primary duty to prohibit its use.

22. Article 51A(e) makes it the duty of every citizen of India " to renounce practice derogatory to the dignity of women." Surely, nothing can be more derogatory of the dignity of women in India to be beguiled and inveigled into becoming acceptors of such long-acting injectable contraceptives only to find the integrity

of their reproductive system disrupted and their progeny possibly deformed. The Ministry of Health and Family Welfare's own guidelines on the use of Net Oen state: "It is of great importance that adequate explanations of the long term effectiveness of the product, its possible side effects and of the impossibility of reversing the effects of each injection are given to potential users". Clearly, there is no informed consent. Even more clearly, since Net Oen has been introduced only very recently, and its long term effects cannot be predicated, at this stage, there can be no informed consent at all.

23. At the legal level, as contra-distinguished from the constitutional plane, court cases on such issues have generally arisen in the area of the tort of negligence (a tort is a civil wrong, other than a breach of contract, the remedy for which lies in award of damages). In law, negligence means failure in "a duty to take care". Such cases have arisen in countries like Canada, the U.S.A. and the U.K. In a Canadian case. - Male v Hopmans -1967 (64) DLR (2d) 105, the Doctor concerned feared serious infection and osteomyelitis being contracted by his patient. Without the patient's specific consent, he decided to administer a drug with known possible side effects of impairing hearing and kidneys. The Ontario Court of appeal held that the Doctor was not at fault in administering the drug but he was liable for failing to carry out recommended tests before using the drug. In another

case, Reibl v Hughes (1980) 114 DLR (3d) 1, the Supreme Court of Canada rejected the adoption by the Courts of "a professional medical standard not only for determining what are the material risks that should be disclosed but also, and concurrently, for determining whether there has been a breach of duty of disclosure". The Court observed " To allow expert medical evidence to determine what risks are material and, hence, should be disclosed and, correlatively, what risks are not material is to hand over to the medical profession the entire question of the scope of the duty of disclosure, including the question whether there has been a breach of that duty". What falls for consideration " is the patient's right to know what risks are involved in undergoing or foregoing certain surgery or other treatment". There are rulings to similar effect of the American and English Courts. Since these countries are governed by legal systems similar to ours, such court decisions rendered in these countries are of immense persuasive value in our own courts. These cases have essentially arisen in the context of a one-to-one Doctor-patient relationship. In the present context of population control and family planning, however, we are concerned largely with a one-to-many Doctor-patients relationship. The concept of negligence, therefore, assumes much wider implications and ramifications. Given our constitutionally guaranteed rights, our courts have generally tended to expand the scope of such principles and there is every probability that the Supreme Court would maintain the same expansive approach in the Net On case pending before it.

24. An allied legal doctrine in the sphere of negligence is derived from the maxim *res ipsa loquitur* (the thing or event speaks for itself). The essential conditions for the application of this principle are:

- (i) The accident was ^{of} a kind which does not ordinarily occur unless some one is negligent.
- (ii) That the instrumentality or agency which caused the accident was in the exclusive control of the person charged for negligence.
- (iii) That the injury suffered must not have been due to any voluntary action or contribution on the part of the person injured.

In the case of a tort on a mass scale, such as, for instance, the Bhopal Gas Leakage Tragedy, the issue of negligence assumes serious proportions affecting the constitutional rights of a large section of the community. Such would be the case of potential tragedy with the use of Net Oen. However, that does not mean that the citizen or the court must wait till the event or tragedy occurs. Once it is accepted that in the very nature of things informed consent cannot be given, and the effects of each injection are irreversible, the court would find ample justification to prohibit or restrain the use of the drug as part of the family planning programme and as a permissible method of fertility control.

25. Population policy and fertility control cannot be rested on such a tenuous and potentially tragic foundation, as brought out above. Constitutional and legal principles warrant the proposition that the use of insidiously invasive and inherently risky methods of fertility control are clearly violative of fundamental human rights.

M.S. GANESH

&

R. VENKATARAMANI

ADVOCATES SUPREME COURT OF INDIA

Government of India
Ministry of Health & Family Welfare

GUIDELINES FOR USE OF NORETHISTERONE ENANTHATE, AN
INJECTABLE CONTRACEPTIVE FOR ITS USE IN GOVERNMENTAL
AND NON-GOVERNMENTAL FAMILY PLANNING CLINICS :

(EXCERPTS)

Criteria for selection :

Healthy informed women who seek Family Planning services to be selected if they fulfill the following criteria :

1. Age between 18 to 40 years
2. Proven fertility
3. Exposed to risk of pregnancy
4. Willing to rely only on Net-en as a method of fertility regulation
5. Regular menses (variation of not more than 10 days between the longest and the shortest menstrual cycle during the last 6 months)

One cycle after M.T.P.

Contra-indications to the use of NET-Enanthate :

1. Cancer of the breast.
2. All genital cancers (Except as treatment for endometrial cancer).
3. Undiagnosed abnormal uterine bleeding.
4. Suspected pregnancy.
5. Should not be given in lactating women. The new recommendation says not to be given during first 6 months of breast feeding.

Cases which require medical supervision, namely, undiagnosed breast lump, abnormal liver function or recent history of liver disease including H/o jaundice in pregnancy or jaundice during the last six months, H/o or evidence of cardio-

vascular disease, congenital hyperlipidaemia, H/o infrequent bleeding, amenorrhoea, diabetes mellitus of H/o gestational diabetes.

The following common side-effects to be explained to each woman :

1. Irregular bleeding and spotting, sometimes prolonged.
2. Amenorrhoea.
3. Delay in becoming pregnant after discontinuing Net-en injection.
4. Headache and weight gain.

It is of great importance that adequate explanations of the long term effectiveness of the product, its possible side-effects and of the impossibility of reversing the effects of each injection are given to potential users.

Duration of use :

If the periodic clinical evaluation does not reveal any adverse effects, the medication can be continued. Net-en should be used primarily for spacing pregnancy in younger women. However, sterilisation or other forms of contraception should be considered for women not desiring any more pregnancies. Beyond 40 years of age, other forms of contraception should be considered.

An annual examination of pelvis and the breast is recommended.

Administration of Norethisterone-Enanthate :

The initial injection of Net-en should be given during the first 5 days of the menstrual period. The woman should be re-examined for the development of any problem and would receive the next injection after every 8 weeks of its use.

Mode of administration :

Since Net-en is a viscous oily solution, special care should be taken while aspirating it into the syringe and during injection in order to ensure that all the material is ejected from the syringe and that no leakage occurs around the needle. If the vial has been stored in low temperature, it is advisable to warm it before giving the injection. The preparation should be given by deep intramuscular injection, preferably into the gluteal muscles (buttocks). The injection site should not be massaged.

Precautions :

If any of the contra-indications to use appear, further injections of the drug should not be given. Similarly, if any of the special problems requiring medical supervision should develop, the advise of the trained medical personnel should be sought prior to giving additional injections.

Warnings :

Do not administer an injectable contraceptive when a pregnancy is suspected. It will not cause abortion but may interfere with the normal development of the baby.

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ONE DAY SEMINAR ON POPULATION POLICY AND ITS IMPLI-
CATIONS FOR WOMEN.

AUGUST 30, 1986 AT JNC CITY CENTRE, NEW DELHI.

Compiled by - Information and Documentation
Voluntary Health Association of India
40, Institutional Area, South of I.I.T.
New Delhi 110 016.

ARE PRIMARY HEALTH CENTRES GEARED TO FACE THE CHALLENGE
OF INJECTABLE CONTRACEPTIVES.?

The national Health Policy under which we seek to attain the goal of Health for all by the year 2000 AD is based on a firm recognition of the fact that the Health Status of the people must be raised, if the quality of life is to improve. Under this policy strenuous efforts are being made to place people's Health in the people's hands through a Comprehensive Primary Health care system reaching out to the population even in the remotest areas with the maximum community participation.

THE HEALTH
CENTRES

Primary Health Care is being provided to the rural population in the country through a network of 83,008 sub-centre(SC) each sub-centre for every 5000 population.

7250 Primary Health Centres(PHC) for serving 30,000 population, 3688 subsidiary Health Centres and 613 upgraded PHCs or Community Health Centres for serving 1,00,000 population. (It will also have 30 beds). There are 5.11 lakh trained Dais and 3.71 lakh Health guides besides large number of rural dispensaries working under the state government/UT Administration.

PHC
SERVICES

The PHC complex constitutes the core of the Rural Health Service program in India. Their operational responsibility is to cover medical care, maternal and Child Health services, Family Welfare, nutrition, Control of communicable diseases, protected Water Supply and Environmental Sanitation.

About Primary Health Care, Dr. Mahler, Director General of WHO states "It is not cheap and primitive technology for poor and primitive people".

The above statement is not put into practice in our PHCs today.

PROBLEMS
&
CHALLENGES

The problems are not as simple as they seem.

- The rural population's concept of Health & Disease is rather traditional and their idea of medical care is some treatment easily accessible and available.
- Limited paying capacity
- Comparative inaccessibility of medical care services due to under-developed communications and transport facilities.

- Scarcity of trained manpower. Besides qualified Health workers do not want to work in rural areas because of professional, personal and social reasons.

PHC DOCTORS

Every now and then we come across titles like "2300 rural posts of Doctors vacant" or "PHCs without Doctors" Why is this situation?

According to Health Statistics of India '85, against the sanctioned 19541 posts (1984-85) of Doctors, only 18281 are filled the rest 1260 are vacant. The reasons are not far to seek.

- The pay scales are unenviable
- Problems of Infrastructure/accommodation.
- 25% of PHCs have no buildings at all.
- Some centres do not have equipments/medicines.

In most of the PHCs the post of the Women Medical Officer remained vacant. Many women are reluctant to be treated by a male Doctor.

In U.P. as many as 739 posts of Third Medical Officer are still vacant.

The government through its working groups announced several incentives to encourage doctors to work in the rural areas.

QUALITATIVE CHANGE IN TRAINING

It is unfortunate that the statement that Doctors are the biggest problem in India's Health Organization continues to be reinforced. Apparently sufficient action has not been initiated by the Medical Council of India and Individual Medical Colleges to train medical men to be leaders of a Health team as against a sickness team. The Doctor is more suited to deliver Hospital based, disease oriented medical care in urban areas and not trained for preventive care in a rural set up. In India what is required today is not a quantitative increase of Doctors but a qualitative change in their training and outlook.

A MASSIVE TASK

We have nearly 5,60,000 villages in India and if there was one Doctor with a well stocked dispensary to serve atleast 6 villages, we will need a minimum of 95,000 Doctors. But we have only 29331 Doctors available in Rural India. Various measures have to be taken from various levels on a war footing to tackle this problem. This presupposes the Coordination among all the Departments functioning as well as welfare agents at the level of planning and execution. People's participation and Health Education are the most important areas which should be tackled first.

THE
ROME
SCHEME

Though the centre has asked each medical college to adopt 3 PHCs with provision of transport facilities for students and interns to promote Health Education and Health Care in the Villages, some medical colleges have not been able to put the scheme into practice. The exposure of medical students and to some extent even the teaching staff to the Health problems in rural areas was considered fleeting and cursory.

THE
"WHITE
ELEPHANT"

Mobile Vans obtained with British Assistance were allotted one to each medical college to support the scheme. Most colleges have not used these vans effectively.

THE
PARAMEDI-
CALS

According to a sample survey of 110 PHCs from 16 States, it is found that about 33.9% of medical officers, 54% of Block Extension officers and Lady Health visitors and 44.9% of all the categories agreed that the Health Centre cannot even provide the Health care it is required to provide.

Para-Medical Manpower in Rural areas - 1984-'85.

	<u>Sanctioned</u>	<u>In position</u>	<u>Vacant Posts</u>
Health Worker (M)	75,396	72,198	3198
Pharmacist	20,457	18,726	1731
Lab Technician	6,972	598	6374

There is also shortage of teaching aids, models, stationery, pamphlets and books.

TRAINING
OF COMMU-
NITY
HEALTH
GUIDES/
VOLUNTEERS.

According to the findings of repeat evaluation of Community Health Volunteers Scheme 1979 (NIHFW)

- The composition of females amongst CHVs continued to remain less than 10%
- About 40% of the PHC staff engaged in training CHVs were themselves untrained.
- Reorientation training of CHVs was found to be the neglected areas because only 6.3% of the CHVs are reported to have received orientation training of 1-7 days duration.
- 60% of the PHC staff claimed that the workload has increased.
- About 45% of potential trainers reported that the existing work would not leave enough time to take up training of CHVs.
- Maintenance of records and reports would get adversely affected.

- 60% of the CHVs did not receive the manual, 33% have not received their medicine kits, 41% of CHVs and 23% of PHC staff stated that supply of medicine is irregular.

The main obsession of PHC official to meet targets has further added Insult to Injury! Originally conceived as the last link in a Community Health and preventive medical chain they are turning out to be seldom guided, Half baked, curative agents!

MEDICINES

The stock of medicines in most of the PHCs would have shocked any doyan of Health. It consists mostly of Carminative mixture, Epsom Salts, Vitamin Pills, Gential Violet, Pencillin Injection, Tetanus Toxoide and the like to battle against common ailment. On a shoestring budget, Drugs, linen and other miscellaneous items have to be purchased for a whole year.

At the PHC, Tokepal, stomach infection abound during the monsoons. The VH guide says he gets many cases of dysentery and vomitting. But he ran out of Kaolin powder and has not been getting Suphaguanadine either. But it turns out there is abundant Suphaguanadine at the PHC. Why were the Health Guides turned without any? The Doctors say they did not know they could divert their own supplies to the Guides!

At the PHC, Pune, medicines are regularly flicked. There are other malpractices also like the Doctors allegedly using government medicine and charging exorbitant rates, gives expired medicines and obsolete tonics all in the name of Rural Health.

At the PHC, Patna (Phulvarisharif) Doctors complain about inadequacy of medicines, both in range and quality. Just Rs.20/- worth of medicines is provided per day when more than 100 patients come daily.

At Bangalore (Hasaraghatta) PHC - an emaciating budget of Rs.12,000/- is allotted for annual purchase of Drugs, linen and miscellaneous items. While at another PHC (Doddaballapur) Rs.25,000/- is sanctioned. They need atleast one lakh rupees per year for medicines, cotton, wool and so on.

Fi

EQUIPMENTS

The condition and availability of equipments at PHCs is still worse. Pathological testing facilities are grossly inadequate. In Pune - Although the PHC has an operation theatre, it is rarely used. There is problem of dust. Only minor operations are done. The rest are sent to the Sassoon Hospital, Pune. In Patna - Oxygen cylinders are empty; non-availability of applicators for loops; The Lab boy complained of lack of water in the lab. In the operation theatre 40 Watt bulbs were used when the need is for 200 Watts. In one PHC the X-Ray machine was installed but there was no provision for the appointment of an X-Ray Technician, the machine could not be used.

Vehicles - were made available but no provision for their replacement when they become unusable. This has resulted in restricting the mobility of medical and paramedical staff in many places. Very often the

vehicle is out of order, the Driver indisposed and patrol sanctioned for the month got spent in the first two weeks itself.

DISTANCE

A Sample of 8 PHCs covering a population of about 6,25,000 according to '71 census.

About 24% of the population of the District resides within 5 km of a PHC.

- 38% - 7 km
- 49% - 10 km
- 70% - 15 km

However on an average nearly 85% of the patients come to a PHC from village falling within a radius of 5-7 km.

PREVENTIVE CARE OF PHCs

Blindness and Vitamin A deficiency

Severe forms of Keratomalacia coupled with malnutrition and infection is believed to be an important cause of blindness among children. As a preventive measure Vitamin A solution in oil form is given to children.

Scheme	Target '84-'85 Physical	Achievement upto Sep. '84 (Physical)	% achievement annual target
Prophylaxis against Blindness among children	270 lakh	131.55 lakh	53.7

The PHC at Uluberia - a sub division of Howrah Dist, has no supply of Vitamin A oil even though 6 children have lost their eyesight and 30 have shown signs of severe night blindness in the past 8 months. The Hospital could not do anything as supplying Vitamin A oil to the village was the responsibility of the PHC.

IMMUNIZATION

It is one of the most cost effective Primary Health Program and important component of PH care services. (In Millions)

Beneficiaries	Vaccine	'84-'85	Achievement upto '84	
Pregnant Women Infants	T.T.	13.00	4.13	Provisional
	DPT	14.50	4.84	"
	POLIO	12.00	2.75 +	Upto Sept. '84
	BCG	14.5	4.84 +	-do-
School Children (5 Yrs.)	DT	13.0	4.56	Provisional
	TYPHOID	11.00	1.85 +	"
10 years	TT	8.0	1.17 *	"
16 years				

A VH Guide from Budhpadar about 9 km from Gidam, looks blank when asked about immunization. He does not know he was supposed to do anything about it and as far as he knows no vaccine has come here in the last few years.

PATNA PHC - Polio Vaccine, Triple Antigen (if at all provided) its potency is doubtful as refrigeration facilities do not exist.

INTRO-
DUCTION
OF INJ.
CONTRA-
AT PHCS

This being the state of affairs of the present functioning of the PHCs, the government is planning to introduce I.C. at the PH centre level. The seventh plan proposes to introduce long acting Injectables (NET-EN) & Subdermal Implant (NORPLANT) progressively in the national family welfare programmes. Both are ICMR Projects.

RISKS
OF ICS

Very little is known about how the drug is metabolized in the body. A large number of pharmacological and biochemical studies conducted so far present too complex and varied findings to yet arrive at a coherent picture.

- Side effects of NET-EN are Bleeding problems, menstrual Disturbances, Cancer risk, liver damage, contraindications like liver disease, gall bladder disease, breast malignancy, genital malignancy, uterine Myoma, etc.

Apart from these the Injectable have to be taken for a longer period of time with preliminary subsequent followeup, visits, examination of blood pressure, systematic pelvic examination, treatment of side effects etc.

CONCLU-
SION

"Health cannot be forced upon the people. It cannot be dispensed to the people. They must want it and be prepared to do their share and to cooperate fully in whatever health programme a country develops"

KATHERIVE ELLIOTT.

Health/
Care

We have already seen the situation of the PHCs. If they are ill-equipped to carry on their present basic/activities how are they going to take up additional responsibilities? What will be the monitoring system? What will be the administrative and operational aspects?

If there are no equipments in PHCs what will be the testing facilities available for the women? Could such tasks be performed by Paramedics? Who will be responsible for the foctal abnormality that may occur due to its exposure to IC in Utero?

So a medically unsafe IC poses additional risks Considering the governments apparant determination to introduce IC inspite of everything and considering the state of affairs prevailing among the Health Care personnel, we must give serious thought to undertaking studies on the nature and extent of the damaging effects of Irregular and random administration of IC & Search for remedial medical measures for the benefit of the subjects who will be persuaded by various means to take IC.

Research is vital especially if it involves human beings.

NOTE: While collecting materials for this paper we found that most of the reports i.e. nearly 85% deal with manpower problems, only 5% regarding availability of medicine, 5% information on equipments and the rest 5% on other items. We felt it quite strange, since only manpower cannot solve the problem, we hope atleast the future researchers will give more weight to the neglected, essential areas.

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