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John Townsend
Population Council

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**TECHNICAL ASSISTANCE
FOR EXPANDING
CONTRACEPTIVE CHOICE
IN INDIA**

FINAL REPORT

John W. Townsend

**The Population Council
New Delhi, India**

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Background

One of the roles of the ANE OR/TA Project in India was to participate in policy dialogues with national counterparts, both in the public sector and among NGOs, about expanding contraceptive choices (ECC), and provide technical assistance as required for facilitating changes in service delivery procedures. The public sector essentially provides five contraceptive methods through its network of approximately 11,500 hospitals, and primary health care facilities (22,500 PHCs and 131,400 Subcentres). Specifically they include two forms of tubectomy (laparoscopy and minilap), vasectomy (including no-scalpel), IUDs (copper T200B), oral pills (combined), and condoms. NGOs, private physicians and pharmacies have access to a somewhat broader range of brands through commercial and social marketing networks, and the recent commercial introduction of Centchroman (commercial product called Saheli), DMPA (commercial product Depo-Provera), and the Today pessary provides additional options for users.

While India is one of the world's leaders in contraceptive research, in recent years products have been slow to come to the market. New technology, however, is often embraced as in the case of the IUD during the 1950s, and new surgical techniques during the past twenty years, while older methods which are perceived as less effective (e.g. pessaries, spermicides) are either dropped from the public program or given lower priority by health workers. Other methods like quinacrine, a non-surgical sterilization method, are strongly supported by some health authorities, although adequate clinical trials have not been performed to determine its safety and efficacy.

The issue of the cost of contraceptive options is not a trivial question in the Indian context. For example, the resources for the purchase of additional contraceptives, on the basis of an estimated 3 percent annual growth in government-provided contraceptives, is US\$24 million per year. US\$32 million are spent each year alone on the free distribution of condoms. The costs of new technology thus are an important element in policy making. Charging for spacing methods in the public sector is one policy option being considered to offset the increasing costs of procurement.

According to the 1993 NFHS, awareness of family planning is nearly universal in India, with 96 percent of women reporting knowledge of at least one contraceptive method. Women are most familiar with female sterilization, closely followed by vasectomy. Sterilization is the most popular contraceptive method throughout India, with 75 percent of users reporting adoption of female sterilization and another 9 percent of women reporting that their spouses were sterilized. Women are almost equally familiar with the three modern spacing methods available in the public program (orals, IUDs and condoms), which are known by about 60 percent of women, but are each currently used by less than 3 percent of the respondents. Injectables, which are available in the commercial market, are known by less than 20 percent of the respondents, and have been ever used by 0.2 percent of the survey respondents. Awareness of implants and pessaries is even less prevalent.

The OR Project became formally involved in effort to expand contraceptive choices in 1993, at the request of the USAID Mission in India, when there was considerable controversy about the role of NORPLANT® in the public program. Mrs. Usha Vohra, the Secretary of Health and Family Welfare, was interested in rapidly expanding the availability of implants and other new technologies through the public sector, with the assistance of approximately 100 medical colleges, including 31 Human Reproductive Research Centres (HRRCs). ICMR previously conducted a trial with

NORPLANT II[®], had purchased a supply of NORPLANT I[®] implants directly from the manufacturer (Leieras, Finland) and was requesting additional donations of supplies from UNFPA and USAID. Donors were concerned about the quality implications of such rapid expansion, and as part of the dialogue which ensued the overriding concern about expanding choices was raised by ICMR.

Mr. V.K. Shunglu, the new Secretary of Family Welfare, who joined the discussion in March 1994, supported the concerns for quality and choice as part of the preparation process for the International Conference on Population and Development held in Cairo in September 1994. Similar recommendations were also made by the Swaminathan Report during the development of a draft national population policy.

Activities

■ Expanding Contraceptive Choice with the Indian Council on Medical Research

At the request of ICMR, two visits were made by Council staff and consultants to work with ICMR on converting plans for a traditional clinical trial on implants to a more comprehensive research program for expanding contraceptive choice. The objectives of the effort to expand choice within ICMR are to improve the quality and effectiveness of reproductive health services as well as to enhance the satisfaction of users of these services.

The first visit was made by Dr. Anibal Faundes, Brazil and Ms. Martha Brady from the Council in New York from September 17-25, 1993. The new approach proposed by the MOHFW, through the ICMR trial in 10 HRRCs, included the following elements: free informed choice, expressed as the "cafeteria approach" without quotas or targets, appropriate counselling, careful technical care, respect for clients interests, good follow-up, and free and immediate access to discontinuation of provider dependent methods. After visits to Baroda, Bombay and Madras HRRCs, the team concurred with ICMR about the importance of expanding the choice of methods (to include diaphragms, injectables and NFP), the need to strengthen counselling for clients, the need to continue the development of the capacity to provide high quality care, the advantages of working with local coordinating committees including women's health advocates, and the idea of progressive and careful expansion of the new approach. In addition to assisting ICMR to assess the status of present services in these areas, they identified areas that need strengthening.

A second visit was made by Drs. Anibal Faundes and Biran Affandi from the University of Indonesia 20-27 April 1994. They attended ICMR workshops in Guwahati, Assam and Belgaum, Karnataka and examined the same areas as the first visit. While much remained to be done in the areas of strengthening, the team was impressed by the diffusion of the new concept of care, and the change in attitude among HRRC staff about the feasibility of a client centered approach. Specific clinical issues on the removal of implants were also addressed, and video taped for future training. The ICMR also met with 15 journalists in an attempt to open the issue of the ECC trial to public inquiry.

In the following months, the Population Council provided the MOHFW with 1200 diaphragms with spermicides, examples of anatomical and visual instructional models for fitting and insertion training, videos for clinicians and clients produced in Brazil and the United States, educational materials on the diaphragm for clients, as well as technical materials from the manufacturer and scientific journals. The diaphragms provided were the Wideseal silicone diaphragms produced by the Milex Company, Chicago, Illinois and ranged in size from 65 mm. to 80 mm.. Each diaphragm came with a kit including a compact container to store the diaphragm, and 20 disposable packs of SHUR-SEAL gel. The active ingredient was nonoxynol 9, and each gel pack had a net weight of approximately 6 gms.

At the same time, the Council submitted technical information and samples of the diaphragms and spermicides to the Drug Controller of India for review and assessment. The Council also worked with ICMR, USAID and JHPIEGO on a strategy for importing 100 Zoe Gynecologic Simulators for the medical colleges. In support of the effort to share recent information on contraceptive research and products, the Council has installed POPLINE in house for the use of collaborators interested in research on new and traditional technology, and has acquired recent year editions of the journal CONTRACEPTION, reprints of which are available to counterparts and the media on request.

In the counselling arena, the Council provided ICMR with a list and C.V.s of five international trainers in counselling, provided materials on the subject from AVSC and PCS, supported Dr. R.N. Gupta to attend an international strategy workshop on counselling organized by AVSC, and participated in a national workshop on counselling as a resource to the MOHFW. Additional support has been provided by Council staff on the data collection instruments for user follow-up in the ECC choice study. The ICMR could not agree on the counselling consultant, and the Council asked AVSC in May 1995 to continue the dialogue with ICMR on counselling issues.

The effort by ICMR has been remarkable during the past two years. It has reshaped the trials into a broader ECC strategy, made consistent efforts to improve provider competence, continues to work on the development of counselling with in-house resources, and has purchased commodities where donated products were unavailable. The preliminary data provided by ICMR to the Council are admittedly limited, but provide some evidence of the change in strategy. Table 1 provides information on the percentage of new acceptors at the 10 participating HRRCs who selected each available method between July 1993 and August 1994. Nearly half of the women selected an IUD, and more than a third opted for tubectomy. Condoms remain popular, accounting for over 12 percent of the users. However, it is unusual for a referral hospital to be a major source of supply for condom users. NORPLANT® users accounted for 1.3 percent, closely followed by vasectomy (1.1 percent).

ICMR expanded the clinical trial from the 10 HRRC to the remaining 21 HRRCs from November 1994. Although the new centers are taking time to begin full participation in the trial, data on acceptance is available as of the end of August 1995 (see Table 2). Specifically, in these expanded trials three new methods were added: Centchroman, the TODAY pessary and the diaphragm. NFP is an method that is still under consideration by the MOHFW and the HRRCs. However, increasing attention is being given to the balanced presentation of the methods and limited counselling. The results differ somewhat from those seen earlier. Among the first 90491 users, the IUD, tubectomy and the condom remain the most accepted methods. Less than one percent of users chose

NORPLANT® or one of the other new methods. This preliminary data through August 1995 suggests that there is little uptake of the diaphragm in the HRRC.

A visit to the HRRC at Safderjung Hospital in March 1995 confirmed that a fuller range of methods is being offered, and that some client counselling is being attempted by primary care physicians. Moreover, many clients select the service site and attend the large public clinic already with a firm decision about their method of choice, usually IUDs and sterilization. Many acceptors are post-abortion clients and have just undergone a medical terminal of pregnancy. Privacy and the use of non-physicians for counselling in a very crowded clinic setting remain important unresolved issues. Nevertheless, progress has been made at the clinic level on the issue of quality.

On the other hand, coordination with the ICMR has been difficult at times due to changing MOHFW priorities, lack of mechanisms for routine follow-up of the collaborating sites, lack of ready access to recent data on the ECC trial, and reluctance to approve consultants for providing technical assistance. Although ICMR had intended to incorporate injectables into the ECC trial, the then Secretary V.K. Shunglu placed the issue of incorporating injectables into the public program and the ICMR trial on hold for two years. It appears as though NORPLANT® implants will be available at some future time in the private sector, while the role of its public sector introduction will continue to be examined in the expanded ECC trials. The Council will continue to play a low key role in providing information to the public and private sectors about the technology and the requirements it places on delivery systems.

■ The Diaphragm for NGOs

In April 1994, the Council organized a workshop on the diaphragm, attended by twenty professionals from organizations with potential interest in the reintroduction of the diaphragm. They included the Family Planning Association of India, Indian Medical Association (IMA), Pariwar Sewa Sansthan, Saheli, Jagori, Prerana, the Council for Social Development, Population Services International, ICMR, AVSC, UNFPA, USAID, CEDPA, and the Rural Women's Social Education Centre (RUWSEC). The Council provided technical information on the diaphragm, briefed the participants about the expanded ICMR trial, and explored interest in an NGO proposal for an acceptability study. The only group with recent experience with the methods was FPAI, which had in recent years discontinued the supply of the diaphragm. From only 56 users among nearly 190,000 acceptors in 1987, only one acceptor was reported in 1993.

Currently, only a limited number of outlets supply the diaphragm in India, and the pharmaceutical industry has discontinued the manufacture and distribution of spermicides. International donors have also sharply reduced the procurement of these supplies due to the explicit policy of GOI to exclude barrier methods other than the condom from the public program. When available, a latex diaphragm costs about US\$6.00 along with a three month supply of spermicide.

The more traditional family planning service organizations were skeptical about the diaphragm's acceptance and impact. The women's health advocates were interested in the method as an alternative and as a additional source of protection against RTIs. The social marketing groups were interested in the results of preliminary studies on demand and costs before considering a trial

marketing effort. The Indian Medical Association would consider including the diaphragm as a product for distribution through its network of affiliates, but is uncertain about the potential demand by clients and the level of interest of gynaecologists.

As a follow-on to this workshop, the Council imported 1200 Milex diaphragms with spermicide for the NGO sector. The Council also developed a proposal with RUWSEC to examine the feasibility of diaphragm services in an urban slum of Madras. A final report prepared by T.K. Sundari Ravindran, Ph.D. is available on the project (Subcontract No. CI94.75A). Essentially, the project demonstrated some demand for the diaphragm, particularly among young low parity women and never users, and few physical barriers to use were reported by poor women. Community education and outreach probably played a major role in adoption. Most users required smaller diaphragms (e.g. 60 and 65 mm. compared to the larger sizes, 70 and 75 mm. requested by the public sector).

Another group decided to form a not-for-profit society, PARIDHI, to market a Brazilian made diaphragm (Semina, Sao Paulo). Samples of several models of diaphragms were provided to interested NGOs, along with materials, examples of fitting rings and training models. Contact was also made with Johnson & Johnson of Bombay to explore the availability of locally manufactured spermicide. They were interested only in bulk orders of more than a 100,000 tubes, which is well beyond the scope of our efforts. Alternative sources and presentations of diaphragms as well as spermicide are being explored.

In June 1995, the MOHFW communicated to SIFPSA, Uttar Pradesh that all studies on the diaphragm had to have the approval of the GOI, and that the distribution of supplies to NGOs was not authorized until such permission was granted. The Council is attempting to clarify this position in the light of future plans for the diaphragm in efforts to expand contraceptive choices.

Recently, the Council has also provided periodic briefings to the USAID Mission's Environment, Energy and Enterprise Program and two of their counterparts, i.e. Federation of Indian Chambers of Commerce and Industry (FICCI, Bombay) and Center for Technology Development (CTD, Karnataka), on the Indian market for contraception and developments in contraceptive research leading to possible manufacture.

■ Potential role for DMPA

Upjohn's injectable, DMPA, is currently approved for commercial sale in India through MaxPharma and has been on the market since 1994. It is being marketed directly to private physicians, and is available with a prescription through pharmacies. Many pharmacies will sell the product without a prescription. The cost per application of DMPA is about US\$5.00, with the additional costs of a disposable syringe and provider fees. Its introduction by MaxPharma in India has been cautious, with considerable resistance from women's health advocates, and there has been little public information on the product. Upjohn is also conducting a post-marketing surveillance study of the cohort of users, and a report should be forthcoming at the end of 1995. The World Bank, USAID and the UNFPA are encouraging the government to include DMPA as part of the range of methods offered in the public sector.

As part of ECC activities, the Council provided the MOHFW with technical information on DMPA from WHO, FHI and PCS. It encouraged ICMR to include the injectable in its expanded trials, although plans for its inclusion were delayed by a two year moratorium on its introduction in the public program by the Secretary. Building on the Council's experience with DMPA follow-up studies in Bangladesh and the Philippines, the Council conducted a feasibility assessment of a DMPA follow-up study with NGOs and large private providers in Lucknow and Kanpur, Uttar Pradesh. Sufficient users were not available in early 1995 to make such a study possible. Further discussion will take place with the IMA about the use of DMPA among its affiliates.

Plans for the Future

The following activities are being considered as a follow-on to this effort. The details on these proposed activities will be included in the Council's Country Strategy for OR/TA in India.

- Maintain communication with ICMR on the expanded contraceptive choice trial, providing a limited scope of technical assistance on request.
- Maintain dialogue with the MOHFW on the potential role of research on DMPA, either as part of a future ICMR trial, or as an experimental option in the experimental districts in Uttar Pradesh.
- Encourage the development of a follow-on proposal with RUWSEC, to more closely examine the issues of acceptability.
- Organize a seminar to share information on the diaphragm with NGOs and the public sector, using the Brazil experience as an example of public-private cooperation.
- Continue to communicate with potential users and suppliers of spermicides to understand the size and characteristics of the potential market. Begin to work on cost issues for both the diaphragm and DMPA.
- If an NGO research project is not forthcoming, explore the possibility of donating the remaining supplies of diaphragms to the government or the IMA for distribution to its members, with GOI clearance.
- Work with the IMA on understanding the potential role of DMPA among its affiliate providers.

How does one judge the success of this technical assistance activity? It is clear that the groups receiving technical assistance are now making use of previously conducted research for improving program design, they are making use of their own resources for providing services, and they are seeking further assistance to improve the quality or sustainability of their program. At the same time, the in-house TA project provides both the Council and the USAID Mission a convenient mechanism for providing timely assistance on requests. The OR Project anticipates developing similar

in-house mechanisms for expanding contraceptive choices during the extension period, while focusing most of their attention on public sector technical assistance through the IFPS project.

Other Council Activities on Expanding Contraceptive Choices

The Council has been involved in related research and technical assistance in India during the past two years. For example, with the authorization of the MOHFW and the support of a private donor, the Council has supported two phases of trials on mifepristone with KEM in Pune. The principal investigator is Dr. Banu Coyagi. The first phase explored efficacy and acceptance of mifepristone and an accompanying prostaglandin for pregnancy termination in a hospital site. The results suggest that there is demand for a non-surgical option and that complete abortions occurred in approximately 97 percent of cases. Physician follow-up is still a required component of the protocol. A second trial is underway to examine the role of this non-surgical abortifacient in satellite clinics. Given the high demand for abortion services, and the limited number of functioning MTP facilities, mifepristone may provide a safe, effective alternative.

Similarly the Council has collaborated with the Ford Foundation on efforts by NGOs in Gujarat and Rajasthan to incorporate RTI detection and treatment as an element of choice for contraceptive users. Technical assistance on this theme is expected to continue in the future in several sites. The topic of emergency contraception is also one being explored by Council staff regionally. In India, literature on emergency contraception was provided to the IFPS Liaison Office, and the topic will be included as part of the orientation package for health workers in OR activities in UP. M.E. Khan also continues to serve on the National Committee on Research in Human Reproduction as a social science advisor.

Finally, the role of the Regional Medical Advisor is still under review by the Council and USAID. Core funding has been allocated for FY95 and FY96 for a senior professional position with the Council's regional office in India. It is anticipated that the position will be filled early in 1996. Some of these responsibilities will be assumed by the Medical Advisor, while others will be addressed through close collaboration.

**TABLE 1
EXPANDING CONTRACEPTIVE CHOICES**

METHOD	ACCEPTANCE OF FAMILY PLANNING METHODS AFTER BALANCED PRESENTATION (JUL 1993 - AUG 1994)	
	NO. OF ACCEPTORS	%
TUBECTOMY	10850	35.4
VASECTOMY	346	1.1
IUD	14872	48.5
ORAL PILL	962	3.2
CONDOM	2283	7.5
NORPLANT-I	412	1.3
NONE/OTHER	936	3.0
TOTAL NO. OF WOMEN	30664	

**TABLE 2
EXPANDING CONTRACEPTIVE CHOICES**

METHOD	ACCEPTANCE OF FAMILY PLANNING METHODS AFTER BALANCED PRESENTATION (NOV 1994 TO AUG 1995)	
	NO. OF ACCEPTORS	%
TUBECTOMY	34940	38.6
VASECTOMY	623	0.7
IUD	30554	33.8
ORAL PILL	5210	5.8
CONDOM	16072	17.8
NORPLANT-I	648	0.7
CENTCHROMAN	365	0.4
TODAY PESSARY	219	0.2
DIAPHRAGM	25	<0.1
OTHER	330	0.3
NONE	1505	1.7
TOTAL NO. OF WOMEN	90491	