

## **CHAPTER X**

### **RESEARCH, MONITORING AND EVALUATION**

Research studies in reproductive and child health are being carried out by the Indian Council of Medical Research, its permanent institutes, its collaborating centres and academic and Research Institutions supported by research grants from the ICMR, DBT, DST and UGC. The National Institute for Health and Family Welfare carries out operational research studies; the International Institute For Population Sciences Bombay and the network of Population Research Centres carry out evaluation studies health and demographic surveys. Many of these institutions are undertaking collaborative studies funded by National Agencies and by International agencies such as WHO, UNFPA, UNICEF, etc. National Commission of Research in Human Reproduction (NCRHR) under the Chairmanship of Secretary (FW) undertakes periodic reviews of ongoing activities and draws up priority areas including those requiring interagency collaboration. The sub-committee of NCRHR under Indian Council of Medical Research (ICMR) has organized several working groups to recommend priority areas for research under : maternal health and women's health and development, child survival and child health, infertility , contraception, safe abortions, adolescent reproductive health and gynaecological problems including RTS/STI in women.

Major focus of the research activities during the last three decades include:

- basic research aimed at better understanding of the physiology of reproduction in women and men, development of newer contraceptives and newer drug delivery systems so that couples in the 21st century will have wider choice of contraceptives.
- clinical testing of newer drugs and devices to determine their suitability for use in the National Family Welfare programme; research studies to investigate the safety and efficacy of available contraceptives in presence of undernutrition, anaemia and prolonged lactation.
- operational research aimed at introducing wider contraceptive choices in the National Programme and to improve quality and coverage of family planning services within the existing health care system so that there is increased acceptance and continued use of the contraceptive methods.
- socio-demographic, psycho-social and communication research so that there is better understanding of the behavioral factors governing contraceptive acceptance and adoption of the small family norm, and testing of newer innovative approaches to improve the knowledge, promote attitudes and practices that could result in improvement in acceptability and continued use of contraception .

Some of the major research activities in contraception which have direct relevance to the implementation of Family Welfare Programme during the last three decades are briefly reviewed.

## **Intrauterine contraceptive devices**

Based on the favourable results reported in clinical trials in major hospitals in India, Lippe's loop was introduced in the National Family Planning Programme in 1965. With the introduction of Lippe's loop the programme had an effective contraceptive method for birth spacing ; this device was also used by couples who did not want any further pregnancy but were not willing to undergo surgical sterilisation. Initially Lippe's loop was introduced in the family planning clinics attached to major hospitals. These hospitals had the infrastructure for effective screening prior to introduction of the loop and provision of follow up care; because of these early problems of expulsion, infection and excessive bleeding during periods could be readily tackled. Following the encouraging experience in these hospital based clinics, an attempt was made to improve availability of Lippe's loop in rural areas through camp approach. A team of trained gynaecologists visited the IUD camps and inserted Lippe's loop to eligible women. This approach ensured careful insertion by trained experts. However, there was no infrastructure available to provide follow up care and counseling to Lippe's loop wearers as and when side effects and complication occurred. Within a very short period this led to the user's disenchantment with the device and fall in the number of Lippe's loop insertion in the country.

In the seventies the second generation Copper IUDs came into use. ICMR undertook a comparative evaluation Copper IUDs and recommended that under existing conditions in India, CuT 200 was a safe and effective contraceptive with relatively few side effects and complications. Studies carried out by the National Institute of Nutrition showed that even though IUD use was associated with an increased blood loss during menstruation, there were no adverse effects on haemoglobin status even in anaemic women. When these women received iron therapy the haemoglobin level improved. Based on these findings Govt. of India introduced CuT 200 into the National Family Planning Programme. Copper IUD insertion were carried out mainly through hospital clinics or Primary Health Centres. Adequate provisions for follow up care were made available to all IUD users. During the seventies IUD insertion showed a progressive increase indicating that once follow up services were provided the women were willing to use intrauterine device . In the eighties and nineties with the improvement in the availability of services in the primary health centres, the number of IUD insertions in the country showed a steady and progressive increase. CuT 200 remains to be the most widely used effective spacing method in the national programme.

Of the major problems in the IUD use in the country at the moment is the poor continuation rates under programme conditions. One of the reasons for the high discontinuation rates could have been the emphasis on the method specific targets and lack of adequate counseling and client centered care. With the abolition of targets from 1.4.96, only women who want to accept the method will undergo IUD insertion. During the ninth plan period there has been a reduction in IUD insertions: Currently there is no information on continuation rates of spacing methods under programme condition . It is essential to get this information. The ongoing operational research studies on

making the balanced presentation about the contraceptive options, counseling, improvement in the quality of care, show that such an approach results in substantial improvement in the continuation rates.

As and when there is substantial improvement in the continuation rates of IUD use, there might be a need to consider the requirement of special groups such as women in their late thirties who desire to use IUD for long term contraception. Studies carried out by ICMR indicate that CuT 380 A which retains its efficacy for 10 years is also a safe and effective contraceptive. Initially the country depended on the import of CuT for use in the National Programme. In the Eighth Plan period the country's requirement is totally met from the indigenous production. The GOI has set up quality control laboratories for testing the IUDs to ensure that devices used in the programme meet the specifications.

### **Oral Contraceptives**

During the seventies a variety of hormonal contraceptive preparations became available. It was felt that some of them could be incorporated in the National Family Planning Programme so that women have wider choice of contraceptives for spacing births. In the seventies almost all the available data on the hormonal contraceptives were derived from studies conducted in developed countries among well nourished women. There was no information on side effects and complications of use of these contraceptives in women among whom infections, undernutrition and anaemia were widely prevalent. ICMR in collaboration with World Health Organisation undertook a study on use of low dosage Combination Pill and DMPA among urban low income group population. Data from the studies showed that side effects of hormonal contraceptives in undernourished women were essentially similar to those reported from well nourished women. Prevalence of undernutrition, anaemia or clinical signs of Vitamin B complex deficiencies were not increased in hormonal contraceptive users. Oral Contraceptive use did not aggravate anaemia. Majority of women using hormonal contraceptives in India are those with one or two children in their twenties, who do not smoke. They use OCs for 2-3 years only. In Asian women, prevalence of thrombo-embolic phenomena is lower. Because of all these, it is likely that serious long term sequelae such as cardiovascular diseases and hypertension are likely to be lower in Indian OC users as compared to OC users in developed countries. Based on the recommendations of ICMR, low dosage Combination Pill was introduced into the National Family Planning Programme. In an attempt to improve accessibility and availability, OCs are also being provided through nongovernmental organisations and social marketing channels at a subsidised costs. During the nineties there has been a steady increase in the OC users. However the continuation rates reported in the programme conditions is low.

### **Medical Termination of Pregnancy**

Studies undertaken in the sixties indicated that in India over 4-6 million illegal abortions were being performed by untrained persons every

year and that sepsis following illegal induced abortion was a major cause of maternal mortality and morbidity. In order to reduce the morbidity and mortality due to illegal abortion, Govt. of India enacted a Medical Termination of Pregnancy Act (in 1972) liberalising availability of MTP. Liberalisation of MTP was done as a health measure to reduce maternal morbidity and mortality due to illegal induced abortion and not as a family planning measure. Soon after liberalisation, Indian Council of Medical Research undertook a nationwide study on sequelae of MTP performed under existing conditions in 13 Medical College hospitals from different parts of India. Data from the study showed that first trimester abortion by vacuum suction is safe. Majority of Indian abortion seekers were married parous women who did not want another pregnancy. About a third of them underwent tubectomy and 1/5th accepted IUD at the time of MTP. The data from ICMR study showed that concurrent contraception at the time of MTP did not result in any increase in morbidity.

Following the reassuring findings from the ICMR study, the government embarked on training of necessary manpower and providing necessary equipment for MTP to make MTP services readily available both in urban and rural areas. Over the next 10 years there was a considerable expansion of the infrastructure and facilities for MTP. However during the nineties there had not been a commensurate increase in number of MTPs done. Nor has there been any substantial reduction in the estimated number of illegal induced abortions and septic abortion admissions over this period. Small scale research studies have shown that problems related to access, availability and confidentiality have come in the way of women seeking safe legal abortion service. Currently efforts are underway to improve accessibility of abortion services in rural and urban areas so that all women will have the benefit of safe abortion. Acceptance of contraception among MTP seekers is good. In 1991 about 1/3 of all women undergoing MTP underwent concurrent sterilization; about 20% accepted IUD and hence repeat abortions are not common in India. In the eighties newer non-surgical methods for termination of early pregnancy became available. ICMR in collaboration with WHO has carried out clinical tests of various drug combinations by various routes for non surgical methods of termination of pregnancy and found that they are safe and effective when carried out in medical college settings. It is important to undertake operational research studies introducing non surgical methods in district hospitals in a phased manner so that there is improved access to safe MTP services in the country; this in turn will result in reduction of morbidity and mortality due to illegal induced abortion.

### **Sterilisation - Vasectomy**

In India the safety and efficacy of vasectomy was quite well known. In the fifties, sixties and early seventies vasectomy was widely used in India. However from the late seventies there has been a progressive fall in the number of vasectomies performed in the country. Small scale research studies have suggested that this fall may be due to several factors:

- men who are not involved intimately in child bearing and child rearing do not readily accept the responsibility of contraception;
- the myths of adverse side effects of vasectomy;
- vasectomy programme is not recognised by the surgeons as an integral part of their services and
- unlike tubectomy services, convenience of the client is not catered to while providing vasectomy services.

Appropriate remedial measures to improve access and good quality vasectomy services may have to be evolved and implemented to improve acceptability of this safe and effective procedure. Introduction of no scalpal vasectomy may play a role in improving acceptance in some groups.

### **Sterilisation -Tubectomy**

In India tubectomy is the most widely used method of contraception. Studies carried out during the last two decades indicate that postpartum sterilization is very safe and effective form of female surgical sterilization. The fact that the women is already in the hospital for delivery, the ease and the safety of the procedure under local anesthesia account for the popularity of the method both among the patients and among the obstetricians. MTP with concurrent sterilization is also safe; and about a third of women undergoing MTP do accept concurrent tubectomy. During seventies laparoscopic sterilization become available in India. Initially laparoscopic sterilizations were being done in major institutions. Data from ICMR's Collaborative Studies on tubal Sterilization showed that mini-laparotomy was the procedure associated with minimal complication rates. Laparoscopic sterilisations mostly interval or post abortal were associated with higher morbidity rates than puerperal sterilizations.

To improve outreach of sterilization in rural areas where sterilization services were not available, 'camp' approach in which trained laparoscopists carried out surgical sterilization in rural camps was used. ICMR's studies indicated that laparoscopic camp sterilizations were associated with higher failure and complication rates; hence ICMR recommended that laparoscopic sterilization should preferably be done only in major institutions. Following an initial peak in 1982 when laparoscopic sterilisations formed over 50% of all sterilisation done in the country, there had been a progressive fall in the number of laparoscopic sterilisation. In the nineties laparoscopic sterilisations form no more than 1/3rd at all sterilisations and are being done mainly in major institutions with adequate facilities and manpower for providing excellent surgery and follow up facilities so that complications and failure rates are low.

### **Contraception in Lactating Women**

In India use of temporary methods of contraception for birth spacing has remained quite low over the last three decades. It is possible that relative infertility during lactation is responsible at least in part for this phenomenon. In developing countries like India, lactation holds the key for

infant survival and growth especially among poorer segments of population. Recognising this, government of India has taken necessary steps to protect the existing practice of prolonged lactation. Lactation prolongs post partum amenorrhea and provides some protection against pregnancy. Studies carried out in India have shown that during the first few months after delivery when infant is solely breast fed and the mother is having amenorrhea conceptions do not occur. However once supplementary feeds are introduced and menstruation returns, fertility return also occurs. Data from the National Health and Family Survey indicate that about a third of lactating women introduce supplements by fourth month. More than 10% of women conceive within one year after last delivery. Early advent of next pregnancy has adverse effects on the mother and the offsprings. It is therefore essential to promote use of appropriate contraception by lactating women .

Research studies in India have shown that:

- ☛ Puerperal sterilisation is safe and effective contraception in lactating women.
- ☛ IUD insertion in the immediate post partum period is associated with high expulsion rates. Insertion of IUD in the hyper involuted uterus during lactational amenorrhea might be associated with a increased risk of perforation of uterus. Taking these factors into consideration it would appear that the optimal time for IUD insertion might be soon after return of menstruation in lactating women.
- ☛ IUDs and sterilisation have no adverse effect on lactation and hence are the contraceptives of choice in lactating women.
- ☛ There may be women who find that these methods are not suitable and opt for hormonal contraceptives. Available data indicate that progestogens only contraceptives are free from any adverse effect on lactation. Combination pills containing low dose estrogens have been shown to reduce the duration of lactation and milk output when initiated early in lactation . However if low dose OC use is begun after 6 month of lactation there was no adverse effect on duration of lactation, milk output, infant growth or development. It is well known that contraceptive steroids are excreted in breast milk. So far there are no reports about any adverse effect attributable to steroid ingestion through breast milk. Taking all these into account and as a measure of abundant precaution, Government of India has issued a guideline that hormonal contraceptives use in the Family Planning Programme should initiated only after 6 months of lactation.

### **Research for Development of Newer Contraceptives**

Research for exploring newer avenues for contraceptive development is an arduous and expensive effort; majority of 'leads' peter out after years of painstaking research studies. However, unless basic research studies exploring newer avenues with innovative approaches are supported, men and women of twenty first century will not have wider options from which they could choose contraceptives to suit their needs. Over years India has developed substantial manpower in human reproduction research, working in

fairly well equipped laboratories. In addition under the ICMR a net work of centres for clinical trials have been established. Taking advantage of this situation immunological methods for fertility control using beta HCG, FSH, inhibin and riboflavin carrier protein has been extensively investigated during the last decade. Central Drug Research Institute has developed a once a week non steroidal contraceptive 'centchroman' which is now available under physicians prescription. Newer drug delivery systems including nasal spray and implants for delivery of contraceptive steroids have been explored. Clinical trials are also underway to test newer vaso-occlusive methods. Efforts are underway to develop spermicides based on plant products such as neem oil and plant saponins.

Some of the ongoing and the proposed studies include

- ☛ evaluation of combined monthly injectable contraceptive Cyclofem for its acceptability, efficacy and side effects when offered through cafeteria approach.
- ☛ evaluation of improved contraceptive implants,(single rod)
- ☛ preprogramme introduction studies with contraceptives evaluated in clinical trials particularly injectable and implants .
- ☛ comparative efficacy of different regimens available for emergency contraception (Levonorgestrel CuT200, RU 486) .
- ☛ phase III clinical studies of indigenously developed male intravasal contraceptive RISUG (Styrene Maleic Anhydride dissolved in Dimethyl sulphoxide)
- ☛ studies on both steroidal and non-steroidal hormonal agents for male contraception
- ☛ clinical trials of newer male condoms as well as female condom Under the RCH programme the Department of Family Welfare has constituted an expert committee for research in reproductive health and contraceptions under modern system of medicine and ISM&H to examine and recommend proposals that require funding. In addition, the Department is making efforts for the creation and support of an appropriate institutional mechanism to test and ensure the quality of products utilised in the programme.

### **Priority Areas of Research during the Tenth Plan;**

#### ***Basic and clinical research***

- ☛ development of newer technology for contraceptive drugs and devices in modern system of medicines, including immunological methods for fertility regulation .
- ☛ examining the safety and efficacy of ISM&H products.
- ☛ identification and characterisation of genes/gene products and detailing their functional role of in reproduction and health of women and children.
- ☛ development and testing of new drug delivery systems for contraceptive steroids.
- ☛ safety and efficacy studies on newer vaso-occlusive methods, spermicides based on plant products such as neem oil and saponins and other plant-based substances.

- ☛ clinical studies on the use of emergency contraception and non-surgical methods of MTP.
- ☛ diagnosis and management of RTI/STI,
- ☛ innovative methods for improving neonatal care at the primary health care level, including assessment of simple methods for the diagnosis and management of sepsis, asphyxia and hypothermia in new born babies.
- ☛ studies on the prevention, detection and management of infections in children.
- ☛ early detection and management of obstetric problems.

### ***Demographic/Operational Research studies***

- ☛ ongoing demographic transition and its consequences.
- ☛ continuation rates and effectiveness of contraceptives under actual programme conditions.
- ☛ operational research to provide integrated delivery of health, nutrition and family welfare services at the village level through the existing infrastructure and manpower.
- ☛ testing of the relationship between couple protection rate and CBR and between the reduction of IMR and reduction in birth rate in states in different levels of demographic transition.
- ☛ improving access to safe abortion services.
- ☛ research aimed at detection, prevention and management of RTI/STI in different levels of health care.
- ☛ socio-behavioural research to improve community participation in increased utilisation of family welfare services.

### **Monitoring and Evaluation**

The NDC Sub-Committee on Population recommended that district-level databases on quality, coverage and impact indicators for monitoring the programme should be created. During the ninth plan the following systems were being used for monitoring and evaluation for the Family Welfare Programme:

- ☛ reports from state and implementation agencies.
- ☛ sample registration system and population census.
- ☛ rapid household surveys.
- ☛ large-scale surveys - NFHS, sample surveys by the NSSO and area-specific surveys by the Population Research Centres.
- ☛ other specific surveys by national and international agencies.

Data from the National Family Health Survey has provided valuable insights in to the performance of the Family Welfare programme during the Nineties (Annexure 10.1) . Data from the survey has shown that during the nineties , there has been some improvement in the performance under each component of the Family Welfare programme, even though service reporting during the same period showed a decline in many parameters. The Department of Family Welfare has constituted regional evaluation teams which carry out regular verifications and validate the data on the acceptance



of various contraceptives. These evaluation teams can be used to obtain vital data on failure rates, continuation rates and complications associated with different family planning methods. RHS data about the progress on programme interventions as well as its impact are being used to identify district-specific problems and rectify them (Annexure 4.1 to 4.6 , 5.1,6.1,7.1,&10.2). To assess the availability and the utilisation of facilities in various health institutions, facility surveys were conducted in 101 districts during 1998-99 and deficiencies found are being brought to the notice of the states and districts concerned. The format for monitoring the processs and quality indicators under the RCH programme have been developed and sent to all the states. These should be operationalised during the Tenth Plan and the information generated used for mid-course corrections.

The substantial investments made in evaluation during the 1990s have increased awareness about the need for improvement in quality of service reporting .The narrowing of gap between service reporting and evaluation surveys regarding coverage has been accepted as a parameter for assessing improvement in quality of service reporting . During the Tenth Plan, efforts will be made to consolidate the gain by putting in place a sustainable system of evaluation at the district level in the form of CRS and district surveys. Efforts will also be made to reduce duplication of efforts through appropriate intersectoral coordination .

**Performance of Family Welfare Programme in the Nineties**

Sl.No.	Indicators	NFHS – I (1992-93)	NFHS – II (1998-99)
1	Female Literacy	43.3	51.4
2	Percentage of Girls below 18	54.2	50.0
3	Children fully immunized (%) (BCG, Polio 3, DPT 3, Measles)	35.4	42.0
3 (a)	<b>Coverage of Individual Antigens</b>		
	BCG	62.2	72.0
	Polio3	53.4	63.0
	DPT	51.7	55.0
	Measles	42.2	51.0
4	Infant Mortality Rate	78.5	67.6
5	3 or more Antenatal Check up for Women	44.0	44.0
6	2 or more doses of IT	55.0	67.0
7	Iron Folic Acid Supplementation	52.0	58.0
8	% Safe Delivery	34.2	42.3
9	Percentage of births of order 3 and above	48.5	45.2
10	Contraceptive Prevalence Rate	40.6	48.2
11	Sterilisation	31.0	36.0
12	Spacing Methods (Modern)	6.0	7.0
	Spacing Methods (Traditional)	4.0	5.0
13	Total Fertility Rate	3.4	2.9
14	Percentage of women with any anaemia	NA	52.0
15	Percentage of children with any anaemia	NA	74.0

**Annexure 10.2**

**Position of Districts - Acceptance of RCH - *District Surveys-I and II***

S.No.	Characteristics		Very Good	Good	Satisfactory	Poor
1	Contribution to birth by birth order 3 & above	Status(%)	<10	10-20	20-40	>40
		No. of districts	6	21	164	313
2	Pregnant women who had IFA tablets	Status(%)	>75	50-75	30-49	<30
		No. of districts	41	88	109	266
3	Three ANC check-ups	Status(%)	>75	60-75	40-59	<40
		No. of districts	95	42	102	265
4	Institutional deliveries	Status(%)	>75	50-75	30-49	<30
		No. of districts	46	62	109	287
5	Safe deliveries	Status(%)	>75	50-75	25-49	<25
		No. of districts	97	128	137	142
6	Children diarrhoea treated by ORS	Status(%)	>75	50-75	25-49	<25
		No. of districts	0	9	82	413
7	Children fully immunised	Status(%)	>75	60-75	40-59	<40
		No. of districts	144	90	118	152
8	Sterilisation	Status(%)	>50	40-50	30-39	<30
		No. of districts	75	101	105	223