96

REVIEW BOARD ON THE USE OF HUMAN VOLUNTEERS

CRL

Principal Investigator CSIERNY, T Trainee investigator(if any) _____

Application No 76-011 DIPH (Revised) Supporting Agency(if Non-CRL) _____

Title of study CONTRACEPTIVE DISTR Project status:
EXTRA SIGNS
( ) New Study
(✓) Continuation with change
( ) No change (do not fill out rest of form)

Circle the appropriate answer to each of the following(If Not Applicable write NA):

1. Source of Population:
   a) Ill subjects Yes (No)
   b) Non-ill subjects Yes (No)
   c) Minors or persons under guardianship Yes (No)
2. Does the study involve:
   a) Physical risks to the subjects Yes (No)
   b) Social risks Yes (No)
   c) Psychological risks to subjects Yes (No)
   d) Discomfort to subjects Yes (No)
   e) Invasion of Privacy Yes (No)
   f) Disclosure of information possibly damaging to subject or others Yes (No)
3. Does the study involve:
   a) Use of records (hospital, medical, death, birth or other) Yes No
   b) Use of fetal tissue or abortus Yes (No)
   c) Use of organs or body fluids Yes (No)
4. Are subjects clearly informed about:
   a) Nature and purposes of study (Yes) No
   b) Procedures to be followed including alternatives used (Yes) No
   c) Physical risks (Yes) No
   d) Sensitive questions (Yes) No
   e) Benefits to be derived (Yes) No
   f) Right to refuse to participate or to withdraw from study (Yes) No
   g) Confidential handling of data (Yes) No
5. Will signed consent form be required:
   a) From subjects (Yes) No
   b) From parent or guardian (if subjects are minors) Yes (No)
6. Will precautions be taken to protect anonymity of subjects: (Yes) No
7. Check documents being submitted herewith to Committee:
   ✓ Umbrella proposal - Initially submit an overview(all other requirements will be submitted with individual studies).
   ✓ Protocol (Required)
   ✓ Abstract summary (Required)
   ___ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (REQUIRED)
   ✓ Informed consent form for subjects
   ___ Informed consent form for parent or guardian
   ___ Procedure for maintaining confidentiality
   ✓ Questionnaire or interview schedule *

*If the final instrument is not completed prior to review, the following information should be included in the abstract summary:

1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific questions to be asked in the sensitive areas.
3. An indication as to when the questionnaire will be presented to the Board for review.

We agree to obtain approval of the Review Board on Use of Human Volunteers for any changes involving the rights and welfare of subjects before making such change.

TCurtis

Principal Investigator

Trainee

Please return 2 copies of entire protocol to Chairman, Review Board on Use of Human

Attachment 1a

INFORMATION TO INCLUDE IN ABSTRACT SUMMARY

The Board will not consider any application which does not include an abstract summary. The abstract should summarize the purpose of the study, the methods and procedures to be used, by addressing each of the following items. If an item is not applicable, please note accordingly:

1. Describe the requirements for a subject population and explain the rationale for using in this population special groups such as children, or groups whose ability to give voluntary informed consent may be in question.

2. Describe and assess any potential risks - physical, psychological, social, legal or other - and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.

3. Describe procedures for protecting against or minimizing potential risks and an assessment of their likely effectiveness.

4. Include a description of the methods for safeguarding confidentiality or protecting anonymity.

5. When there are potential risks to the subject, or the privacy of the individual may be involved, the investigator is required to obtain a signed informed consent statement from the subject. For minors, informed consent must be obtained from the authorized legal guardian or parent of the subject. Describe consent procedures to be followed including how and where informed consent will be obtained.

   (a) If signed consent will not be obtained, explain why this requirement should be waived and provide an alternative procedure.

   (b) If information is to be withheld from a subject, justify this course of action.

6. If study involves an interview, describe where and in what context the interview will take place. State approximate length of time required for the interview.

7. Assess the potential benefits to be gained by the individual subject as well as the benefits which may accrue to society in general as a result of the planned work. Indicate how the benefits outweigh the risks.

8. State if the activity requires the use of records (hospital, medical, birth, death or other), organs, tissues, body fluids, the fetus or the abortus.

The statement to the subject should include information specified in items 2,3,4 and 7, as well as indicating the approximate time required for participation in the activ

Revised
Recd 29/5/78

SECTION I - RESEARCH PROTOCOL

1) Title: Contraceptive Distribution Project, Matlab
2) Principal Investigators: Shushum Bhatia, Trinidad Osteria*
3) Starting Date: 1 October, 1977
4) Completion Date: 30 September, 1980
5) Total Direct Cost: $ 554,344.08**
6) Abstract Summary:

This proposal is a modification and extension of the ongoing protocol Contraceptive Distribution Project (CDP), Matlab (July 1975 - September 1978). The objective of the CDP is to assess the requirements for an inexpensive and effective delivery system for fertility control in a less developed country. The initial study design involved the regular provision through CRL female village workers of non-clinical contraceptives (oral pills and condoms) to all married couples in half (population 130,000) of the Matlab surveillance area (MSA) with the remaining half serving as controls.

Two years of experience with this simple but intensive household distribution program suggested that program performance may be improved substantially through several modifications which were introduced beginning in October 1977. A new cadre of 80 better trained female village workers, backed by stronger field supervisory and technical staff, were deployed in 70 villages (80,000 population) to provide family planning and selected health services; a wider array of clinical services, including IUD, sterilization, and menstrual regulation, as being provided at the CRL Matlab Treatment Unit. Improving the quality and scope of services establishes three study cells: (1) original household distribution (40,000); (2) intensive health and family planning program (80,000); and (3) control (45,000).

This project will continue till September 1980 and will be evaluated to determine the acceptability of the technologies under this approach, and the demographic and health impact.

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* The CDP is a collaborative project between the Ministry of Health and Population and CRL; the Co-directors are Drs. Atiqur Rahman Khan and W.H. Mosley, respectively.

** Most of the costs of the first year of this protocol is provided by a U.S.AID grant (Contract No. AIC/pha-C--1105). Special funding for subsequent years is now being negotiated.

7) Reviews:

a) Research Involving Human Subjects: _____

b) Research Committee: _____

c) Director: _____

d) BMRC: _____

e) Controller/Administrator: _____

A. INTRODUCTION

1. Objective:

The Cholera Research Laboratory, in collaboration with the Ministry of Health and Population, initiated, in October, 1975, a simple but intensive house-to-house distribution program of non-clinical methods of contraception (oral pills and condoms) to a population of 125,000 in the Matlab surveillance area. The remaining 135,000 population serviced by the regular Government program was the control group. The objective of this program was to determine the feasibility and impact of a household delivery system.

After an initial relatively high acceptance, continuous evaluation revealed by eighteen months a limited impact. This was due to a combination of a rapid fall off in new acceptors after the initial distribution combined with very low rates of continued use among acceptors.

To overcome the deficiencies of the simple household distribution system, major modifications in the field structure and program activities were introduced in October, 1977. A new cadre of better educated, better trained, and better motivated female village workers backed by strong field supervision and technical staff were introduced into seventy villages (population 80,000) to provide family planning and selective health services. The field program was backed-up by augmenting the Government family planning clinic activities to provide the full range of clinic-based fertility control services. This strengthened program was incorporated into a new study design which permits a comparison of the effect of the more intensive field efforts on both a part of the original household distribution area (population 40,000) and a part of the original control area (population 40,000). A part of the control population (45,000) and of the original household distribution (population 40,000) are maintained for further comparative purposes. Preliminary results at the the end of January, 1978, indicate the prevalence of use rate in the intensive area rose from 7% to 27%.

This project document summarizes activities (and costs) to date in FY 1977, and proposed activities in FY 1978 and FY 1979. The following questions are to be addressed in the extension of the project:

1. What is the acceptability and use effectiveness of the various contraceptive technologies with this modified programmatic approach?

2. What is the demographic impact of this new programmatic strategy?

3. What changes will be achieved in the demand for contraceptives?

4. What is the impact of this programmatic effort on overall health and welfare in the population?

5. What are the relationships between cost and output of the original and modified program strategy.

The answers to these questions can provide guidance for programs orientated to the rural areas regarding not only the appropriate mix of technologies that may be offered, but also to what degree reinforcement and back-up for services in the rural areas can more effectively maintain contraceptive practice.

2. Background:

Like several other countries in Asia, Bangladesh has had a national family planning program for over a decade. Despite substantial commitment and resources, the program apparently has not been reaching effectively the rural population. The 1968 Bangladesh National Impact Survey, for example, reported that while 55% of married women expressed a desire to cease childbearing and 13% were willing to consider contraceptive use, only 1.9% and 3.7% of the rural and urban populations, respectively, were actually using a modern method of contraception. Similar dissonance between "reported" desires and actual practice were noted by several recent surveys, both national and regional. A crucial hypothesis underscored by these studies was that lack of information about, and availability of, modern contraceptive methods were major constraints to program success.

Original Study Design

To meet this and subsidiary hypotheses, the CRL in collaboration with the Ministry of Health and Population initiated in October, 1975, a simple but intensive house-to-house distribution program of non-clinical methods of contraception (oral pills and condom) in 150 villages (125,000 population) of the Matlab Surveillance Area (MSA). The remaining 84 villages (135,000 population) serviced by the regular Government program, was the control group.

The specific objectives of this distribution program were "to assess a household delivery system of oral contraceptives and condoms in rural Bangladesh in terms of: (a) feasibility of organizing and implementing such a delivery system; (b) total demand for these contraceptives; and (c) demographic impact".

The long-term goal of the project is to assess the requirements for "an inexpensive and effective delivery system and fertility control technology for use in developing countries".

Over the first two years of the project a variety of research undertakings were conducted. These included sample surveys on: (1) quarterly prevalence of reproductive status and contraceptive usage; (2) knowledge, attitude, and practice (KAP) (Oct. 1975 and May, 1977); (3) oral pill side-effects; (4) health beliefs and practices; (5) depo-provera effectiveness and side-effects; (6) condom knowledge and use; (7) follow-up of sterilization clients; and (8) female village worker knowledge and effectiveness.

Broadly, the results indicate the following:

Demand for Contraception: The baseline KAP survey suggested that, while modest, there exists significant demand for contraception in this rural area of Bangladesh. About 22% of married women, before program initiation, were either current users of contraception or expressed a desire to cease childbearing and an interest to use contraception in the future. An even more important finding was that the overwhelming majority of women wanted large families and expressed no interest in contraception.

Prevalence of Contraceptive Use: Three months after contraceptive distribution was started, 17.1% of eligible women claimed to be using oral pills. After 18 months of program effort, the prevalence of oral pill use had declined to 8.7%. The corresponding prevalence rates for use of all methods in the program villages were 18.0% and 13.0%, respectively. No significant change in the use-prevalence of all methods (2.4%) was observed in the control area.

Contraceptive Acceptance and Continuation: The declining prevalence rates were due to both declining rates of new acceptors and briefer rates of method continuation over time. The number of new pill acceptors in the distribution area, for example, declined from 24% of the eligible women in the first 3 month period to only 2% in a corresponding period 18 months later. Oral pill continuation rates similarly declined with each successive cohort of acceptors. Less than half of the first 3 month cohort were continuing users 6 months after acceptance and by 12 months the proportion had declined to a third. The second cohort of acceptors had 38% and 26% continuing users by 6 and 12 months, respectively, after acceptance. The third cohort had only about 15% continuing after 6 months.

Contraceptive Technology: Several constraints were noted regarding the modern technologies employed in the program. Oral pills, which require regular, daily administration, were often irregularly and improperly used. Side-effects, such as irregular menstrual bleeding and dizziness, discouraged acceptance and continuation. Knowledge on the effective use of condoms was limited at program initiation and although acceptance increased over time, condom use was accepted by only a small proportion of eligible couples. A small-scale trial with long-acting hormonal contraception suggested that injectables were acceptable as back-up for oral pill drop-outs, but side-effects were also troublesome. These factors in total resulted in a situation where the gap between those who wanted to cease childbearing and those who were actually using acceptable, safe, and effective contraception remained largely unfilled.

Delivery System: Supported by the logistical and staff resources of the CRL, the distribution program was found to be simply implemented at reasonable cost - although its replicability by other institutions facing different operational constraints is questionable. The CRL female village workers, in particular, were noted to be inadequate for several reasons. Although these workers were knowledgeable about their village and the technologies employed, they themselves were too elderly to have ever practiced family planning; some accorded the extra work (without extra compensation) low priority; they were rarely contacted by women experiencing side-effects who preferred instead to rely on traditional practitioners; and they may have been perceived as socially inferior by potential clients, thereby limiting their effectiveness.

Some of these limitations are undoubtedly unique to the CRL because of its operations in the area, but some are inherent in a house-to-house distribution design which restricts time available for counselling, excludes contact with community leaders, head of households, and husbands, and limits the scope and quality of other welfare services provided to a family.

The results of the project after 2 years, confirmed that there exists an unmet demand for contraception in rural Bangladesh that can be met in part by a simplified house-to-house delivery system; however, there were several major weaknesses in the program. First, the original study design cannot genuinely address the long-range goal of the project, that is determining a cost-effective delivery system and fertility control technologies for developing countries. The current program restricted the choice of technologies available to couples desiring contraception. Furthermore, the cadre of village workers and the training and supervision that they received did not appear to be the most suitable. Finally, it appears that provision of related health services to foster rapport between the program and potential acceptors, particularly care of side-effects and the provision of maternity related preventive health services, may constitute essential components of effective service delivery.

The Modified Study Design

These conclusions led to substantial modification in the field structure and program activities which were initiated in October, 1977. The modified program introduced a new cadre of better-educated and better-trained female village workers (FVW) backed by stronger field supervision and technical staff in 70 villages (population 80,000) to provide family planning and selected health services. This intensified program population was drawn equally from the two cells of the original study. This, in essence, establishes three study cells:

(1) original household distribution (population 40,000)*; (2) intensive family planning and health (population 80,000) which has been created from a part of the distribution area (40,000), and a part of the control area (40,000); and (3) control (population 45,000)*.

Field Operations: In one half of the original distribution area, the household distribution activity has been terminated in April, 1978, after ensuring that all families have adequate supplies. In the remaining half of the distribution area and half of the control area, the new field structure was developed. In these 70 villages, 80 new female village workers (FVW) were recruited in October, 1977, to replace the current demographic surveillance female village workers. The educational qualifications of these workers was 7th grade pass, married with children, and with personal contraceptive experience. These workers were recruited from their local communities, with community participation in their selection. Each of these workers covers a population of approximately 1,000, or 200 families visiting each family every fortnight, or about 20 families per day.

In November, 1977, these FVWs were trained to undertake the following tasks:

1. Family Planning: (a) discuss family planning with potential clients and if requested provide and resupply non-clinical methods (oral pill, condoms and long-acting hormonal contraceptives; (b) advise potential clients of availability of clinical fertility control services at sub-centres (IUD) and the Matlab centre facility (IUD, sterilization); (c) refer those desiring such services to the appropriate facilities; and (d) follow-up and reassure users regarding actual or perceived side-effects and referring those with complications to the central facility.

2. Record Keeping: (a) interview all families to get baseline data on family size, and contraceptive use. (b) record fortnightly selected family planning and health information. A list of the questions is given in Appendix I. These records are primarily designed to guide the worker in her service activities. They also constitute the major basis for supervision and evaluation activities.

*These populations represent the reduced areas that will be under demographic surveillance effective May 1, 1978.

The FVWs are supported and supervised by 4 senior field assistants (SFA) and 4 lady health-family planning visitors (LFPV) residing and operating out of 4 sub-centres dispersed in the area. The sub-centres, opened in February-March, 1978, primarily operate as a support and training facility. SFA's supervise the work of FVW's and in addition discuss health and family planning with community leaders, head of households, and male spouses. The work of LFPV's primarily involves technical back-up of the work of FVW's. In addition, LFPV's provide IUD services at the clinic and back-up the use of long-acting hormonal contraception by FVW's. The village-level and sub-centre workers are supervised by and overall field supervisor. Technical back-up, moreover, is provided by physicians stationed at the Matlab centre, but also responsible for the technical support of the sub-centres.

Clinic Services: Staff and facilities for delivering the full range of FP services have been developed in the Government FP Clinic in January, 1978. The facility is staffed by physicians, LFPVs, clinic attendants, a record-keeper and a ward cleaner. Services provided include: (a) IUD insertions and removal; (b) male and female sterilization; (c) menstrual regulation; (d) treatment of severe side-effects or complications associated with contraception and induced abortions; and (e) selected maternity services, such as retained placenta. These activities are operated under the jurisdiction of the Government Thana F.P. Officer, and are fully supported by Bangladesh Government funds.

Research and Evaluation: The study design of the modified three-cell program permits an independent evaluation of the effect of this augmented effort superimposed upon the original simplified delivery scheme as well as the effect of this augmented effort in a previously unserviced population. Further, sufficient population is remaining in the original distribution area to determine the longer-term trend of the simplified delivery system. To evaluate the program, several data gathering mechanisms will be employed. These are: (1) an independent demographic surveillance system; (2) field record forms maintained by FVW's in the augmented area to generate acceptance, continuation use, prevalence information: (3) Matlab clinic record forms; (4) sample KAP surveys. There will be longitudinal data on all eligible women in the intensive area; surveys will be conducted in the remaining areas for comparative purposes. The KAP survey will be conducted at the end of FY79. Specialized surveys will be conducted on an ad hoc basis, depending upon study requirements, worker availability, and logistical and data processing absorptive capabilities.

3. Rationale:

The original study design for the household contraceptive distribution project addressed certain fundamental hypotheses. These were:

1. There is an unmet demand for family planning in the rural population.

2. A significant barrier to family planning practice is logistical; that is, time, cost, distance.

3. Another barrier to practice is ignorance concerning family planning methods.

4. A simple household distribution system of oral pills and condoms can efficiently overcome these logistical and ignorance barriers and effectively serve the unmet demand.

5. Such a service delivery system can create additional demand among previously unreceptive couples.

As noted in the background summary, the first two years experience substantiated some hypotheses but failed to support others. There is a substantial unmet demand for family planning services. This is attested by the fact that prior to the distribution program only 4% of the population had ever used pills or condoms with only 1% currently using these methods. With the household distribution, more than 30% of the couples accepted and used the supplies for some periods of time. Coupled with this was a substantial increase in general knowledge about contraceptive use.

Unfortunately, the hypothesis that such a simple delivery system could effectively meet the demand was not confirmed. After 18 months, less than one-third of those couples who initiated practice with pills and condoms were able to sustain use. Further, there was no evidence that the program activities actually generated new demands; rather, there was simply a saturation of all of the potential acceptors within the first few months followed by extremely low new acceptance rates thereafter.

Based on this experience, the service delivery program was modified on the basis of additional hypotheses relating to barriers to initiating and sustaining contraceptive practice. These are:

1. Modern contraceptive methods represent alien technologies requiring significant behavioural changes. These run against strong psycho-social barriers which are reinforced by family and community members.

2. These barriers may be partially overcome by well-trained, highly motivated workers who provide personal reassurance and social reinforcement, for practice, to the couple and others in the community.

3. Provision of the full-range of fertility control methods can more effectively meet the widely varying needs of the interested couples.

4. Effective medical support to meet real or imagined side effects of the contraceptive methods is essential to sustain continued use.

5. Provision of preventive health measures and information related to other aspects of reproductive health will both give legitimacy to and reinforce the concept and principles of family planning to individual couples. This will not only promote continued practice among current users, but also stimulate demand among couples without a preventive health and family planning orientation.

The questions being addressed by this research project are of fundamental importance to the international effort to efficiently and effectively deliver family planning services to rural populations. It must be recognized that the social, economic, and cultural background of each country is different and thus the experiences in any one locality will not be wholly transferable to other areas. On the other hand, certain principles can apply generally. This project, for example, which is operating in a very poor rural tradition-bound population has clearly revealed that there is substantial unmet demand for family planning, even in these circumstances. At the same time, it has shown that this demand cannot be easily met by simplistic delivery systems, particularly when alien technologies are involved.

This project incorporates the principle of flexible study design. Thus, as soon as it became clear that the simple household delivery system was not effectively serving the needs, the field structure and clinic support were modified to overcome the obvious barriers that have been identified. Incorporating this dynamism into the project requires a high level of capability to rapidly collect, process and analyze the data as it is being generated. It also requires a quality of project leadership that can rapidly make major structural and programmatic changes within a short period of time.

The project is continuing to keep in sight the primary objective of the original study; that is, "to determine the most inexpensive and effective delivery system and fertility control technology for use in developing countries". The initial study design concentrated almost entirely on the first component of that goal (inexpensive) by examining the effect of the most simple and efficient programmatic activity. Recognizing the serious deficiencies of the most efficient system, the modified design has incorporated structural changes both in the field and at the clinic level that are quite appropriate, feasible and relevant for rural Bangladesh in order to assess what will be the enhancement and effectiveness. The full range of technologies have also been provided to examine the relative appropriateness and use effectiveness of each of these as well.

This project represents a unique resource in the rural developing world. It not only covers a large population, permitting definitive answers to the questions being addressed, but also it has demonstrated the capability of both rapid assessment of the results and a comprehensive restructure on the basis of the findings from on-going evaluations. This combination of capabilities ensures that the project is a continuing source of practical information that can be of use to program planners and administrators.

B. SPECIFIC AIMS

The following are specific questions which will be addressed:

1. What is the acceptability and use-effectiveness of various contraceptive technologies?

2. What are appropriate strategies for introducing contraception in a population where the women already have prolonged lactational amenorrhea?

3. What is the demographic impact of this new programmatic strategy?

4. What changes will be achieved in the demand for contraceptives?

5. What is the impact of the programmatic effort on overall health and welfare in the population?

6. What are the relationships between the costs and output of the original and modified program strategy?

C. METHODS OF PROCEDURE

The modified structure of field activities and clinic services that have been implemented to date during this last fiscal year of the current project period have been outlined in the background statement given above. Basically, the primary service delivery in the modified program will be provided by a female village worker who is at least 7th grade education. These workers have essentially the same qualification as the Government female family welfare workers in the national program. The CRL salary is approximately 10% higher since the project position is only a temporary position (currently due to terminate in September, 1978).

Eighty FVW's have been recruited to cover a population of 80,000. This was the same density of coverage given by the female worker involved in the household distribution program. It is only about one-fifth of the area covered by a Government family welfare worker. The Government, however, does have an equal number of male village level workers as well as other types of village health workers so that the "theoretical" intensity of coverage is only about twice that currently programmed for the Government health system.

This modified study design incorporates a population of 40,000 which were under the original household distribution system and a population of 40,000 originally in the control population.

For comparative purposes there is a remaining control population of 45,000. This entire population is, of course, concurrently serviced by the Government health system. Further, the facilities available at the central clinic are free for use by the entire population. The experience with the control area so far suggests that these level of services have not had a major impact in the absence of some direct household effort at the field level.

During the current fiscal year the FVW's in the intensive distribution area have been given an intensive four week training course related to the delivery of family planning services and management of side-effects. This has been reinforced both by regular supervisory visits in the field, as well as by weekly group meetings with the senior staff to review the progress of the work, identify field problems, and discuss appropriate solutions. Also, the use of role-playing to establish rapport and overcome resistance is an important component of this on-going training effort.

Preliminary results to the end of January, 1978, indicate that the prevalence of use rate in the modified area rose four times from 7% to 27% by the end of January, 1978 (see July - December, 1977 Semi-Annual Report).

The project is to continue for a period of two additional years, beginning October 1, 1978. The specific activities that are proposed during this continuation period and the specific objectives to be accomplished are as follows:

Services

1. Male motivation. Special activities will be initiated in the current year to inform males about family planning methods and the rationale for considering family planning.

2. Maternity related preventive health services.* During the latter part of the current fiscal year and in the next fiscal year the FVW's will be trained to provide certain preventive services and information related to maternal health care. The FVW's will be given training so they can guide mothers on proper practices relating to nutrition during pregnancy and lactation, appropriate hygienic practices during pregnancy, delivery and the neonatal period and appropriate nutrition practices for breast-feeding and weanling children. The FVW's will be taught to detect certain anticipated complications at pregnancy, such as preeclampsia and provide simple treatment where possible or appropriate referrals. Tetanus toxoid will be made available in the antenatal period as well as vitamin and iron supplementation where indicated.

3. Infant and child related services.* These services will be initiated in the next fiscal year. These, again, are primarily focused on preventive measures and effective treatments for life threatening conditions. The FVW's will be given training to provide the mothers with appropriate guidance relating to infant and child nutrition. DPT immunizations will be made available. Mothers will be given instructions regarding full rehydration for the management of diarrhea. Families will be given instruction for appropriate management of chronic infestations such as intestinal parasites and scabies. Specific therapy will be provided for life threatening illnesses such as antibiotics for pneumonia.

Date Collection Activities

1. The service records of the FVW's will provide a continuous monitoring of the prevalence of contraceptive practice in the intensive distribution area. These data will be summarized monthly. Sample surveys for prevalence of practice in the original distribution area and the control area will be conducted semi-annually for comparative purposes.

* To be developed under separate protocols.

2. KAP surveys will be obtained on a sample of the study and control populations annually. The surveys will be designed particularly to identify changes and levels of knowledge and attitudes, as well as demand for contraception over the life of the project.

3. Vital Registration. The vital registration system will operate continuously in the entire Matlab area to provide on-going data for analysis of demographic impact.

4. Special surveys related to contraceptive technology and other issues. Special surveys will be undertaken on an ad hoc basis as required to evaluate effectiveness and acceptability of contraceptive technologies. Among the special surveys proposed for the next fiscal year are the following:

   a) a case control follow-up of injection acceptors looking for continuation rates and demographic impact;

   b) a case control follow-up of sterilization clients to assess demographic impact;

   c) in depth study of traditional contraceptive practices; and

   d) a follow-up of the long-term outcome and subsequent fertility of women receiving menstrual regulation.

Data Analysis

The dynamic nature of this research project with a flexible study design has led to a major restructuring of the field and clinic service delivery program during the third year of the current project period as noted above. Continuation for an additional two years, beginning October 1, 1978, is required in order that the following research questions may be adequately answered.

1. What is the acceptability and use-effectiveness of the various contraceptive technologies with this modified programmatic approach? There are some complications in obtaining answers to this question because the modification introduced both more intensive field motivation and follow-up care as well as a wider range of services. Several types of analyses, however, can provide the specific answers required. Among these are:

a) a comparative study of the first cohort of pill acceptors in the original distribution area with pill continuation rates of the new pill acceptors in the intensive distribution area;

b) a comparison of continuation rates of injection acceptors from the original clinic based program with continuation rates of new injection acceptors in the intensified area;

c) because of switching of methods that is occurring with a widerange of choices of services now available, the new cohort of acceptors of any method in the intensive area will be followed prospectively to determine their "all method" continuation rates;

d) because various new modalities are being offered simultaneously, it will take some time for ultimate patterns of preference and use to sort themselves out. The assessment of this transition of patterns of use will be carried out through examination of cohorts of acceptors who are initiating various modern methods such as pills, injections, or condoms. By evaluating the choices made over time by the acceptors including ultimately sterilization, one can determine the relative acceptability and use effectiveness of different contraceptive technologies.

The answers to these questions can provide programmatic guidance regarding not only the appropriate mix of technologies that may be offered, but to what degree reinforcement and back-up for services in the rural areas can more effectively maintain contraceptive practice.

2. What are appropriate strategies for introducing contraception in a population where the women already have prolonged lactational amenorrhea? This question is particularly important when dealing with temporary methods such as oral contraceptives which have relatively short continuation of use relative to the prolonged lactational amenorrhea. For example, an analysis of pill acceptors and matched controls from the original household distribution project indicates that pill use prolong the average live birth interval of 32 months by only about five months to 37 months. Lactational amenorrhea had already contributed about 18 months to the live birth interval.

3. What is the demographic impact of this new programmatic strategy? This question cannot begin to be addressed for more than a year after the program has been implemented. Two approaches will be utilized to answer this question. The first will be through the on-going vital registration system, covering the entire area. This, however, lacks considerable sensitivity as well as specificity by method. Therefore, methods-specific analysis will be undertaken by case control follow-ups.

   As an example, we already have data from a matched case control follow-up of the first cohort of acceptors from the household distribution program. The results for 629 acceptors indicate the average interval to the next birth was prolonged by only about five months as compared either to the matches for to the preacceptance birth interval. Ultimately, 95% of the first cohort of pill acceptors in the household distribution study have gone on to have another live birth. These changes are indicative of the program having been able to achieve, temporarily, about a 15% drop in the period birth rate, but ultimately less than 1% decline in cohort fertility.

4. What changes will be achieved in the demand for contraceptives? The "theoretical" demand has been estimated by the base-line and follow-up KAP surveys simply as the percent who either desire no more children or who intend to use contraceptives. For those not intending, the reason was obtained. With the original project, empirical evidence suggested that no new demand was created. This was attested both by the fact that there were extremely few acceptors after the first round of saturation as well as by a follow-up KAP survey after 18 months which showed very little change in response to these questions.

   It is hoped that this new program strategy, which puts family planning into its appropriate context as oneof the many measures to promote reproductive health for the family, will reach those couples who current see no rationale for accepting fertility control in isolation. The elasticity of demand in response to these measures will be assessed by changes in patterns of response on follow-up KAP surveys as well as more importantly by evidence of a continued recruiting of additional acceptors over time from those cohorts which initially expressed no interest in contraceptive practice.

5. What is the impact of this programmatic effort on overall health and welfare in the population? The only real rationale for providing family planning is to improve personal health and ultimately provide an overall benefit to the society. This project design provides the opportunity to accurately assess the health impact of the fertility control services as well of the related maternal and child health measures. In the case of the fertility control services, the same case control procedure that has been used to assess demographic impact above can be adapted with certain simple clinical examinations to assess to what degree cohorts of couples effectively controlling their fertility are achieving measureable benefits in personal health and health of their children.

6. What are the relationships between costs and outputs of the original and modified program strategy? In undertaking this analysis cost data will primarily relate to direct field costs for operating the program including personnel, supplies, equipment, logistics, etc. These data are available from the Controller. Critical attention will be given to the output measures, both in terms of the parameter to be used and the time period over which the measurement is taken.

   By way of example, for the original household distribution program the cost per acceptor in the first three months was relatively low; this is because two-thirds of the acceptors of the first eighteen months actually accepted in the first three months. Thus after eighteen months of the same programmatic strategy, the cost had increased 600%, but the number of acceptors by only 35%. The cost-effectiveness ratio per acceptor, therefore, increased by a factor of seventeen times over this time period. If continuing users (prevalence) is used as the indicator, then the cost output ratio would increase again by a factor of three since only one-third of the acceptors were users by eighteen months. Finally, if births averted were selected as the output, the cost output ratio would again rise about one hundred times, as the matching study suggests less than a one percent impact on net cohort fertility.

With the revised program strategy, the cost output analysis will utilize all of the above indicators but will consider the time frame of analysis. Further, additional and more important outputs related to incremental improvements in family health, such as changes in nutrition, morbidity and mortality status will be assessed.

D. SIGNIFICANCE

This project was initiated on the premise that there exists in rural Bangladesh an unmet demand for family planning services. Two years of experience have established the validity of that premise. It has, however, added another premise just as fundamental; that is, we do not know the best strategy to effectively meet that demand. The purpose of this project is to test a complex field and clinic based strategy which has been designed to take into account most of the deficiencies that have been detected with the simple household distribution system.

This project is being carried out in an area already serviced by a Government rural health and family planning program. The fundamental design of this project basically involves a substantial, but feasible augmentation of the Government's programmatic effort to a selected population of 80,000. Obviously, by being a research project conducted by the CRL, the attention to the programmatic inputs will be optimized. Thus, the outputs must be considered as the result of the optimum implementation of this programmatic strategy. It would have to be recognized that such a level of performance could not be expected if a similar strategy was applied on a national scale.

This limitation, however, should in no way invalidate the results. Rather, if the program were highly successful, it could establish levels of achievement that are feasible and the magnitude of cost and field and clinic structures to attain these goals. On the other hand, if optimum implementation achieves extremely limited results such as with the original household distribution project, this in itself provides important information for future strategy considerations.

F. FACILITIES REQUIRED

The Cholera Research Laboratory shares the Matlab Bazaar Thana Rural Health Centre with the Government Health and Family Planning Program. The CRL is just completing a construction program at the health center in collaboration with the Government to provide sufficient space for the expanded family planning clinic services. The family

planning clinic services at the health centre will be operated under the jurisdiction of the Matlab Thana Family Planning Officer. All personnel involved in the operation of the family planning clinic will be paid for out of separate Government of Bangladesh funds allocated to the Cholera Research Laboratory for patient care services.

Four sub-centres, each staffed by a lady family planning visitor have been established within the intensive distribution area for back-up clinical services and for training activities. Three of these sub-centers occupy Government buildings donated by the community for this activity. The fourth sub-centre is in private houses rented by the project. Communications in the field are maintained by out-board motor boats. There is a daily messenger service as well as a two-way radio between Dacca and Matlab.

Data processing facilities are located in Dacca. The CRL has 2 key-punch machines, 2 verifiers, a sorter-counter and access to computer facilities located in the Bangladesh Government Nureau of Statistics.

The proposal for extension does not require major expenditures for equipment or facilities.

F. COLLABORATIVE ARRANGEMENTS

This project is being conducted in direct collaboration with the Government of Bangladesh. Dr. Atiqur Rahman Khan, Co-director of this project with Dr. W.H. Mosley, is Director of the Bangladesh Fertility Research Program. He has joint responsibility for all aspects of the project and participates in all phases of project design and data analysis.

The clinic based services are provided in coordination with the District, and Subdivisional, Planning Program and all services are coordinated with the Thana Family Planning Officer.

SECTION III
DETAILED BUDGET

1. PERSONNEL SERVICES:

Administration

Name	Position	% of Effort	Annual Salary	Project Requirement Taka	Dollar
Shushum Bhatia	Investigator	90	$21,250	-	12,125
Trinidad Osteria	Investigator	90	$25,000	-	22,500
Makhlisur Rahman	Investigator/ Branch Head	40	Tk.38,077	14,230.00	-
J.Chakraborty	Supervisor	90	Tk.37,327	33,747.30	-
Female Village Worker(80)	-	100	Tk. 6,327	506,160.00	-
Senior Field Asst.(5)	-	100	Tk.22,108	88,432.00	-
Lady Family Planning Visitors (6)		100	Tk.13,460	80,760.00	-
Chowkidar/Asst.(4)		100	Tk. 3,500	14,000.00	-
FSA (2)		100	Tk.28,060	56,120.00	-
Physicians (2)		100	Tk.31,581	63,162.00*	-
Clinic Attendant(2)		100	Tk. 3,000	6,000.00*	-
Record Keeper (1)		100	Tk.24,523	24,523.00*	-
Ward Cleaner (1)		100	Tk. 8,162	8,162.00*	-
Senior Statistical Asst.		100	Tk.23,830	23,830.00	-
Coders (4)		100	Tk. 9,000	36,000.00	-
t Research Aides (2)		100	Tk.22,108	44,216.00	-
				119,276.00	22,500
			Sub Total:	1,000,342.30	44,975
			Sub Total $ Equivalent:	$66,689.49	44,975
			Total:	$111,664.49	

2. Supplies and Materials

Items	Amount	Unit Cost	Project Requirements TAKA	Project Requirements DOLLARS
Program Operation				
Clinic				
Sponge holding forcep	4	Tk. 20	80	
Vaginal speculum, medium	4	Tk. 200	800	
Vaginal speculum, small	4	Tk. 150	600	
Vulsellum forcep	10	Tk. 100	1,000	
Uterine sound	3	Tk. 100	800	
Artery forcep, large	8	Tk. 30	240	
Artery forcep, medium	8	Tk. 25	200	
Scissor blunt, medium	4	Tk. 15	60	
Needle holder	4	Tk. 15	60	
Needle, cutting, round	8	Tk. 10	80	
Needle, straight	8	Tk. 10	80	
Silk or Nylon	4	Tk. 12	48	
Dissecting forcep, tooth	4	Tk. 12	48	
Dissecting forcep, non-tooth	4	Tk. 20	80	
Lifter	6	Tk. 15	90	
Kidney dish, large	8	Tk. 20	160	
Catheter, rubber	8	Tk. 90	540	
Loops & insertion kit	6	Tk. 6	24	
Karman syringes & cannulac	20	Tk. 20	400	
Pan with cover	8	Tk. 150	1,200	
Blood pressure instrument	4	Tk. 800	3,200	
Stethoscope	4	Tk. 200	800	
Thermometer	10	Tk. 6	60	
Savlon 1 gln/tin	5	Tk. 200	1,000	
Cotton 1lb. each	12	Tk. 12	144	
Gauze 1 than each	5	Tk. 40	200	
Gauze, bandage, sponge 1 pkt ea.	5	Tk. 3	15	
Spirit 1 lb. each bottle	12	Tk. 10	120	
Adhesive tape 1 roll each	5	$ .28		1.40
Plastic syringes, 3 c.c. each	500	$ .05		25.00
Plastic syringe, 5 c.c. each	300	$ .07		21.00
Needle 20 x 1"	1000	$ .03		30.00
Bucket plastic	10	$ 6.73		67.30
Phenyl 1 Gln/Tin	5	Tk. 11	55	
Tray 12" x 18"	5	Tk. 60	300	
Scissor, Household ordinary	4	$ 1.73		6.22
Stapling machine with staples	4	Tk. 40	160	
Staple remover	4	Tk. 20	80	
Ballpoint pen with refill	12	Tk. 1.75	21.	
Scotch tape	4	$ .61		2.44
Maskin tape	4	Tk. 1.50	6	
Eraser	4	Tk. 10	40	
Basket	4	Tk. 10	40	
Envelope	500	Tk. 1	500	

			Project Requirements	
			TAKA	DOLLARS
Supplies & Materials (Contd.)				
Items	Amount	Unit Cost		
Razor	2	Tk. 75	150	
Surgical Sponge brush	2	Tk. 50	100	
Lysol	1 lb	Tk. 50	50	
Benzoin	2 lbs.	Tk. 15	30	
Silk	2 rolls	Tk. 6	12	
White cloth gauze	20 yds.	Tk. 2	40	
Catgut Chromic OO		Tk. 25	25	
Catgut plain O		Tk. 15	15	
Register book, 500 page lined	8	Tk. 90	720	
Stamp pad	4	Tk. 45.50	182	
Pencil lead	12	Tk. 1	18	
Ruler 12"	4	Tk. 2	8	
Soap toilet	12	Tk. 268	32.16	
Soap Washing ball	12	Tk. 2	24	
Towel bath	4	Tk. 16	64	
Thread 1 ball	4	Tk. 2	8	
Duster cloth	16	Tk. 6	96	
Pens magic markers	4	Tk. 11	44	
Paperweight	4	Tk. 6	24	
Torch light	4	Tk. 85	340	
Battery	12	Tk. 3.50	42	
Aerosol spray	4	Tk. 28	112	
Safety match 1 dozen/box	4	Tk. 2.400	9.60	
Stoves	4	Tk. 65	260	
Pad foolscap	8	Tk. 7	56	
Pad octave	8	Tk. 4	32	
Clipboard	12	Tk. 7	84	
			47,892.60	153.36
DRUGS				
Inj. Penthidine 10mg	300 amps	Tk.2	600	
Inj. Seduxen 10 mg	300 amps	Tk. 125	375	
Inj. Atropine 6 mg	300 amps	Tk. .50	150	
Inj. Phenergan 50 mg	300 amps	Tk. 1.25	275	
Inj. Xylocaine 500 c.c.		Tk. .50	250	
I/V Normal saline	18 blts.	Tk.10.35/btls	186.30	
Tab. Multivitamin	60,000	Tk. 90/1000	5,400	
Tab. Fersolate	60,000	Tk. 120/1000	7,200	
Tab. Calcium lactate	20,000	Tk. 50/1000	1,000	
Tab. Methergin	3,600	Tk. 50/1000	180	
Inj. Methergin	1,200	Tk. 2	2,400	
Inj. Baralgin 2cc	300	Tk. 1	300	
Tab. Baralgin	6,000	Tk. 50/1000	300	
Tab. Aspirin	12,000	Tk. 90/1000	1,080	
Tab. Flagyl	6,000	Tk. 67/100	4,020	
Tab. Triple sulph	120,000	Tk.65.75/1000	1,890	

			Project Requirements TAKA	DOLLARS
Supplies & Materials (Contd.)				
Items	Amount	Unit Cost		
Tab. Vit. A & D	30,000	Tk.100/1000	3,000	
Lotion Benzyl Benzoate	60 lbs.	Tk.3.25/lb	195	
Syr. Ascapar	120 lbs.	Tk.25.50/lb	3,000	
Inj. Benzyl Pencillin	1200	Tk. 12	14,400	
Syrup tetracycline	6 liters	$ 2.54		15.24
Syrup Ampicillin	3 liters	$ 15.80		47.40
Injection Ampicillin	600 vials	$ 0.56/vial		336.00
Cap. Tetracycline	12 btls.	$ 18.39		220.68
Inj. Combiolies	3000 vials	Tk. 2.01/vial	6,030	
Tab. Penitrial	6000 tabs	Tk. 38/tab	2,280	
Distilled water 6000 vials	60 boxes	Tk. 30.44	1,826.40	
Tetanus Toxoid	10,000 doses	Tk. 4.10	40,000	
Inj. Vit. A	10	Tk. 5	50	
Infusion set 21	1 box	$ 9.29		9.29
Venopak	1 box	$ 11		11.00
Inj. Dextrose	100 amps	Tk.1.50/amp	150	
			96,637.70	639.61
Project Evaluation				
Printing costs	200,000	Tk. 6.50/ sheets	24,000	
IBM Cards	40,000	$ 8/10,000		32.00
Computer tapes	4	$ 8.19/tape		32.76
Stapling machine w/staples	4	Tk. 40	160	
Staple remover	2	Tk. 20	40	
Ballpoint pens w/refill	40	Tk. 1.75	70	
Lead pencils	40	Tk. 1	40	
Ruler 12"	10	Tk. 2	20	
Pad	30	Tk. 7	210	
Envelopes (large)	100	Tk. 5	500	
			25,040	64.76

			Project Requirements TAKA	DOLLARS
Equipment				
Item	Amount	Unit Cost		
Project Operation				
Table 4 x 3	4	Tk. 400	1,600	
Chair	8	Tk. 125	1,000	
Bench 6 x 1¼ x 1½	16	Tk. 200	3,200	
Exam room table 5 x 2½ x 2½	4	Tk. 350	1,400	
Bookshelf 3½ x 1 x 3	4	Tk. 350	1,400	
Almirah 5½ x 3 x 1¼	4	Tk. 1000	4,000	
Stool 13" x 13" x 18"	8	Tk. 125	1,000	
Drum 9"	3	Tk. 20	60	
Tubectomy set	2	Tk. 2,500	5,000	
Instrument tables	1	Tk. 300	300	
Project Evaluation				
Calculators 1 Programmable		$ 150		150
2 simple	$ 50	$ 50		100
			18,960	250
Transportation				
Transporration allowance of 80 FVW's at Tk. 50/FVW for 6 months			24,000	
Country boatmen (8) for Senior Field Assistants and LFPV's at Tk. 360/mon. for 10 months			28,800	
CRL Transport				
a) Mileage - Dacca 15,000 miles at Tk. 1.50/mile			22,500	
b) Speedboat 2000 hours at Tk. 100/hr.			200,000	
			275,300	
Computer time	Tk. 800/hours	40 Hours	32,000	
Contribution ot Demographic surveillance				33,000
TOTAL		Tk. 1,496,172.60 $ 99,749.84		$ 79,082.73

TOTAL DOLLAR COST: $ 178,827.57

	Year 1		Year 2		Year 3	
	Taka	Dollars	Taka	Dollars	Taka	Dollars
1. Personnel	1,000,342.80	44,0	1,070,366.26	44,[illegible]	1,145,291.89	44,[illegible]
2. Supplies & Materials.	169,570.00	857.7[illegible]	181,446.00	11[illegible]	194,140.89	[illegible]
3. Equipment	14,960.00	250.10	-	-	-	-
4. Transport	257,300.00	-	294,571.00	-	[illegible],190.97	-
5. Computer time	2,000.00	-	2,000.00	-	2,000.00	-
6. Contribution to Hydrographic Surv.	-	3[illegible],000	-	3[illegible],000	-	3[illegible],000
	1,496,[illegible]12.80	[illegible],082.7[illegible]	1,[illegible]78,377.26	[illegible]8,852.[illegible]	1,[illegible]86,[illegible]23.46	[illegible]8,951.01
	$ [illegible],[illegible]34.84		$ 105,[illegible]25.15		$ 112,[illegible].58	

TOTAL DOLLAR COST = $ [illegible],[illegible].57 [illegible],[illegible].02 [illegible],[illegible].5[illegible]

(1 Tk. = $ [illegible])

TOTAL COST FOR 3 YEARS = [illegible],[illegible].0[illegible].

ABSTRACT SUMMARY

The proposal is a modification and extension of the ongoing protocol Contraceptive Distribution Project (CDP), Matlab (July 1975 - September 1978). The objective of the CDP is to assess the requirements for an inexpensive and effective delivery system for fertility control in a less developed country. The initial study design involved the regular provision through CRL female village workers on non-clinical contraceptives (oral pills and condoms) to all married couples in half of the Matlab surveillance area (MSA with the remaining half serving as controls).

Two years of experience with this simple but intensive household distribution program suggests that program performance may be improved substantially through several modifications. This protocol proposes that a new cadre of better trained female village workers, backed by stronger field supervisory and technical staff, be deployed in 70 villages (80,000 population) to provide family planning and selected health services and that a wider array of clinical services, including IUD, sterilization, and menstrual regulation, be provided at the CRL Matlab Treatment Unit. Improving the quality and scope of services would, in essence, establish three study cells: (1) original household distribution (40,000); (2) intensive health and family planning program (80,000); and (3) control (45,000).

The intensive program in 70 villages will be operational by January, 1978 and will run till September, 1980. A baseline survey on family planning practices and reproductive status was carried out on about 20,000 eligible women prior to program implementation. Records plus specialized surveys will be used to assess field and program performance.

This modification of the CDP represents and initial stage in the development of a rural health services research program with the broader goal of disease prevention and improvement of maternal and child health.

The following should be considered by the Ethical Review Committee in considering this protocol.

1. This protocol is a collaborative project between the Ministry of Health and Population, Government of the People's Republic of Bangladesh, and the Cholera Research Laboratory. The Co-Director is Atique R. Khan.

2. The methods and procedures with regard to the services to be provided to the study population are precisely those package of health and family planning services being planned and implemented by the Government. In family planning, the non-clinical distribution of oral pills and condoms is customary Government practice. Also, IUD insertions would be done by Government-trained, CRL-employed lady family planning workers. Sterilizations and menstrual regulation would be done at the Matlab clinic, which is being designated as the official Government family planning clinic for the thana. Long-acting injectable contraceptives delivered by the village workers is approved by Government of Bangladesh. In fact, our supply of this commodity is being

... / 2.

provided by Government of Bangladesh to this project.

3. Similarly, the health services are only those activities currently approved by Government of Bangladesh. These include maternal nutrition education, iron-folate supplementation and tetanus inoculations during pregnancy. Child services include routine immunizations (BCG, DPT), nutrition education, and possible treatment of common infections.

4. As such, the actions involved in this protocol are service-oriented and non-experimental. The experimental component is an evaluation of the impact and constraints related to the delivery of service.

5. There will be no physical risk to the patients involved. No specimens, samples, etc. are planned outside those required for service purposes. Future protocols or amendments would be submitted if any actions are contemplated involving physical procedures - eg. blood drawing and the like. These would be covered in later protocols.

6. The only potential risk is invasion of privacy because information is needed to evaluate the program. Such information however does not extend beyond those required for program monitoring, and service delivery. Confidentiality of records will be maintained. Data analysis will only contain coded information, whereby the identity of individual subjects will not be possible. The primary data, which contains identification information, will be stored in secured cabinets and access will be restricted to only those involved in coding or analysis.

7. Obviously, normal service records maintained at the CRL clinic will also be used by the evaluation. Again these data would be transformed into coded information for analysis, thereby protecting the identity of the subjects.

[illegible] [illegible] [illegible]
[illegible] [illegible] [illegible]

[illegible]

I, voluntarily and knowingly fully well about the amendments, give consent to the operation on my family size - [illegible] to [illegible].

I have _____ [illegible] _____ daughters at present, [illegible] wife is alive [illegible] full consent to such [illegible].

Couple's Age

husband _____ year

wife _____ years

Least child's age _____ years

C.I.I./Liq. _____

Full name _____

Present address :

V.I.S. No. _____

Vill _____

P.O. _____

P.S. _____

Dist. _____

Permanent address :

Vill _____

P.O. _____

P.S. _____

Dist. _____

কলেরা রিসার্চ ল্যাবোরেটরি
পরিবার কল্যাণ কেন্দ্র, মতলব।

সম্মতি পত্র
==========

আমি স্বেচ্ছায় এবং ফলাফল সম্বন্ধে সম্পূর্ণ অবহিত হইয়া আমার বন্ধ্যাকরণের (টিউবেকটমী/লেপারোটমী) জন্য অপারেশনের অনুমতি দিতেছি।

আমার ---------- পুত্র ও ---------- কন্যা বর্তমানে আছে। আমার স্বামী/স্ত্রী জীবিত আছেন এবং বন্ধ্যাকরণের ব্যাপারে স্বামী/স্ত্রীর পূর্ণ মত আছে।

সম্মতির বয়স

স্বামী ---------বৎসর

স্ত্রী ----------বৎসর

সর্বশেষ সন্তানের বয়স -------বৎসর

টিপ/সহি ----------

পুরা নাম ----------

বর্তমান ঠিকানা

ডি, পি, এস, নং --- ----------

গ্রাম ---------- ----------

পোষ্টঅফিস -- ----------

থানা ----------

জিলা ---------- ----------

স্থায়ী ঠিকানা

গ্রাম ----------

ডাকঘর ----------

থানা ----------

জিলা ----------

APPENDIX IA

FIRST VISIT - CONTRACEPTIVE DISTRIBUTION PROJECT

Background Information

Date of Interview

A. Demographic Information

A1. Village?
A2. Household No./Individual No?
A3. Woman's name?
A4. FSA No?
A5. Age of wife?
A6. Age of husband?
A7. Occupation of husband?
A8. Education of wife?
A9. Number of living children?
A10. Living sons?
A11. Date of termination of last live birth?
A12. Sex of last live birth?
A13. Is the last live birth still alive?
A14. If no, date of death?
A15. Husband present?
A16. If no, reasons for husband's absence?
A17. Duration of husband's absence?
A18. Frequency of husband's visit to the household?

B. Contraceptive Knowledge and Practice

B1. There are several methods nowadays which married couples use to delay and prevent pregnancies. Have you heard of any of these methods?

Methods: Pill, IUD, Injection, Condom, Female Sterilization, Vasectomy, Menstrual Regulation, Rhythm, Withdrawal, Douche, Others (specify)

B2. What methods have you heard of?
B3. For methods not mentioned and for those who have not heard of any - ask - have you heard of.....?
B4. For methods volunteered B2 and not probed B3 - ask - have you used.....?
B5. Which methods are you currently using?
B6. Do you want more children?

FOR THOSE NOT USING ANY METHOD AS OF INTERVIEW DATE:

B7. Do you think you and your husband may decide to use some method to avoid or delay pregnancy?
B8. After how many children? Sons?
B9. If not, why not?

APPENDIX IB

COUPLE VISIT CARD
CONTRACEPTIVE DISTRIBUTION PPOJECT
FORTNIGHTLY QUESTIONS

Name?

1. Village No?
2. Family No?
3. Individual No?
4. Date of visits?
5. Menstruation/pregnancy status -

   M - menstruation
   P - pregnant
   PPA - postpartum amenorrhea
   A - amenorrhea for other reasons

6. If pregnancy is terminated during interval before visit:

   Date of termination?
   Outcome - SB - stillbirth
   MC - miscarriage
   LB - single (male (M) or female (F))

7. Lactation Status?

   B - breastfeeding fully
   BP - breastfeeding partially
   NB - not breastfeeding

8. Contraceptive use in the 15 days preceeding visit?

   N - not using any contraception
   CU - continuing users
   A - new acceptors

   Pill.....
   IUD.....
   Injection 3 mos.....
   6 mos.....
   Condom.....
   Tubal Ligation.....
   Vasectomy.....
   Menstrual regulation..
   Others.....

Reason(s) for discontinuance or method shift?

Complaints?

Management?

Persons responsible for Management?

Comments?

CHOLERA RESEARCH LABORATORY
CONTRACEPTIVE DISTRIBUTION PROJECT

CONSENT FORM

I was informed that the Cholera Research Laboratory is using Depo-Provera injection for spacing of births and for prevention of pregnancies. I was further informed that there may be some irregularities in menstruation for a while after the injection or there may be symptoms of the first stages of pregnancy. But these are temporary. I was fully informed that the Cholera Hospital is using this injection as a method of contraception. It is being used for the same purpose in different countries of the world. But our Government of Bangladesh has limited its use only on a trial basis.

Knowing fully well the effects of this injection, I am using this injection for 3/6 months period at my own accord. My husband is alive and he has given his consent. The workers of the Cholera Hospital have assured me that I may stop using the injection anytime I desire to do so. I am also assured that the Cholera Hospital will take full responsibility for treatment of any side effects.

Thumb impression
or Signature _____

Name: _____

V.T.S. No. _____

Village _____

Date _____

[illegible] রিসার্চ ল্যাবরেটরী
[illegible]

সম্মতি পত্র

আমি ইহা অবগত হইলাম যে, কলেরা হাসপাতালের কর্মীগণ সন্তান দেরীতে হওয়া অথবা না হওয়ার জন্য ডিপো-প্রভেরা ইনজেকশন দিতেছেন। এবং আমি আরও অবগত হইলাম যে এই ইনজেকশন [illegible] পর্যন্ত [illegible] কিছু অনিয়মিত [illegible] দিতে পারে [illegible] এবং [illegible] মেয়েদের যে উপসর্গ দেখা দেয় [illegible] উপসর্গ দেখা দিতে পারে [illegible] সাময়িক। আমি সম্পূর্ণ ভাবে অবগত হইলাম যে, কলেরা হাসপাতাল এই ইনজেকশন [illegible] জন্মনিয়ন্ত্রণের পদ্ধতি হিসাবে [illegible] পৃথিবীর অন্যান্য দেশেও একই উদ্দেশ্যে ব্যবহৃত হইতেছে। কিন্তু আমাদের বাংলাদেশে [illegible] এখনও ইহা পরীক্ষা নিরীক্ষা [illegible] পর্যায়ে রাখিয়াছেন।

আমি এই ইনজেকশনের ফলাফল সম্পর্কে সম্পূর্ণ অবগত হইয়া স্বেচ্ছায় এই তিন মাসের ইনজেকশন নিতেছি। আমার স্বামী জীবিত আছেন এবং এই বিষয়ে তাঁহার সম্মতি আছে। এই বিষয়েও কলেরা হাসপাতালের কর্মীগণ আমাকে নিশ্চয়তা দিয়েছেন যে, যে কোন সময় আমার ইচ্ছানুযায়ী আমি এই ইনজেকশন নেওয়া হতে বিরত হতে পারবো। এবং এই ইনজেকশন নেওয়ার জন্য যে কোনরূপ পার্শ্ব প্রতিক্রিয়া দেখা দিলে কলেরা হাসপাতাল [illegible] দায়িত্বে আমার চিকিৎসার ব্যবস্থা করিবেন।

টিপ বা দস্তখত ------------------------

নাম ------------------------

ডি, এস, এস, নং ------------------------

গ্রাম ------------------------

তারিখ ------------------------

Contraceptive Distribution Project

List of Reports
(upto September 1977)

1. AR Khan and DH Huber, "Household Contraceptive Distribution Program in Rural Bangladesh - Six Months' Experience", CRL, June 1976.

2. GT Curlin and AR Khan, "Contraceptive Distribution Project: Semi-Annual Report, January - June 1976", CRL, July 1976.

3. AKMA Chowdhury and DH Huber, "Fertility and Mortality - Recent Changes in Matlab, Bangladesh", Abstract presented at the World Population Society Conference, 5-7 December 1976, Washington D.C.

4. DH Huber, AR Khan, GT Curlin, R Langsten, "Contraceptive Distribution Project in Rural Bangladesh", paper presented at the Seminar on Fertility in Bangladesh, 13-15 December 1976, Cox's Bazaar, Bangladesh.

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7. DH Huber, AR Khan, GT Curlin, and R Langsten, "Contraceptive Distribution Project in Rural Bangladesh - One Year Experience", CRL Technical Committee presentation, February 1977.

8. AR Khan and DH Huber, "Household Distribution of Contraceptives in Bangladesh - Rural Experience", paper presented at the Regional Conference "Village and Household Availability of Contraceptives", Tunis, 27-30 March 1977.

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10. M Rahman, "Utilization of Dais in Promotion of Contraceptive Practice", draft CRL report, March 1977.

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14. GT Curlin, AR Khan, WH Mosley and M Rahman, "Contraceptive Distribution Project: Semi-Annual Report, January - June 1977", CRL, July 1977.

15. M Rahaman, "Some Facts about Low Acceptsnce and High Discontinuation of Contraceptive Practices among the Population under House-to-House Contraceptive Distribution Project, Matlab", CRL draft mimeo; June 1977.

16. R Langsten, "Alternate Recommendations for Beginning Contraceptive Use: The Case of Bangladesh", CRL draft mimeo, June 1977.

17. DH Huber, "An Experimental Design for Assessing the Effectiveness of Household Contraceptive Distribution", paper presented at the Congress of the IUSSP, Informal Session No. 6, Mexico City, 8-13 August 1977.

18. AR Khan and others, "Experience with Household Contraceptive Distribution Programme in Rural Banglsdesh and Evolution of New Strategy" draft paper to be presented at the Bangladesh Workshop on Innovative Population Programs, Comilla, date not yet announced.