ORAL CONTRACEPTIVE PILOT PROJECTS

Under Government of India: Their initiation and present status

by

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Background

When clinical trials conducted by the Indian Council of Medical Research established that certain oral contraceptives were safe and effective in preventing conceptions in Indian women, the Government of India decided to launch a Pilot Project to study the feasibility of including oral contraceptives in the National Family Planning Programme.

The aims and methodology for such oral Pilot Projects were considered by the Technical Committee on Family Planning which decided that oral Pilot Projects should be set up in a study designed to assess the use-effectiveness and use-acceptability of oral Pills. This programme was to be taken up as an adjunct to the IUCD programme, and offered only to those women who are not able to accept IUCD. Subsequently, this proposal was sent out for consideration by all the States and various organizations involved in the IUCD programme. The response was encouraging and accordingly 121 oral Pilot Projects were initially selected all over the country with the intention of covering 5,000 to 10,000 women in each State for a period of 12 months.

As requests from the States and Voluntary Organization increased and there was assurance of a good supply of oral Pills, a decision was made to expand this programme and at present 326 projects are approved, of which 193 have already been commissioned.

Pre-requisites for the training of medical and paramedical personnel and the methodology indicating the essential steps to be taken in the running of these projects were intimated to the AMOs/FPOs with copies to all the State Governments/Union Territories and Regional Directors of Family Planning.

During the training period, it was stressed that initial care of patients with regular follow-up visits would help patients to continue on the Pills. This was based on the common observation that most of those who stop Pills, stop in the first month, and 20% of those who discontinue, do so in the first week. Most drop-outs are because of side-effects which are fairly manageable if regular visits are paid by paramedical personnel either in the homes or in the clinics. It is essential during this follow-up visit to see whether the patients are actually taking the Pills daily.

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A second principle that was stressed was that a continuous flow of supply must be maintained in the centres so that there is no delay in making available the requisite supplies to the patients.

Not all the projects followed the steps and hence the turn-out of the programme was fairly poor in some Pilot Project centres.

Training

Guidelines for the special training programme in oral contraception for medical and paramedical personnel were drawn up and the training was imparted at Chandigarh, Lucknow, Bombay, Madras, Calcutta and Delhi through the various Family Planning Training Centres. The training programme was streamlined by implementing the recommendations made by the Regional Directors and the Officers-in-Charge of these six Training Centres at a meeting held in New Delhi under the chairmanship of the Commissioner of Family Planning in January, 1968. The training programme not only covers the hormonal, pharmacological, motivational and educational aspects of this programme, but also demonstrates the necessity of team action for the efficient running of these projects. This training programme provides actual team experience to the trainees in the selection and follow up of patients and in the maintenance of records and returns.

In view of the fact that the number of oral contraceptive Pilot Projects has been expanded and the training load has gone up considerably, it has been decided to establish training programmes at those Regional Fammily Planning Training Centres which have the necessary facilities including an adequate case load for oral contraception training. Expansion of the training programme to the various Regional Family Planning Training Centres will also train the district family planning officers and other family planning personnel associated with the Pilot Project programme whether in the capacity of supervision or actual running of individual projects.

The commission of a Project takes place after the staff has undergone the requisite training, and the necessary pills, record forms, return and other material are made available to the Project by the Centre.

Reporting and Evaluation

The evaluation of the programme will depend largely on correct and regular reporting of cases, supplemented by an "in depth" study of the participating staff and clinics and of the patients. The importance of the report and record keeping is stressed during the training in oral contraception and the same is followed up by occasional visits by the Central and State staff. The recording system has been made quite simple by supplying pre-coded oral contraceptive records (case cards), discontinuation sheets, monthly reports and follow-up case cards for clinic and home visits. The Doctor in Charge is expected to submit copies of the record forms, discontinuation sheets and monthly report to the State Family Planning Officer. A summary analysis of these reports from all the Projects in the country is fed back to all the Projects with copies to the SFPO's Regional Direc-

TABLE I

Continuation Rates on Oral Contraception

Percentage on Pills at the beginning of the month continuing till the end of the month

Month of entry	No. of new entrants during the month	Months								
		1st	2nd	3rd	4th	5th	6th	7th	8th	9th
August	47	61.7	86.2	92.0	91.3	85.7	94.4	94.1	87.5	100.0
September	64	65.6	83.3	85.7	96.7	79.3	91.3	90.5	94.7	
October	50	70.0	97.1	91.2	96.8	83.3	96.0	100.0		
November	74	70.3	96.2	83.0	87.5	97.1	100.0			
December	117	70.1	85.4	92.9	95.4	100.0				
January	258	79.8	88.8	98.9	99.4					
February	362	86.5	94.3	98.6						
March	361	89.2	98.8							
April	451	98.4								
All months	1784	85.3	93.4	95.5	96.5	91.5	96.0	95.2	91.4	100.0

*The figure indicates the percentage of those, who started the pills during the first month and continued till the close of the first month.

TABLE II

Continuous Rates on Oral Contraception,Number of persons continuing the Pill in the specified month in which they enter the Programme

	Aug. 67	Sept. 67	Oct. 67	Nov. 67	Dec. 67	Jan. 68	Feb. 68	March 68	April 68	May 68	% Continuation	
		1st month	2nd month	3rd month	4th month	5th month	6th month	7th month	8th month	9th month		
August, 67	47	29	25	23	21	18	17	16	14	14	29.7	at 9 months
Sept. 67		64	42	35	30	29	23	21	19	18	28.8	at 8 months
October, 67			50	35	34	31	30	25	24	24	36.6	at 7 months
November, 67				74	52	50	40	35	34	34	40.8	at 6 months
December, 67					117	82	70	65	62	62	46.0	at 5 months
January, 68						258	206	183	181	130	58.5	at 4 months
February, 68							362	313	295	291	68.0	at 3 months
March, 68								361	322	318	75.8	at 2 months
April, 68									451	441	85.9	at 1 month
May, 68										72	..	
Totals	47	93	117	167	254	468	748	1119	1412	1854		

N.B. : The new entrants in the various months are underlined.

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tors and heads of the other organizations involved in this programme. Thus a continuous monthly evaluation of the Pilot Projects is being done and the validity of the analysis will depend on the reports from the individual Projects.

Additional steps for improvement of the programme

In spite of having taken the desirable initial measures possible in setting up the Pilot Projects, the programme still lacks proper implementation. Certain States have done fairly well in setting up and conducting projects, but others have a long way to go. The projects already approved cannot be commissioned till the staff has undergone the necessary training. In spite of the urgency of this research, personnel are not released for these training programmes. The difficulties of the State and Institutional authorities regarding the release of personnel for the training are well appreciated. It may be due to a dearth of personnel, yet while the personnel may have already been trained generally in the subject, specific training for this study in acceptability has to be undertaken even by those who have the necessary knowledge of oral contraception.

The failure to establish such projects may be due to lack of enthusiasm on the part of the authorities or the personnel, or else the projects proposed by the States were suggested at places where a full complement of staff was not available for IUCD Services and follow-up as required under the conditions for setting up such projects.

The following additional steps are being implemented as necessary for the success of this programme:

1. The trainees must be released in time to undertake the training.

2. Additional training programmes at Regional Family Planning Training Centres are being set up to undertake the increased load from the expansion of the projects. It is essential that the District Family Planning Officers supervise these centres in their respective districts to assure correct record keeping and efficient follow-up services by the paramedical personnel. These DFPOs should be assisted by the State Family Planning Officers and the Regional Directors. It has been decided to expose District Family Planning Officers and other staff concerned with supervision of these projects to training in Oral Contraception.

3. To assure a regular supply of Oral Pills to the Pilot Projects, the work has been entrusted to D.A.D.G., Medical Store Depot, Bombay. Tablets (Pads) of indenting forms have been issued to the projects who can place an indent directly with the D.A.D.G., Bombay. Those in charge of the Pilot Projects must ensure that sufficient supply of Orals is always available with them.

4. All the records, returns and educational material such as "Instructions to the Patients", "Questions and Answers" are supplied to the Oral Contraceptive Projects directly from the Centre.

5. The Training Centres responsible for training in oral contraception will also assist the State Family Planning Officers and the District Family Planning Officers in the

follow-up of the trainees in the field.

6. Correct and regular record keeping and monthly submission of these reports to the Department of Family Planning is necessary; monthly summary analysis will be fed back to the projects from the Department of Family Planning.

Follow-up of patients

As mentioned earlier in the context, a regular follow-up of the patients concentrated over the first month is very necessary.

One pattern of initial care suggested is that the patient receives two visits in the first month of taking pills and that the patient receives one visit within the first week of beginning the pills and again in the third week. These dates are selected because nausea might be a problem in the first week and irregular bleeding might be a problem in the third week. The supply of pills for the second month should be furnished at the visit in the third week. The same pattern may be followed for two visits in the second month. In the third month the patient needs a single visit. Thus, if a patient receives these five visits, she would have essentially continued the Oral Pills for a period of three months and thereafter visits once a month or once every two months should suffice. These visits will help in bringing down the drop-out rate which has been observed to be very high in the first month, especially in the first week.

All the patients displaying any side-effect as per report of the paramedical personnel at home or in the clinic must be immediately attended to and given the necessary reassurance and treatment by the doctor. These side-effects can be managed by supplementary medication and psychological support through the interest of the clinic staff; good follow-up clinic services may decrease the percentage of drop-out rate.

Preliminary results

As of May 31st, 1968, 72 centres have sent in reports out of a total of 118 commissioned. It is expected that the necessary supervision authorized by the District Family Planning Officers will ensure the reports being sent from the remaining centres as well.

The group of 1863 case cards received upto 31st May, 1968, has been analysed by the Department of Family Planning and the Central Family Planning Institute; the following facts have been elicited and fed back to the individual projects:

(a) More than 60% of the women who have accepted the Oral Pills fall in the age group 15 to 29, the maximum being in the age group of 20-29, indicating that this method is a popular one for spacing purposes.

(b) Distribution of Oral Pill acceptors by total number of live births demonstrates that 57% of the acceptors had no more than three live births, again indicating that this method is fairly popular for spacing. Distribution of Oral Pill acceptors by number of living boys shows that 75% of those who accepted the Oral Pills had two or less number of living boys; 13.07 out of this 75% had no living boys. The most interesting feature to note is that the percentage of Oral Pill acceptors by number of

living girls was fairly parallel to that of the number of living boys. However, the number of those accepting the Oral Pills with no living girl was somewhat higher, i.e., 21.26% as against 13.07% having no living boys.

(c) The number of Oral Pill acceptors by income shows that nearly 73% of these acceptors fall in the income group Rs. 600-3600 per year. The high motivation in this comparatively lower income group may be due to the fact that the Oral Contraceptives are being issued free of cost in our Oral Projects, hence no positive conclusion can be drawn.

(d) Nearly 30% of the group accepting pills had never tried to prevent pregnancy earlier and about 20% only occasionally practised contraception. This suggests that the method is helping to reach new groups who are willing to join the programme in spite of the fact that they have either never used any method for conception control or have used it only occasionally.

(e) The distribution of Oral Pill acceptors by method of previous prevention used demonstrates that 36.82% were using IUCD. An interesting fact has also been brought out that 7.03% of the acceptors were already on Oral Pills and joined this programme. This can probably be explained by the fact that the Oral Pills were made available to them free of cost and hence this motivated group of Orals joined in this Pilot Projects Programme.

(f) The misconception which many women have, that during the period of lactation they cannot get pregnant, seems to be dwindling. Nearly 63% of the women who accepted the pills were in the lactation period.

(g) Distribution of Oral Pill acceptors by educational standard demonstrates that nearly 29% of the women who accepted the pills were illiterate and out of the literate group, 6.87% had no schooling and 19.0% were primary pass. Thus a total of 55% of our pill acceptors have an educational level of primary education or below. 45% of the group fall between middle pass or graduates. This fairly demonstrates that educational standard is no bar to women accepting the pills.

(h) Distribution of the Oral Pill acceptors by residence (Rural/Urban) demonstrates that 77.24% were urban acceptors as compared to 22.65 rural acceptors. However, as this corresponds very fairly with the distribution of urban (82%) and rural (18%) centres, we can arrive at the conclusion that place of residence shows no change.

(i) The distribution by age of Oral Pill acceptors shows that with the increase of age, the proportion of acceptors of oral contraceptives increase.

It will be seen from these findings that though the initial months have a high dropout rate, the rate seems to settle down and even diminish with the number of months of use. It may also be seen from these records that the number of new entrants has gone up with successive months and that the percentage of new entrants continuing

on the Pill has steadily increased in the later months of the programme as compared to the first and second months.

Not all of the Pilot Projects already commissioned are sending in their reports regularly. However, the 115 centres reporting upto 15th of October, 1968 indicate that 5,664 cases have been registered and out of these 1,284 have discontinued the use of Oral Contraceptives over these months.

From this report of the organizational stage it may be seen that the development of this Research Programme has been steady, and it can be expected to produce valid figures from which can be made an accurate estimate of the acceptability and use-effectiveness of Oral Contraceptives by Indian women.