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ETHICAL REVIEW COMMITTEE, ICDDR,B.

DC

Principal Investigator DR MGM ROWLAND

Application No. 85-027

Title of Study COMMUNITY HEALTH SERVICES PROJECT, MATLAB: THE REVISED MCH-FP SERVICES AND RECORD-KEEPING SYSTEM

Trainee Investigator (if any)

Supporting Agency (if Non-ICDDR,B)

Project status:
( ) New Study
(X) 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 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
   (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure (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 Committee:
   - ✓ Umbrella proposal - Initially submit overview (all other requirements be submitted with individual stud
   - ✓ Protocol (Required)
   - ✓ Abstract Summary (Required)
   - ✓ Statement given or read to subjects 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 Committee for review.

I agree to obtain approval of the Ethical Review Committee for any changes involving the rights and welfare of subjects before making such change.

MGM Rowland
Principal Investigator

Trainee

85-027

SECTION I - RESEARCH PROTOCOL

1.	Title:	Community Health Services Project, Matlab: The Revised MCH-FP Services and Record Keeping System.
2.	Principle Investigator	Dr. M.G.M. Rowland (Acting)
	Co-Investigators:	Mr. J. Chakraborty Dr. M. Koenig Dr. K. Zaman
	Consultants:	Dr. Md. Yunus Dr. S. Bhatia Dr. M.G.M. Rowland
3.	Starting Date:	October 1, 1985
4.	Completion Date:	September 30, 1987
5.	Total Direct Costs:	1985 US$ 286,000 1986 US$ 385,000
6.	Source of Funds:	NORAD
7.	Scientific Program Head:	Dr. M.G.M. Rowland Associate Director, Community Services Research

This protocol has been approved by the Community Services Research Working Group:

Associate Director
Community Services Research

Date

Reviews:

Ethical Review Committee: _____

Research Review Committee: _____

Director: _____

ABSTRACT SUMMARY

This protocol outlines the nature of the basic MCH-FP services, delivery and record-keeping system, in the Matlab field study area of the ICDDR,B. This represents a modification of the current activities which were initiated in 1980 and 1982, in the so-called MCH-FP intervention areas: blocks A, B, C, D with a total population of around 90,000, rationalized on the basis of preliminary findings to date and forthcoming research requirements. The components will consist as before of:

Growth Monitoring and Nutrition Intervention:

Nutrition surveillance and advice at the domiciliary level was listed in the previous protocol but never effectively implemented. Because this is potentially a major area of service and research in itself it will be dealt with in separate protocols. Plans are in hand to upgrade the central hospital facility for the treatment of patients with severe malnutrition.

Oral Rehydration Therapy:

The current distribution system of packets of oral rehydration salts (WHO formula), locally prepared in Sub-centres, will be continued using bari mothers as before. The quantity in each packet will be reduced to that suitable for preparing ½ litre (instead of 1 litre) of solution in line with the current practice of GOB, and the necessary education and training carried out.

Referral service facilities at the Matlab Treatment Centre for diarrhoeal and related morbidity from our survey areas will be maintained and other severe problems will be directed for medical help in more appropriate quarters.

Breast Feeding:

Documentation of breast feeding and weaning patterns will be extended from the current MCH-FP intervention areas to include the comparison areas in the context of work to be described elsewhere.

Immunization:

Tetanus toxoid will be offered in the intervention areas to all married women between the age of menarche and menopause i.e. all women at risk of pregnancy.

Measles immunization coverage will be extended at the end of 1985 and offered in all blocks of the intervention area to children over the age of 9 months up to the age of 2 years.

In 1986 we aim to introduce DPT immunization for all infants up to the age of 2 years in the intervention area.

Family Planning:

Essentially we will continue the existing domiciliary "cafeteria-type" service. The current tubectomy and vasectomy service at Matlab Treatment Centre will be gradually phased out in favour of referral to the Government Upazilla Health facility next door, thus avoiding unnecessary duplication of resources and services. New restrictions regarding referral for menstrual regulation are documented in the main text.

Pregnancy and Delivery Care:

Current activities designed to reduce morbidity and mortality associated with pregnancy and delivery will be continued.

Thus this protocol documents an overall simplification and slight extension of the service component in the Matlab field area which is in itself both a source of research and provides a support structure for other studies.

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Overall Objectives:

To deliver joint family planning and MCH (MCH-FP) services to a target population in rural Bangladesh to reduce the total fertility rate and maternal and child morbidity and mortality.

To continue to monitor the effectiveness of these services in achieving these ends.

To identify the major causes of mortality and morbidity which are not effectively modified by the MCH-FP programme.

To keep under review the methods of delivery, documentation, evaluation of the services and where necessary to systematically develop/modify the individual components of the service programme.

2. Background

In 1975 Matlab was the site for testing the effectiveness of an intensive contraceptive distribution programme, which failed in that the impact was transient (Rahman et al, 1980). In 1977 a new programme was introduced in which family planning services were augmented by the MCH inputs introduced sequentially as part of a 3-tier programme with a central facility at Matlab Treatment Centre, outlying Sub-centres, and a strong domiciliary component (Bhatia et al, 1980).

The next revision of the Community Health Services Project commenced in November 1980. The stated principal overall objective was to test the relative effectiveness of family planning and MCH services, delivered

jointly and separately in reducing the total fertility rate and maternal and child mortality.

The family planning component consisted of fortnightly domiciliary visits by community health workers who motivated "at-risk" women to accept contraceptive measures (or sterilization in selected cases). They offered a door-step service supplying condoms, foaming vaginal tablets, oral contraceptives, long-acting injectables and also advised potential clients on the availability of other fertility control measures such as IUDs, tubectomy and vasectomy.

The MCH component comprised tetanus immunization, the use of oral rehydration and clinical MCH services with domiciliary screening and referral. This MCH component was upgraded in January 1982. The objective was to improve care of high risk pregnancies and deliveries, improve coverage of the tetanus immunization programme, introduce nutritional surveillance of children under five years, and DPT and referral immunizations, mass treatment of parasitic infections and referral of young children for clinical treatment when indicated. The aim was a reduction in maternal and child mortality and upgradation of MCH competence of domiciliary workers.

These interventions were introduced in such a way as to facilitate evaluation of the effectiveness of various components of the MCH programme.

In one half of the intervention area (c. 40,000 people in blocks A+C on the attached map) an "intensive" regime was introduced, comprising measles immunization of all children over the age of 9 months, tetanus toxoid for all women at risk of pregnancy or pregnant. ORS was distributed through a system of "bari mothers". CHWs were given some basic nutrition education and resource material

to equip them to discuss nutritional problems with mothers. There was also provision of simple medication for minor illness through CHWs, and iron and folic acid supplements were given during pregnancy.

CHWs also carried out screening and referral of "at risk" pregnancies and distribution of safe birth kits. and there was training of traditional birth attendants (TBAs).

In the"standard MCH-FP" area, blocks B and D,tetanus toxoid was administered only during pregnancy. Family planning services were present in both areas. Measles vaccination was not given and safe delivery practices were not implemented. No TBA training was given.

The above programme clearly made major advances in the promotion of widespread contraceptive use in the community with a current acceptance rate of around 45% amongst eligible women. A marked fall in total fertility rate and birth rate has been sustained from 1978 through 1983. In that year the TFR was 4.96 in the Treatment area and 6.32 in the Comparison area. Comparable figures for birth rates were 34.2 and 42.6. A modification of this programme is being replicated in conjunction with the health services of the Government of Bangladesh in the extension areas outside Matlab Upazilla.

Increasing levels of contraceptive acceptance have also been associated with falling childhood mortality rates principally in the 0-1 month and 1-4 year age group. Thus the 1984 neonatal mortality rate in the Intervention areas is between 55.9 and 56.9, cf the comparison area with 70.9 per thousand live births. In 1983 the 1-4 year death rate were 21.6 and 35.3 respectively per 1000 population. However, the overall achievement in this respect is still inadequate, particularly with respect to infant mortality rate which was around 98 per 1000 in 1983.

The constraints still operating in this respect are not understood. For example, it is widely believed that increasing degrees of

childhood malnutrition are associated with a measurably higher risk of death. "Malnutrition" is common and often severe in Matlab yet we are totally ignorant of the extent to which it is caused by inadequate dietary intake, the burden of infectious diseases or both. The adequacy of breastfeeding and weaning practices have yet to be determined on a quantitative basis, and the extent to which they are related to maternal nutritional status and other factors requires further refinement of surveillance systems. The role of different infectious illnesses impairing growth is also largely unknown apart from a relatively small and localized study incriminating diarrhoea of varying aetiology. Though death rates are known relatively accurately this is far from true of the cause of death.

Insight into these problems is required before radically new interventions can be logically developed in an attempt to further reduce mortality. Thus the recommendations in a recent consultancy report would appear particularly relevant, namely the need to analyse the effect of current interventions and establish systems of morbidity surveillance, growth monitoring and nutritional surveillance (in mothers and children).

With the exception of the question of female literacy such a programme would facilitate the development, introduction and evaluation of the missing components of the currently recommended approach to reducing morbidity and mortality in developing countries--namely GOBI-FFF (growth monitoring, oral rehydration therapy, breastfeeding, immunization, fertility regulation, selected feeding inputs and female literacy programmes.

Rationale

Major progress has been made in the Matlab study area with respect to family planning measures and reduction in fertility during the last 5 or more years.

The planned MCH component of the programme has been only partly implemented and the reduction in childhood mortality is modest. Data collected on the interventions which have been introduced in various blocks as part of a scientific research programme remain largely unanalysed. This will be addressed as a matter of priority.

B. SPECIFIC AIMS

- To further reduce fertility by maintaining and developing or modifying existing family planning services.
- To further reduce child mortality in all age-groups by standardizing existing inputs throughout the intervention areas.
  * due to neonatal tetanus by improving coverage of tetanus immunization by offering tetanus toxoid to all women, pregnant or "at risk" of pregnancy.
  * due to problems related to pregnancy and delivery by further improving coverage and quality of safe birth practices.
  * due to diarrhoeal diseases by maintaining and improving the delivery and usage of oral rehydration therapy and perhaps by developing other strategies.
  * due to nutrition-associated morbidity (see separate protocol).
  * by improving quality of medical care at the Matlab Diarrhoeal Treatment Centre and Sub-Centres.
- To continue to develop the Record Keeping System (RKS) in current use with emphasis on portability, speedy data handling and accessibility.
- To support research initiatives directed to improving understanding of nature of childhood morbidity and mortality not controlled by the above programme.

In the meantime the infrastructure of the MCH-FP delivery systems and the various components of the programme need to be rationalized in the light of experience to date. Any major modifications will be undertaken as a separate research issues under separate protocols.

C. METHODS OF PROCEDURE

1. Population served.

Approximately 186,000 people are currently documented and vital events registered in the activities of the Matlab Demographic Surveillance System, representing between one third and one half of the population of Matlab Upazilla (425,000 in 1982).

Of these c. 90,000 live in the so-called MCH-FP treatment area currently divided into 4 blocks (A-D) in which the package of health care delivery varies, as described above.

It is questionnable whether this variation of inputs any longer serves a useful function and in this protocol it is proposed to standardise the delivery of MCH-FP services throughout the area, meeting the needs of approximately 14,400 eligible mothers and of their children under the age of five years.

2. MCH-FP Services Personnel

These are delivered through a well-established infrastructure as shown below:

		Manager, Health Services		
Treatment Centre	Sub-Centres	SFRO[1]		
MCH-FP Physicians 2	FRO[1]		FRO	
SHA 2	SHA[2]	SHA	SHA	SHA
LFPV 3	LFPV[3]	LFPV	LFPV	LFPV
	20 CHWs[4]	20 CHWs	20 CHWs	20 CHWs
Blocks:	A	B	C	D

1 (S)FRO - (Senior) Field Research Officer. Trained in supervision skills by ICDDR,B at Matlab.

2 SHA - Male Senior Health Assistant. ICDDR,B trained. Responsible for day-to-day supervision of CHWs, discussions with community leaders, with husbands etc.

3. LFPV - Lady Family Planning Visitor. Matlab equivalent of Government Union-Level Family Welfare Visitor having received 18 months training in a government FWV training institute and additional training in Matlab.

4 CHW - Community Health Worker. Matlab equivalent of Government Village-level Family Welfare Assistant having been given 8 weeks training by ICDDR,B at Matlab. They are selected from their local community on the basis of being married, contracepting women with at least one child and a minimum of grade VIII education.

MCH-FP Service "Package".

1. Growth Monitoring and Nutritional advice.

This hitherto neglected aspect of the programme will be developed and presented in a separate protocol.

2. Oral Rehydration Therapy.

Bari mothers (selected women from grouped households sharing a common courtyard) have been trained in the past in the preparation and administration of oral rehydration fluid. The ingredients of WHO ORS will be supplied to Bari mothers, free of charge, in the form of ½ litre sachets locally prepared at Matlab Treatment Centre and Sub-centres.

They then distribute these to diarrhoea patients in the bari and may give dietary advice during and following diarrhoea. Consumption of packets is noted; CHWs maintain records and supplies during regular fortnightly visits. They also check on current usage.

More serious cases are treated at the Matlab Treatment Centre or at Nyergaon where a recently constructed building fulfils the dual role of Sub-Centre (equivalent Government Family Welfare Centre) and Community Operated Treatment Centre (for diarrhoea).

3. Breastfeeding.

There are no specific inputs in this area at present except to promote breast feeding without interruption during illness and to discourage bottle-feeding/breast milk substitutes.

4. Immunization.

The aim is to give all pregnant and "at risk" women two doses of 0.5 ml at least four weeks apart.

a) Experience in Matlab has shown that much higher coverage is achieved by offering tetanus toxoid to all women who are pregnant and at risk of pregnancy (i.e. women aged 15 to 45 years and even younger if married and menstruating) than to the former group alone. The respective coverage in terms of achieving at least two doses of tetanus toxoid prior to delivery is now around 90% using this blanket approach and 40% in the area where only pregnant women are immunized (data from unpublished annual reports). The wider approach will therefore become standard throughout the treatment area. Male subjects will also be eligible to avail themselves of the vaccine if they seek it.

b) Measles vaccine coverage will also be extended to the full treatment area aimed at giving 1 dose to all children over the age of 9 months up to the age of 2 years.

c) We also plan eventually to provide cover against diptheria, tetanus and whooping cough with a course of three doses of DPT given at least 4 weeks apart to infants after the age of 3 months. For logistic reasons it will not be possible to start this before 1986.

Supplies of vaccine are procured from the Bangladesh Government (GOB) with the assistance of the WHO Office in Dhaka.

Vaccine is transported nonthly to Matlab in insulated carriers. Tetanus toxoid is stored at between 4° and 8°C in specially designed Refrigerators and measles vaccine below 0°C in freezers. During campaigns vaccines are despatched daily to the Sub-Centres (Nyergaon, Torky, Khadergaon, Bordia) for distribution to CHWs who deliver them at household level with the aid of cold carriers replenished with freezer packs. Injections are given with disposable needles and reusable syringes. Unused vaccine left over at the end of the day is discarded. Measles vaccination is carried out in 4 "drives" per year, each lasting around 10 days. Because of the excellent coverage achieved, tetanus toxoid coverage is now carried out on an "as-needed" basis.

As part of their fortnightly surveillance of eligible women, CHWs identify high risk pregnancies, on the basis of one or more of the following: a history of bleeding per vagina, suspicion of diabetes (a history of polydipsia, polyuria) severe clinical anaemia, convulsions, oedema, high parity (>5 births) high age (>35 years), short interval between pregnancies (<2 years). Such cases are referred in the first instance to the LFPV who re-assesses and if necessary sends for formal medical assesment to the MCH clinics supervised by an MCH-FP Physician at Matlab Centre or one of the four Sub-Centres.

Safe delivery practices are promoted mainly by CHWs training traditional birth attendants (dais) in clean techniques, assisted by the provision of a safe birth kit, and in recognizing complicated deliveries requiring referral to the Government Maternity Centre which may be in Matlab, Chandpur or Dhaka.

Family Planning.

CHWs discuss family planning methods with potential clients during their regular fortnightly visits. The service is essentially "cafeteria-type" --they are equipped with government-supplied condoms, foaming vaginal

tablets and oral contraceptives, long-acting injectables (Depo Provera) and also advise potential clients on the availability of other fertility control measures such as IUD (Copper-T) insertions at Matlab, Sub-Centres or at home, and tubectomy or vasectomy facilities at Matlab ICDDR,B or government facilities, They are also trained to assess, advise and if necessary refer clients with complications to the appropriate facility.

Record Keeping.

Each CHW is provided with a regular register book containing basic identification and background data (which is now produced from computer data files) which she carries with her on her routine (usually fortnightly) visits to her study families (roughly 175 of them) in the MCH-FP intervention area. This book is then updated in consultation with mothers and bari mothers with respect to marital status, menstrual, pregnancy or contraceptive status, immunization, breast-feeding and various other related details.

The material gathered is reviewed for error-checking and inconsistencies by her immediate supervisors (SHA or LFPV) during regular random checks at household level and also more frequently during fortnightly congregations at one of the Sub-Centres by higher level supervisors.

New data is transferred at these latter sessions for further checking initially at Matlab and later for computerization in Dhaka.

We intend to extend the questionnaire activities slightly by asking the same details of mothers within the comparison areas with respect to contraceptive practice, and breastfeeding/weaning behaviour. This will permit more meaningful analysis of differences between the comparison and intervention areas. The system of collection would be the same, based on existing CHWs (currently being utilized exclusively by the DSS) who will first receive the necessary training.

D. SIGNIFICANCE

This programme will maintain the current structure of the MCH-FP delivery system, the service component of which will be rationalized and upgraded at little or no incremental cost, whilst existing documentation and data handling techniques will continue to be improved, with emphasis on accessibility for review and linkage with other programmes. This infra-structure and environment will facilitate further research developments both of the various MCH-FP components and of other related research in the Matlab area.

E. FACILITIES REQUIRED

This programme would continue to use existing facilities in the same manner as at present. No radical extension of these facilities is proposed. They comprise:

1. Office space at Matlab Treatment Centre and Sub-Centres.
2. Laboratory space - minimal as at present
3. Hospital resources refer essentially to MCH-FP clinic facilities at the Treatment Centre and Sub-Centres plus the operating suite for tubectomies at Matlab. The latter may be modified to provide space for nutritional rehabilitation of seriously malnourished children identified during routine screening by CHWs or presenting for treatment from the intervention area.
4. Animal resources - nil
5. Logistical support - Up to 2 Jeep ambulances and between 2 and 5 speedboats out of the fleet of 19, are used for delivery of clinical services, moving patients or carrying personnel on health-related duties. These have been budgetted for on a full cost-recovery basis. Cost of Dhaka-Matlab trips is similarly covered.
6. Major items of equipment for replacement or additions include furniture and equipment such as: Bengali typewriter, microcomputer for data handling, a simple photocopier, duplicating machine, calculators;

lab and clinic equipment, including autoclave, oxygen cylinders and meters and suction device for resuscitation; and teaching/training equipment including overhead and slide projectors, plus voltage stabilizing equipment. A replacement vehicle may be required to replace the existing one loaned from the MCH-FP extension project.

F. COLLABORATIVE ARRANGEMENTS

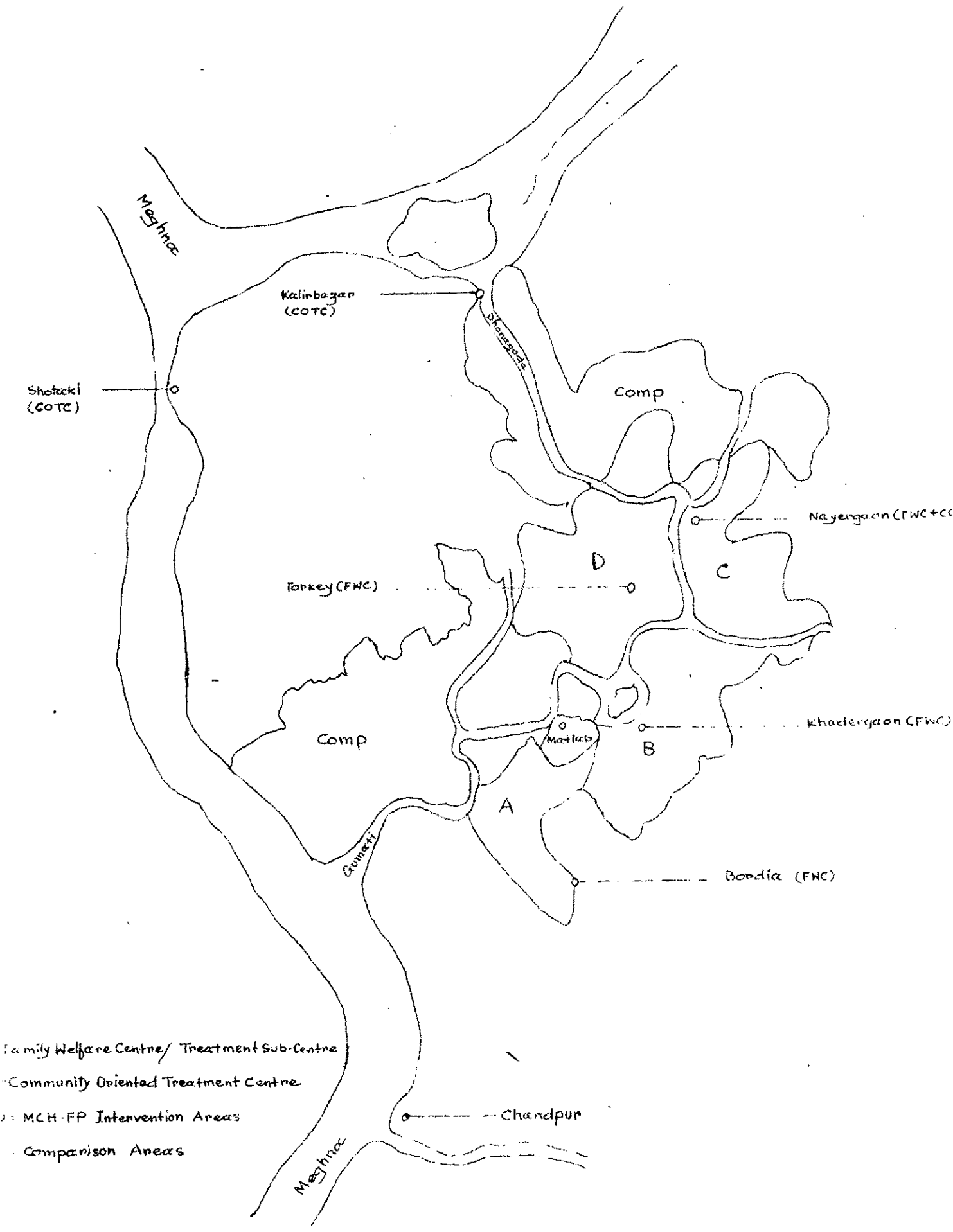
Community Health Workers are employed 75% of their time on MCH-FP work and for the remainder of the time on the DSS (which is separately funded).

REFERENCES

1. Bhatia S.; W.H. Mosley, A.S.G. Faruque, and J. Chakraborty 1980 "The Matlab Family Planning Health Services Project," Studies in Family Planning, 11(6):202-212.

2. Rahman M.; W.H. Mosley, A.R. Khan, A.I. Chowdhury, and J. Chakraborty, 1980 "Contraceptive Distribution in Bangladesh: Some lessons learned," Studies in Family Planning, 11: 191-201.

MGMR:ls


Meghna
Kalinbazar (COTC)
Dhanagoda
Shotaki (COTC)
Comp
Nayergaon (FWC+CC
D
C
Tarkey (FWC)
Comp
Matlab
Khaterpara (FWC)
B
A
Gumati
Bondia (FWC)
Chandpur
Meghna
Family Welfare Centre/ Treatment Sub-Centre
Community Oriented Treatment Centre
MCH-FP Intervention Areas
Comparison Areas

ABSTRACT SUMMARY

1. This protocol documents, with some modifications the current service components of the Matlab MCH-FP activities and seeks approval for the continuation of these service inputs. No changes in the study population are proposed; this comprises all women pregnant or at risk of pregnancy and their children under the age of two years in one half of the Matlab study area, having a total population of approximately 90,000 people.

2. The various components of the MCH-FP services are in use by Government of Bangladesh MOHPC and/or are of established value and safety. Some contraceptives may be followed by side effects. These have not been found to be a serious problem during the last five years and our support services have been able to deal adequately with those that have arisen.

3. Existing medical procedures will be followed for protecting against or minimising known risks associated with sterilization, IUDs and Depo Provera. These are detailed in Appendix I.

4. Clinical and field records in Matlab are confidential, and initial data collection is entered into books now in use by Community Health Workers (CHWs). These records are largely service orientated and of necessity contain basic information on morbidity, utilization of services and special needs for various service components. Data from the MCH-FP record keeping system may be linked with information from the Matlab Demographic Surveillance System to facilitate evaluation. Staff handling such data are trained in their jobs and understand its confidential nature. Linkages are carried out mainly on the basis of coded identification numbers rather than names. Data analysis is carried out on anonymous files and identifications are not published.

5. No consent forms are necessary for most services with the obvious exception of sterilization for which signed consent is obtained. The current form has been in use for the last 5 years having been approved by the ICDDR,B's Ethical Review Committee (Appendix 2a,b,c).

Abstract Summary

6. Only questions directly relating to need and utilization of services are proposed. This will include a fortnightly interview of "at risk" mothers by CHWs who will discuss the need for various services such as immunization and contraception. Such interviews will not exceed 20 minutes and may be much shorter.

7. We aim to reduce maternal and child morbidity and mortality and to reduce the total fertility rate.

8. The comments in section 4 apply. The only body fluids that would be sampled would be in relation to normal clinical care, eg. measuring the haemotocrit or screening for proteinuria in pregnant women.

APPENDIX Ia

DETAILED DESCRIPTION OF MEDICAL PROCEDURES

Procedures in this study are based on methods and guidelines of the MOHPC, GOB. None of the methods or procedures in this study are experimental. The procedures are described in detail as follows:

STERILIZATION

Female sterilization as part of Family Planning service was started in Matlab in January 1978. The surgery under this protocol is done by the Mini Laparatomy method. The procedure has been done by the Lady Family Planning Visitors (Female Paramedic) under the supervision and presence of a trained physician. The LFPVs are a group of paramedics who have 18 to 24 months training in various methods of Family Planning and basic maternal and child health care.

MOTIVATION

The CHWs during their fortnightly visits will discuss sterilization with potential clients. Discussion emphasizes the permanence of the procedure and its irreversibility. The CHWs will approach only those women who have two or more children. In case of women having two children, the youngest will be five years of age or more. They will explain to the women that the surgery is done by 2 small incisions about 1" in length of the lower abdomen. The consenting women will besent to Matlab in the afternoon of the operation day.

HISTORY, PHYSICAL EXAMINATION AND SCREENING: In the Clinic the LFPV on duty will take a detailed history including the obstetric history of the client. Then she will perform a physical examination including pulse, respiration, temperature, clinical anaemia, an internal examination (per vaginum) will be done by the LFPV to determine the position of uterus and to identify patients with pelvic inflammatory disease or tumor which would constitute a contraindication to operation. Routine urine examination for albumin and sugar and haemotocrit will also be done. The LFPV will then review the findings of history, physical examination and laboratory tests with the MCH-FP physician who will then determine the clients suitability for surgery. In case of doubt, the physician will make a physical examination. After final conclusion signed consent form will be obtained from each client. The consent form will be filed securely.

PREPARATION:

On the day before the operation, preoperative measures such as cleaning and shaving of the lower abdomen will be done. Also LFPVs will autoclave instruments and prepare linens. Prophylactic antibiotic (Injection Cambiotic or Inj. Procaine Penicillin) will be applied. In the evening, a light meal will be provided to the clients followed by a mild laxative.

On the morning of the operation, Inj. Phenergan (50 mgm) and Inj. Pethidine (100 mgm) will be given intramuscularly about one half hour before surgery.

SURGICAL PROCEDURE

The LFPVs perform the tubectomy via a Mini-Laparatomy under the direct supervision of the Physician.[1] [2]If the Physician cannot attend the procedure will be postponed or cancelled.

POST OPERATIVE CARE

After the operation, the clients will be provided a cot in a recovery room. Routine post operative care will be provided by the paramedical nursing staff on duty. Physician coverage for the period 24 hours following the operation is mandatory. The clients will be kept for two consequetive nights for post operative care. Antibiotic coverage will be maintained during the post operative period. The usual compensation of the Government Family Planning Department will be provided to all clients by the local Family Planning Authority. If any of the specified post operative standards cannot be met, the procedure will be postponed or cancelled.

...

1/ This role of LFPVs is sanctioned by the current 5 year plan (Planning Commission, 1980) without specifying that a physician must be present. Our requirement that a physician must be present is the only aspect in which Matlab procedures differ from the officially sanctioned procedures. This was sanctioned by our own ERC and we see no reason to depart from it.

2/ Currently ICDDR,B Matlab Treatment Centre carries out approximately 150-200 tubectomies per year, half of whom now come from outside the intervention area and some from without the comparison area. The service duplicates the government facility a few hundred yards away in Matlab Bazaar. Discussions are in progress with a view to discontinuing the ICDDR,B tubectomy service whilst maintaining motivation activities and referral to the government facility. If generally acceptable we anticipate phasing out the activity during 1985; during that period we will probably continue to be responsible for pre and post operative care of intervention area subjects and certainly for their longer term follow-up and care in the community.

FIELD FOLLOW-UP

After the clients go home, the CHW will make daily follow-up visits to the clients and provide antibiotic injections for two days. During the follow-up visits, the FVWs will also enquire about any problems and examine the incision site for evidence of swelling or infection. If there are any problems, the LFPV at the appropriate sub-centre will be informed, and will take necessary action such as cleaning and dressing of the incision site or referral to a physician.

On the eighth day following the operation, the CHW will remove the stitches aseptically in the patient's home. All CHWs are presently trained for the purpose. If field follow-up standards cannot be met, the procedure will be postponed or cancelled.

DEPO PROVERA (DMPA)

Depo Provera is provided to women in the village at the time of consent. Injections are given by the CHW in the deltoid muscle of the upper arm. The site of injection is cleaned with ethanol. A disposable syringe is used only once and is then destroyed.

Contraindications are as follows: 1. History suggestive of hypertension; 2. jaundice. 3. lump in the breast, 4. a history of menstrual irregularity or excessive bleeding, 5. evidence of diabetes, 6. overdue menstruation (pregnancy) or, 7. severe concomitant illness.

Injections will be given on the fifth day of the menstrual cycle. Among lactating women injections will be at least 6 months post partum.

Nulliparous women will not be given Depo Provera. Recent medical research has shown that terminators of Depo Provera return to fertility normally. However, in view of the controversy that could arise if subfecund adopters were to attempt to have children, Depo Provera is not generally used for nulliparous women.

CHWs have been taught to recognize problems and refer clients with side effects to the LFPVs who have been trained to deal with them.

The consent form appears in Appendix 3.

Appendix 1k

Notes on tubal ligation and follow-up at ICDDR,B Matlab based on GOB MOHPC practices

(by Dr. K. Zaman)

Tubal ligation is the permanent surgical method of sterilization for females.

CLIENTS

The clients are motivated by the Community Health Workers (CHWs) in the field and referred to central clinic.

(a) Must be married
(b) Age within reproductive period
(c) Minimum 2 children, the youngest one must be over 1 year,
(d) Mentally/Medically fit
(e) Consent - self/husband

MEDICAL SCREENING

(a) Socio Demographic history
(b) History of present/past illness
(c) Menstrual/obstetrical history
(d) Detailed physical/pelvic examination
(e) Laboratory investigations - Urine - Routine analysis
Blood-TC/DC/Hct/ESR

SIGNED CONSENT

After final selection for surgery, signed consent is obtained from each client.

PRE OPERATIVE PREPARATION

(a) Clean bath

(b) Cleaning and shaving the area

(c) Light food previous night

(d) No food for 4 hours before surgery

(e) Laxative Tablet for bowel clearance

MEDICATION

(a) Pre-operative - at least 45 minutes before surgery 10 mgm Diazapam is to be given orally. The client must pass urine immediately before entering the Operation Theatre.

(b) Operative - When the client in on the operation table the following 3 drugs are to be mixed in a glass syringe together:

1. Inj. Pethedine 50 mgm
2. Ing. Antropine Sulph - 1/100 gr or 0.60 mgm
3. Inj. Phenergan - 25 mgm

It is to be pushed intravenously usually through anticubital vein very slowly. After pushing half the total amount the vital signs (pulse, respiration, BP) to be checked and have to wait for 2 minutes. If these signs remain unaltered the remaining volume of medicine should be given slowl All these will produce good systemic analgesia but the patient will remain awake and be able to answer any question.

(c) Local Anaesthesia - 1) About 10 c.c. 1% lideocaine is to be infiltrated into the skin in the midline, left, right, up and down of the incision area. 2-3 minutes should elapse before making any incision.

2) Another 5 c.c. lideocaine is to be given into the peritoneum and peritoneal cavity after opening the Peritoneum.

..3

SURGICAL PROCEDURE

(1) Modified pomeroy technique
(2) Transverse incision less than 1 inch just above symphysia pubis.
(3) Opening of the abdomen by cutting and spliting of different layers.
(4) Both tubes are picked up, ligated and excised.
(5) Closure of the abdomen in layers.

POST OPERATIVE MANAGEMENT/MONITORING

(1) Post operative monitoring of pulse, respirations, BP every 15 minutes for 1st hour after operation then 4 hourly until discharge.
(2) No food within 6 hours of operation.

DISCHARGE

A patient is discharged after 2 overnight stays if no complications.

INCENTIVE

In our national program there is a provision of providing a wearing cloth & Tk. 175.00 for fooding, transportation and home dislocation.

FOLLOW-UP

(1) Daily visit by CHW upto 7 days
(2) Stitches removed on 8th day.
(3) In case of complication clients are referred for medical care
(4) Thereafter routine fortnightly follow up.

*Menstrual Regulation (MR)

Presently we are not doing any menstrual regulation (MR) in our Matlab Clinic or Subcentres. Because of a recent USAID embargo we are no longer permitted to carry out active referral to government facilities for this purposes Ref. letter dated 17th July,1985 by Dr. Eeckels in response to USAID's of 7th July.)

Appendix 2a

International Centre for Diarrhoeal Disease Research, Bangladesh
(Community Health Services Project, Matlab)

Letter of Consent

1. I am aware that I can have an operation performed that will permanently prevent me from having any additional pregnancy. This operation involves having an incision in the lower abdomen while I have local anesthesia. This incision will be painful after the anesthesia subsides.

2. I understand that in rare cases there may be infection around the incision. If any such problem arises I can seek treatment from the ICDDR,B.

3. I understand that I must have 2 living children of whom the youngest is at least five years old.

4. My husband has given his full endorsement of this operation.

_____
Signature or thumb impression

Census number: _____

Name: _____

Date: _____

_____
Signature of Physician

Appendix 2b

International Centre for Diarrhoeal Disease
Research, Bangladesh
(Community Health Services Project, Matlab)

অনুমতি পত্র

১। আমি অবগত আছি যে আমার যাতে বাচ্চা সন্তান না হয় তার জন্য পছন্দ করলে আমি অপারেশন করিয়ে নিতে পারি। এই অপারেশন প্যারেটের বিশ্রামাগার অবশ করে ঐ স্থান কেটে করা হয়ে থাকে। অপারেশনের পর অবশতা কমে গেলে কাটা স্থানে ব্যাথা অনুভব হয়।

২। আমি এও জানি যে কোন কোন সময় কাটা স্থানের চতুর্পার্শ্বে ঘা হতে পারে এবং তখন আমি আই,সি,ডি,ডি আর,বি'র নিকট থেকে চিকিৎসা সুবিধা নেয়ত পারি।

৩। আমি আরও জানি যে অপারেশন করাতে হলে কমপক্ষে দুটি জীবিত সন্তান থাকতে হবে এবং সর্বকনিষ্ঠ সন্তানের বয়স কমপক্ষে পাঁচ বছর হতে হবে।

৪। আমার স্বামী এ অপারেশনে সম্পূর্ন সম্মত আছেন।

স্বাক্ষর/বৃদ্ধাঙ্গুলীর ছাপ

তারিখ

ডাক্তারের স্বাক্ষর

Appendix 2c

CONFIDENTIALITY STATEMENT

The study involves provision of MCH-FP services and maintaining details of utilization. Services will only be provided to consenting subjects. Linkages of various items of information on any individual is done through use of an identification number. Staff with access to identification codes are specially trained and aware of the confidential nature of the information. Results of analysis are published in aggregate and do not refer to individuals.

Appendix 3a

International Centre for Diarrhoeal Disease Research, Bangladesh
(Community Health Services Project, Matlab)
Letter of Consent

I have come to know that the workers of the ICDDR,B are providing Depo Provera for delaying or stopping conception. Acceptance of this injection may be followed by irregularity in menses. Most women experience temporary symptoms which are similar to the temporary symptoms of pregnancy. Menses usually stops while Depo Provera is used and women who discontinue often experience delays before menses resume. Some women who stop experience long delays before they can become pregnant. I have been told that some women are concerned that Depo Provera may reduce breast milk, but I have also been told that this is not confirmed.

I have been told that this Depo Provera injection is for birth control only and has no other medicinal benefits. Also I understand that I can stop taking injections at any time and if any problems arise I can seek advice and available treatment from ICDDR,B workers.

Signature or thumb impression

Date: _____

আই, সি, ডি, আর, বি, খুলনা

(জন্ম নিয়ন্ত্রণ পদ্ধতি বিতরণকল্পে স্বেচ্ছামূলক কার্যক্রম)

সম্মতি পত্র

১। আমি অবগত হলাম যে বাধার বড়ি, কনডম, আই,ইউ,ডি, ইত্যাদি অস্থায়ী পদ্ধতি তাই স্বেচ্ছায় গর্ভাধারণ অপারেশনের রাজি আছি।

২। আমি জানি যে এটা এক ধরনের অপারেশন ও এর জন্য সামান্য ঝুঁকি আছে। ঝুঁকি ও অপারেশনের পদ্ধতি সম্বন্ধে ডাক্তার সাহেব আমাকে অবগত করেছেন।

৩। ডাক্তার সাহেব আমাকে এটাও অবগত করেছেন যে উক্ত অপারেশনের পর আমি সন্তান জন্মদানে অক্ষম হলেও আমার যৌন ক্ষমতা অথবা যৌন প্রবৃত্তি অপরিবর্তিত থাকবে।

৪। আমার এই সিদ্ধান্ত সম্পূর্ণ স্বেচ্ছায় এবং কোন প্রকার ভয়, প্রলোভন অথবা বাধা আরোপিত নয়।

৫। এই অপারেশনের আমার স্বামী + স্ত্রী এবং অভিভাবকদের পূর্ণ সম্মতি রয়েছে।

৬। আমি জানি যে এটা স্থায়ী জন্ম নিয়ন্ত্রণ পদ্ধতি এবং এটাকে পূর্ববর্তী অবস্থায় ফেরত আনা যাবে না। এবং আমি ইহাও অবগত হইলাম যে এই অপারেশনের পরে আমার কোন সন্তান জন্ম দেওয়ার ক্ষমতা থাকবে না।

অপারেশন করার জন্য স্বেচ্ছায় সম্মতি পত্রে স্বাক্ষর করছি।

ক্লায়েন্ট-এর স্বাক্ষর/টিপ সহি
ডি,টি,এস নং ----------
নাম ----------
তারিখ ----------

স্বামী

১। নাম ---------- ঠিকানা ----------
স্বাক্ষর ----------

অপারেশনকারী চিকিৎসকের স্বাক্ষর ও পদবী

আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র, বাংলাদেশ

মাতৃসেবা শিশু কল্যাণ ও পরিবার পরিকল্পনা কার্যক্রম সংক্রান্ত

সম্মতি পত্র

আমি ইহা অবগত হইলাম যে, আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্রের কর্মীরা সন্তান পেটে হওয়ার জন্য বা না হওয়ার জন্য ডিপো-প্রভেরা ইনজেকশন দিতেছেন এবং আমি আরো অবগত হইলাম যে ঐ ইনজেকশন নেওয়ার পর সাময়িক ভাবে মাসিকের কিছু অনিয়মতা দেখা দিতে পারে বা গর্ভাবস্থায় এবং গর্ভবতী মেয়েদের যে উপসর্গ দেখা দেয় সেই রকম কিছু উপসর্গ দেখা দিতে পারে তবে এইগুলি সাময়িক। আমি সম্পূর্ণ ভাবে অবগত হইলাম যে, আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র এই ইনজেকশন জন্ম নিয়ন্ত্রণের পদ্ধতি হিসাবে দিতেছেন যাহা পৃথিবীর অন্যান্য দেশেও একই উদ্দেশ্যে ব্যবহৃত হইতেছে। কিন্তু আমাদের বাংলাদেশ সরকার এখনও ইহা পরীক্ষা নিরীক্ষার মধ্যে সীমাবদ্ধ রাখিয়াছেন।

আমি এই ইনজেকশনের কার্যকর সম্পর্কে অবগত হইয়া স্বেচ্ছায় এই তিন/ছয় মাসের ইনজেকশন নিতেছি। আমার স্বামী জীবিত আছেন এবং এই বিষয়ে ওনারও সম্মতি আছে। এই বিষয়েও আন্তর্জাতিক উদরাময় গবেষণাগারের কর্মীরা আমাকে নিশ্চয়তা দিলেন যে, যে কোন সময় আমার ইচ্ছামত আমি এই ইনজেকশন নেওয়া থেকে বিরত হতে পারবো এবং এই ইনজেকশন নেওয়ার ফলে যে কোনরূপ পার্শ্বপ্রতিক্রিয়া দেখা দিলে আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র ইহা নিরাময়ের জন্য তাহাদের নিজ দায়িত্বে আমার চিকিৎসার ব্যবস্থা করিবেন।

টিপ সই/স্বাক্ষর ____________________

নাম ____________________

ডি, টি, এস, নং ____________________

গ্রাম ____________________

তারিখ ____________________

আই, সি, টি, ডি, আর, বি, মতামত
(জন্ম নিয়ন্ত্রন পদ্ধতি বিতরনমূলক কার্য্যএলাকা)

সম্মতি পত্র
=========

১। আমি অবগত হলাম যে খাবার বড়ি, কনডম, আই,ইউ,ডি, ইত্যাদি অস্থায়ী পদ্ধতি তাই স্বেচ্ছায় বন্ধ্যাকরন অস্ত্রোপচারে রাজি আছি।

২। আমি জানি যে এটা এক ধরনের অস্ত্রোপচার ও এর জন্য সামান্য ঝুঁকি আছে। ঝুঁকি ও অস্ত্রোপচারের পদ্ধতি সম্বন্ধে ডাক্তার সাহেব আমাকে অবগত করেছেন।

৩। ডাক্তার সাহেব আমাকে এটাও অবগত করেছেন যে উক্ত অস্ত্রোপচারের পর আমি সন্তান জন্মদানে অক্ষম হলেও আমার যৌন ক্ষমতা অথবা যৌন প্রবৃত্তি অপরিবর্তিত থাকবে।

৪। আমার এই সিদ্ধান্ত সম্পূর্ণ স্বেচ্ছায় এবং কোন প্রকার ভয়, প্রলোভন অথবা চাপ আরোপিত নয়।

৫। এই অস্ত্রোপচারে আমরা স্বামী + স্ত্রী এবং অভিভাবকদের পূর্ণ সম্মতি রয়েছে।

৬। আমি জানি যে এটা স্থায়ী জন্ম নিয়ন্ত্রন পদ্ধতি এবং এটাকে পূর্ববর্তী অবস্থায় ফেরত আনা যাবে না। এবং আমি ইহাও অবগত হইলাম যে এই অস্ত্রোপচারের পরে আমার কোন সন্তান জন্ম দেওয়ার ক্ষমতা থাকবে না।

অপারেশন করার জন্য স্বেচ্ছায় সম্মতি পত্রে স্বাক্ষর করছি।

ক্লায়েন্ট-এর স্বাক্ষর/টিপ সহি
ডি,টি,এস, নং _____
নাম : _____
তারিখ: _____

স্বামী

১। নাম _____ ঠিকানা _____

স্বাক্ষর _____

_____
অস্ত্রোপচারকারী চিকিৎসকের স্বাক্ষর ও পদবী।