

Date November 21 1971

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REVIEW BOARD ON THE USE OF HUMAN SUBJECTS, ICDDR,B.

J. Phillips P. CLAQUIN

Principal Investigator M. RAUMAN

Trainee Investigator (if any) _____

Application No. 80-042

Supporting Agency (if Non-ICDDR,B) _____

Title of Study The Community

Project status:

Services Project

New Study

Continuation with change

No change (do not fill out rest of form)

Give appropriate answer to each of the following (If Not Applicable write NA).

Category of Population:

(a) All subjects Yes No

(b) Non-ill subjects Yes No

(c) Minors or persons under guardianship Yes No

(d) the study involve:

(1) Physical risks to the subjects Yes No

(2) Social Risks Yes No

(3) Psychological risks to subjects Yes No

(4) Discomfort to subjects Yes No

(5) Invasion of privacy Yes No

(6) Disclosure of information damaging to subject or others Yes No

(7) 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

(d) subjects clearly informed about:

(1) Nature and purposes of study Yes No

(2) Procedures to be followed including alternatives used Yes No

(3) Physical risks Yes No

(4) Sensitive questions Yes No

(5) Benefits to be derived Yes No

(6) Right to refuse to participate or to withdraw from study Yes No

(7) Confidential handling of data Yes No

(8) 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 to Board:

— Umbrella proposal - Initially submit 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.

See to obtain approval of the Review Board on the Use of Human Subjects for any change affecting the rights and welfare of subjects before making such change.

J. Phillips
Principal Investigator

Trainee

ABSTRACT SUMMARY - PARTICULAR ITEMS

1. Not applicable.
2. There may be some side-effects from contraceptive use which will be told to each acceptor beforehand. The benefits of contraceptive use have been documented, however, to outweigh probable side-effects.
3. The standard and prescribed medical procedures will be followed for protecting or minimising likely risks associated with sterilization, IUD and menstrual regulation (for details, see Appendix A).
4. Informed consent will be obtained at the time and place of providing services (for detail, see Exhibit B1, B2 & B3).
5. See Exhibit B1, B2 & B3.
6. Once in a fortnight the ICDDR,B community health services worker will visit each family of her area and talk with eligible members about MCH-FP services. The duration of discussion will depend upon the eligibility of the member for obtaining services. In no case, however, the discussion will take more than 20 minutes.
7. The protocol envisaged provision of MCH-FP services which are beneficial both to the individual acceptors and community in general from a reduction of maternal and child mortality.
8. The study will use service statistics data and the Matlab demographic surveillance data.

CONFIDENTIALITY STATEMENT

The study involves provision of MCH-FP services and maintaining service statistics. Consent will be obtained at the time of providing services. It is necessary to code census numbers of individuals to link users characteristics and service use records. Staff with access to the identifying information are trained and aware of its confidential nature. Data will be published only in aggregate.

Access to data: James F. Phillips, Makhlisur Rahman, P. Claquin.
Personnel in Data Management.

SECTION I - RESEARCH PROTOCOL

1. Title: The Community Health Services Project,
Matlab.
2. Principal Investigator: James F. Phillips, Makhlisur Rahman and
P. Claquin
3. Starting Date: January 1, 1980
4. Completion Date: December, 1983
5. Total Direct Cost: \$ 827,104
6. Scientific Programme Head:

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

* Signature of Scientific Programme Head: N.B. S

Date: 23/11/80

* This signature implies that the Scientific Programme Head takes responsibility for the planning, execution and budget for this particular protocol.

- (7) Abstract Summary: This protocol summarizes the service activities and overall research plans envisaged in the UNFPA proposal entitled: "Matlab MCH-FP Project".

The proposal extensively modifies an existing field study that provides intensive contraceptive care and referral services to 14,000 Matlab couples. Although the existing project has been oriented principally to the delivery of family planning services, maternal and child health (MCH) components have been added piecemeal over time. Workers have been trained in birth practices, have been informed of methods of nutritional consultation, and have been trained to deliver tetanus immunizations and establish home-based oral therapy services for diarrhea. While elements of this program have been highly successful, it is clear that MCH services under this project can be greatly improved. Neonatal mortality remains at unacceptably high levels and post neonatal mortality is unaffected by the program. Without a coherent and comprehensive revision of MCH services, future mortality effects cannot be anticipated.

Only two MCH elements function in the existing program: immunization of women during pregnancy with tetanus toxoid and oral therapy for diarrhea. In this protocol we propose addition of 5 MCH components: 1) identification, surveillance and care of high risk pregnancies, 2) improvement of safety of delivery practices through training of the individuals who plays a significant role as birth attendants, 3) nutritional surveillance of under-5 children to include monitoring of weight through monthly "weight clinics", 4) immunization to include DPT, and 5) referral services for children under-5 to include care for respiratory diseases, scabies and diarrhoeal diseases.

While there is need to upgrade MCH services in Matlab, there is a strong research rationale for doing so. The World Health Organization, the Bangladesh Government, and many governments around the world have endorsed a policy of integrating family planning with MCH under the assumption that health and well-being of rural people are best served by integrated programs. At the heart of this recommendation is the notion that synergism ensues when family planning and MCH are implemented jointly.

No field study has successfully demonstrated this synergism effect. Thus the proposed study address one overall hypothesis; namely that family planning and MCH services are more effective when implemented jointly than when implemented separately. Accordingly, a four celled experimental design is specified in which one cell has the existing service system, a second has intensive MCH without family planning, a third intensive MCH with family planning, and a fourth no special interventions. This design permits comparison of fertility effects of family planning with and without MCH, and mortality effects of MCH with and without family planning.

Our review of the background literature notes that the efficacy of family planning services has been much debated and that questions concerning the level of effects, the reasons for a plateau in effects in Matlab, and means of further improving effects represent important policy and research issues. Moreover, we note that much needs to be learned about appropriate composition of services and operational strategies for MCH in Bangladesh. We therefore propose a series of studies addressed to these questions. Each study cannot be supported by the above study design and will therefore have separate research protocol.

This protocol, in summary, is a service protocol: it defines general research goals and activities, it documents services to be addressed to research objectives, and it proposes a service statistics system and general analysis plans. It does not include several special research projects considered by the investigators to be essential components of the overall objectives of this research; namely, the re-expansion of the DSS area, the development and refinement of cause of death statistics, the development of specific MCH operations, and special studies of the determinants and consequences of program failure or success. Instead we document those services that we now know will continue for three years, and the broad outline of our objectives and plans. Within calendar 1981 we will submit an MCH service addendum for review--an addendum to be developed from a series of MCH limited studies, that will clarify and document in detail our MCH service strategy.

(8) Reviews: (leave blank)

(a) Research involving Human Subjects: _____

(b) Research Review Committee: _____

(c) Director: _____

(d) BMRC: _____

(e) Controller/Administrator: _____

SECTION II - RESEARCH PROTOCOL

A. INTRODUCTION

1. Objectives

This protocol addresses ICDDR,B research and services envisaged in the UNFPA proposal entitled "Matlab MCH-FP Project". Our primary purpose is to document service activities under this protocol and the general research questions to which those services are addressed. It is anticipated that future health and family planning research protocols will use services and information from this study. Each will be a separate research protocol or limited study with the Community Health Services Project as its primary resource.

It has long been argued that family health and family planning services are appropriately linked. This protocol is motivated by the observation that the rationale for linking health and family services has never been rigorously tested. That rationale can be stated as follows: When maternal and child health services are combined with family planning services, the two components are more effective when integrated than when implemented separately. This proposition has two subsidiary hypothesis namely: that family planning services can have fertility effects, and that rural MCH services can reduce maternal and child mortality. The family planning hypothesis is much debated, while the MCH hypothesis is less controversial. Nevertheless the appropriate mix of MCH strategies for rural Bangladesh remains an open issue.

Our overall objective is to test the joint effects of two interventions, the independent effects of which are also of interest. Figure 1 shows our three intervention cells:

Figure 1

Family Planning

		Present	Absent
Intensive MCH	Present	I	III
	Absent	II	IV

Cell I is the "joint effect" cell in which we hypothesize greater fertility effects of family planning than in Cell II and greater mortality effects of MCH than in Cell III. We hypothesize main effects of both family planning and MCH as evidenced by comparison of II and II with IV for fertility and mortality respectively.

2. Background

Issues in the family planning literature: The discussion of the efficacy of contraceptive service programmes in the demographic literature is characterised by varying assumptions and considerable debate. Without exception, the family planning programmes in Asia have been implemented with the goal of reducing rates of population growth. Underlying this policy is an assumption that convenient and inexpensive contraceptive services to some degree obviate the need for strong personal motivation to limit fertility. This assumption is based on the observation that many respondents in sample surveys express attitudes and intentions consistent with birth planning behaviour despite a low prevalence of contraceptive practice. This has suggested to some researchers that an "unmet demand" exists for family planning. The purpose of programmes is thus viewed as one of narrowing the gap between reproductive goals and behaviour with convenient modern contraceptive technology. While some authors have taken the position that contraceptive services alone can initiate fertility change (cf. Ravenholt and Chao, 1974; Bogue, 1967), most authors have argued that rigorous contraceptive service programmes can only accelerate fertility declines in settings where concomitant social change is occurring. Areal analysis of country data lend support to that hypothesis (cf. Mauldin and Berelson, 1978; Freedman and Berelson, 1976) as do several studies of survey data from specific countries. At issue, then, is whether contraceptive services can induce fertility control in the absence of concomitant social change.^{/1} Several authors have argued that social change that produces changes in reproductive motives must precede or accompany an increase in levels of fertility control (cf. Davis, 1969; Blake and Das Gupta 1975). Thus a debate exists in the literature regarding the fertility control rationale for contraceptive service programmes.

This debate in the scientific literature has far reaching policy implications. At issue is whether special population control efforts can succeed or whether funds are more appropriately invested in economic and social development programmes. In particular it is argued that family planning as an adjunct to health services may

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A useful paper advancing this view is Bogue and Tsui (1979). A critique of that paper is in Demeny (1979).

complement an existing fertility decline, but can never induce one. According to this position, family planning will have no effect in Bangladesh because the total demand is inadequate to start a trend even if modern contraceptives were available (Sirageldin et al., 1975) and in any case, no sustained downward trend has ever been detected (Arthur and McNicoll, 1978). Thus, so the argument goes, resources invested in contraceptive service programmes are resources wasted. This policy debate continued through the 1970's and is unresolved to date.¹

Findings from Matlab suggest that neither of the positions in the population debate can be fully supported nor completely rejected. We find that a low level of demand exists, that this demand can be met with contraceptive services, and that a fertility decline ensues once the demand is met. But we also find that intensive information, and follow-up have no effect on demand. Thus once demand is met, programme effects remain at a plateau. Whether policies can influence fertility motives is unknown. We argue below that the demand for contraception is unlikely to increase unless mortality declines and unless couples perceive that general health and wellbeing are improving.

Thus we have tested the hypothesis of unmet demand and we will continue to demonstrate the demographic effects of meeting that demand by monitoring demographic trends over time. In this protocol we turn to the general question of whether service programs can generate new demand, and whether maternal and child care can serve as the means to that end. Before we turn to a discussion of MCH activities addressed to this question, we will review Matlab findings from previous contraceptive service projects.

Contraceptive services were first introduced in Matlab in 1975 in a project known as the Contraceptive Distribution Project (CDP). The services of the CDP were limited to distribution of contracep-

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Useful reviews can be found in Teitelbaum, 1974 and Freedman and Berelson, 1976. The debate emerged as a major issue in the World Population Conference of 1974 (see, Mauldin et al., 1974 and Finkle and Crane 1975).

tives and largely excluded rigorous follow-up, consultation, or referral care. This approach was based on the observation, reported in the 1968 Bangladesh National Impact Survey, that while 55% of married women expressed a desire to cease child-bearing 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 was 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 programme success. This suggested that a simple supply and information system could achieve significant results.

To address this and subsidiary hypotheses, the ICDDR,B in collaboration with the Ministry of Health and Population, initiated a simple but intensive house-to-house distribution programme of non-clinical methods of contraception (oral pills and condoms) in 150 villages (125,000 population) of the Matlab Surveillance Area. The remaining 84 villages (135,000 population) serviced by the regular Government programme were the comparison group. The CDP tested (a) feasibility of organizing and implementing such a delivery system; (b) the total demand for contraceptives; and (c) demographic impact of the contraceptive distribution approach.

Over the first two years of the project, a variety of research under-takings were conducted. These included sample surveys on: (1) quarterly prevalence of reproductive status and contraceptive usage; (2) knowledge, attitude, and practice (KAP) October 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 of this contraceptive distribution project (CDP) indicate the following:

- 1) The baseline KAP survey suggested that, while modest, there exists significant demand for contraception in this rural area of Bangladesh. About 33% of married women, before programme initiation, were either current users of contraception

or expressed a desire to cease childbearing and an interest to use contraception in future.

- 2) Three months after contraceptive distribution was started, 17.1% of eligible women claimed to be using oral pills. After 18 months of programme effort, the prevalence of oral pill use had declined to 8.7%. The corresponding prevalence rates for use of all methods in the programme villages were 18.0% and 13.0%, respectively. No significant change in the use-prevalence of all methods (2.4%) was observed in the comparison area.
- 3) 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% in the 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.
- 4) Several constraints were noted regarding the modern technologies employed in the programme. 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 effectiveness of condoms was limited at programme initiation and although knowledge of condoms 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 their totality 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 unfulfilled.
- 5) Supported by the logistical and staff resources of the ICDDR,B the distribution programme was found to be simply implemented at

reasonable cost - although its replicability by other institutions facing different operational constraints was considered questionable. The ICDDR,B female village workers, in particular, were considered inadequate for several reasons. Although these workers were knowledgeable about their village and the technologies employed, they themselves were too old 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 ICDDR,B 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.¹

These conclusions led to substantial modification in the field structure and programme activities which were initiated in October 1977. We refer to this project as the modified CDP. The modified programme 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 health services. This intensified program population was drawn equally from the two cells of the original study. Thus, in essence, three study cells were established; (1) original household distribution (population 40,000); (2) intensive health and family planning (population 80,000) which has been created from a part of the distribution area (40,000), and a part of the comparison area (40,000) and (3) comparison (population 45,000).

In one half of the original distribution area, the household distribution activity was terminated in March 1978, when dais provided acceptors a six month supply and advised them to contact local Government Family Planning workers for their future supplies. In the remaining half of the distribution area and half of the comparison area, a new field structure was developed.

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Useful reviews of the CDP and its impact appear in Huber and Khan (1979) and Makhlisur Rahman et al. (1980).

The findings from the CDP project¹ were as follows:

- 1) Acceptance rates increased as new adopters were attracted by the wider array of methods offered. While pill and condom prevalence remained relatively unchanged growing numbers of women chose "Depo-Provera" and laparoscopy. At present approximately half of all contraceptors use Depo-Provera while a fourth are sterilized.
- 2) Continuation rates increased owing to the wider acceptance of more permanent methods (IUD'S, Depo-Provera, and Sterilization) and more intensive follow-up and referral services.
- 3) As a consequence of higher acceptance and continuation rates use prevalence increased precipitously in the first 6 months of the program and remained at between 32 and 34 percent of the eligible couples thereafter. This level of use is consistent levels of demand predicted from pre-program surveys, and such levels of use are likely to reduce fertility. The program is nevertheless, best characterised as a qualified success; an unmet demand has been served, but little if any new demand has been generated.
- 4) Demographic effects are unknown at present, but preliminary results suggest that fertility effects are significant. By early 1981, the full effects should become apparent. It seems probable that the program will account for a 10 point decline in the CBR on the average, but that program effects are seasonal. When comparison area fertility is naturally low, program area fertility is correspondingly low; and when fertility is naturally high the gap between program and comparison area fertility is pronounced. Thus the program seems to dampen natural swings in fertility.² The contraceptive use dynamics that account for seasonality of effects has not been investigated and are poorly understood.
- 5) Anecdotal evidence suggests pronounced areal variation in program effects, most notably by bari, but also by village. The scientific

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A useful description of this project appears in Bhatia, et al., 1980.

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A paper by Becker (1979) documents and models the pronounced seasonality of Matlab fertility.

validation of this observation is appropriate, for to establish such clustering of effects is to provide the basis for investigation of social and programmatic correlates of individual contraceptive behaviour. Studies of ecological determinants of fertility have been the subject of intense interest in recent years (see, for example, Freedman, 1974 and Mason and Palan, 1978) although it is often noted that cross community variation in socio-economic standing is minimal in Bangladesh and that variation in social organisation and human ecology has little fertility effect relative to the effects of individual attitudes and characteristics (see, for example, Alauddin, 1980).

The view that emerges from Matlab is that the "population debate" is unduly polarized. We find that family planning does fulfill an unmet demand, and that fertility change can be initiated by rigorous contraceptive delivery. However, we find that a limit is soon reached in magnitude of effects from this type of program, and that this is below the levels of effectiveness that are required to produce fertility change targeted for Bangladesh under the current five year plan. Thus more questions than answers emerge from the Matlab findings: What accounts for this plateau? Does substantial areal variation in fact exist? We find that some villages have 70 percent of the couples contracepting while others have 10 percent. Are the high performance villages served by FVW's who fail to report dropouts, thereby producing spuriously high prevalence; or, are the data valid? If the data are valid and the variation is real, then what accounts for the observed differences? How do such villages, bars, or households differ - by socioeconomic attainment, by social organisation, by service quality and intensity; and what is the relative contribution of these factors to the observed differences in program effectiveness? What explains adoption, dropping out, reacceptance, method change and other aspects of contraceptive behaviour? If program factors have an effect on contraceptive behaviour, then how can the program be improved? As initial fertility trends become apparent questions will emerge about the nature of the fertility transition in Matlab. How does the pattern of fertility change with time? What is the magnitude of change and how long does it take for full effects to be realized? As we will show below, Matlab is perhaps the first documented instance of fertility decline in the absence of prior mortality change and the only site with complete vital data where high mortality and moderately high levels of fertility control coexist. What fertility effects will accrue from future mortality change (to be discussed further below)?

We do not claim that three scientists can address all such questions; or that all relevant issues can be addressed in a single protocol. Rather, we argue that past and proposed services generate an important scientific resource for the ICDDR,B and that research on this project will greatly expand our understanding of the casual role of contraceptive service programs in demographic change.

MCH Background: A vast literature on the concept and implementation of maternal and child health (MCH) programs exists. MCH is at the heart of the WHO strategies for primary health care and of universal health care by the year 2000. The motivating factor in establishing MCH programs are the elevated risks of death to mothers and children in the pregnancy, delivery, and postpartum period. Accordingly, MCH programs typically identify pregnancies; safe delivery practices through training of birth attendants and pregnant women's education; immunization for childhood diseases (such as: tetanus, tuberculosis, diphtheria, whooping cough, poliomyelitis and measles); surveillance of the nutritional status and growth; education of mothers and curative low cost technology for preventing or treating the major causes of mortality and morbidity. The oral rehydration programs, under-five clinics and weight clinics represent attempts to mobilize communities to improve health education and expand indigenous participation in health service delivery.

In the rural areas of Bangladesh, maternal, infant and neonatal mortality is high even by LDC standards. A 1970 study by Chen et al. (1974) estimated the maternal mortality rate to be 7.1 per 1000 reported pregnancy terminations. More recent studies by Makhlisur Rahman et al. (1980) cited a neonatal mortality rate of 78.3 per 1000 live births. The incidence of neonatal tetanus is believed to be 271 per 1000 according to the WHO Community Health Programme (1979).

Among the leading causes of death of Matlab children under 5 are diarrhea and dysentery (16.4 percent), tetanus (15.7 percent), measles (10.4 percent) and respiratory infections (7.7 percent) (Chen et al, 1979). Most estimates of the prevalence of parasitic infections exceed 80 percent of the children under-five, 30 percent of the children under 3 are severely malnourished, and 92 percent of the children under under-two have Vitamin A deficiency or iron deficiency anemia (ISRT, 1977). Clearly, the Bangladesh population experiences high mortality and morbidity rates from childhood diseases.

The modified contraceptive project in 1977 approached this child death problem by adding MCH components gradually to a family planning project. As a consequence, workers were thoroughly oriented to comprehensive family planning work, but MCH activities have been somewhat fragmentary with each activity viewed as separate. The modified program was therefore not a package of health care activities that was classically MCH in its approach. Rather, we had two "vertical" research projects; namely, the tetanus immunization program, and the oral therapy program for diarrhoeal diseases. We shall review each briefly.

In June 1978, immunization of pregnant women with two injections of an aluminium-absorbed tetanus toxoid was initiated on a schedule of 0.5 ml any time after the fifth month of pregnancy and another 0.5 ml at the minimum of four weeks apart, preferably before one month of the delivery date. An analysis of the results of the first two years of the program has shown that about one-third of the eligible women during this period accepted full immunization (2 injections) and about 5 percent accepted partial immunization (one injection). The data provide conclusive documentation of the impact on neonatal mortality from active immunization of pregnant women. Full immunization of pregnant women with two tetanus injections reduced neonatal mortality rates by about one-half (Makhlisur Rahman et al. 1980). A disturbing finding, however, is the failure of the acceptance rate to increase with time as the programme matured. The acceptance rate remained almost stable, around 33 percent, during the two years of observation. Reasons for non-acceptance as reported by the women were husband or in-law's objection, fears of harming the fetus and failure of workers to inform pregnant women about vaccination early enough (Makhlisur Rahman, 1980). The most important reason for non-acceptance appeared to be linked to a misperception that tetanus injections were intended to protect against three traditionally recognized syndromes (known in Bangla as alga, takuria, and dhanutonkar) when, in fact, these syndromes are often caused by non-tetanus related diseases. Thus, when mothers mis-diagnosed neonatal deaths among tetanus immunized neonates, they mistakenly believed that the immunization was ineffective--a view that soon became prevalent among the mothers at large.

Certain questions regarding low acceptance rates emerge from this study. While beliefs were explored in detail, we do not know if resistance to adoption relates in some way to family planning resistance. Are there characteristics of village, baris and household

which explain nonacceptance of all health innovations? If such factors are elucidated, perhaps services can be modified to improve the efficacy of a wide range of MCH-FP interventions.

One hypothesis, that we intend to test in the present study, is that a "vertical" tetanus program has low acceptance rates because other vital MCH components were missing. If pregnancies are identified early and if special attention is addressed to education and surveillance of pregnancy problems both workers and mothers will better perceive the importance of tetanus immunization, and acceptance rates will increase.

Beginning in January 1979, a field trial of home-based oral therapy diarrhoea was mounted within the context of the MCH-FP services. Two types of oral rehydration fluids, one made with WHO recommended glucose electrolyte packets, and other with labon (common salt) and gur (molasses) were used to assess their acceptability, effectiveness and safety. The FWVs trained about 1,400 village women (bari mothers) to prepare, distribute, and manage the use of oral fluids within their baris. The ingredients were supplied to bari mothers without a charge.

An examination of oral fluid samples prepared by bari mothers revealed that the oral fluid prepared by the bari mothers agreed well with the standard preparation. Three months after the initiation of the programme, about 85 percent of people reporting diarrhea to field workers also reported using oral therapy fluids. During the first year of the programme there were fewer diarrhoea patients hospitalized from both the treatment and control areas than during the baseline year, 1978. However, this reduction was significantly greater for the treatment areas.

These preliminary findings indicate that village women with little or no education could be trained in management of diarrhea and that easy and ready availability of supplies would ensure wider service coverage and reduce the need for hospitalization. However, one important question remains to be answered is the assumed beneficial effects of oral rehydration fluid on nutritional status. An extension of ORS over the next three year period will provide an opportunity to answer important research questions regarding the long term health benefits of this programme.

The interrelated triad of malnutrition, infection and poor pre-natal care have seriously detrimental effects which have not been effectively elucidated by past applied research in Bangladesh. We propose, therefore, to test in the course of three years several modes of MCH interventions, either alone or in association, and to assess

their impact on mortality in the population served.

MCH-FP Integration Background: Proponents of programmatic links of family planning with MCH base this policy on the observed inter-relationship of fertility with mortality. We therefore review this literature briefly and subsequently the policy issues have emerged.

Because early work on historical data suggested that mortality declines in Europe preceded fertility declines, population scientists have long regarded mortality decline as a prerequisite fertility change (Carr-Saunders, 1936). Recent areal analyses of European data suggest, however, that this view is overly simplified. Small area analyses of historical data demonstrate that fertility declined before mortality in many settings (Matthiessen and McCann, n.d.). Work on contemporary demographic change nevertheless shows that in virtually all low income countries where substantial fertility change has occurred, there was a prior pronounced decline in mortality and that in every case where infant mortality declined to low levels, a birth rate decline has followed (Taylor et al, 1974). It can be argued, however, that concomitant socio-economic change affected both fertility and mortality, and that the posited mortality effect on reproductive motives is largely attributable to other factors.

The posited mechanisms for mortality effects on fertility fall into two general categories: biological effects, stemming from the effect of child mortality on mother's fecundability, and behavioural effects, stemming from the direct and indirect effects of mortality on reproductive motives. The biological effect arises from the relationship of fecundability with fetal survival and with post partum amenorrhoea. Amenorrhoea in term, is affected by lactation. Infant mortality truncates lactation, thereby reducing the duration of amenorrhoea and the birth interval and increasing fertility (cf. Knodel, 1975; Chowdhury, 1975). Behavioural effects arise from three sources: 1) replacement effects, wherein couples deliberately replace children who die (see Preston, 1975); 2) insurance effects, wherein couples set high fertility goals in anticipation of child mortality (see Heer and Smith, 1968) and 3) societal effects wherein high fertility customs, norms, and beliefs evolve in response to high mortality (see Nag, 1968).

In Bangladesh pronounced biological effects have been observed

(Chowdhury, 1975) but behavioural effects of mortality on fertility are unknown. Now that a population exists in Matlab where fertility control is prevalent and infant and child mortality rates are high, the behavioural response to the death of a child can be investigated. In particular we hypothesize higher termination rates among contraceptors and lower acceptance rates among noncontraceptors if a child death has intervened. Such effects are hypothesized to interact with sex of child, as preference for males is pronounced.

Less established in the literature than effects of mortality on fertility are effects of fertility control on mortality. It has been demonstrated that health benefits accrue from child spacing and low fertility¹, but no study has shown directly that maternal mortality or infant mortality decline if fertility control is prevalent². We therefore intend to examine the health benefits of contraception - - an objective that is readily pursued in Matlab where the surveillance of families is rigorous³.

The literature indicates, in summary, that synergistic effects can be

/1

A useful review article appears in Wray (1971).

/2

We acknowledge that the study of the IMR impact of contraception possess difficult and interesting statistical problems. Chowdhury (1980), for example, hypothesized a spurious IMR effect in which contraception has its greatest fertility effects among women whose potential children have a high chance of surviving. Births averted are therefore low risks births, and births occurring are relatively high risks infants. Thus as fertility control increases, the population of infants shifts to a higher risk group and the IMR increases. One notes, nevertheless, a decline in the CDR owing to the decline in the proportion of the population under age one.

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One large study in the Narangwal area of Punjab was designed to test this hypothesis. This study did not produce statistically significant differences in fertility across treatments, perhaps because the program did not continue long enough to produce results that could be interpreted without ambiguity. Moreover, problems have been noted with the differential completeness of data across treatments. These conclusions appear in a preliminary report of the study, and cannot be formally cited. We raise them here, however, because we are aware that questions may arise about the utility of conducting a study that appears to replicate aspects of the Narangwal design.

expected from successfully combining MCH with family planning. Why, then, is field research needed? First, as we have noted above, interrelationships have not been investigated in Bangladesh, apart from the work by Chowdhury (1975). Secondly, we do not know whether changes in family size motivates accrue from improved health conditions. Thirdly, we know little, in Bangladesh, about the operational problems of conducting an integrated program. While we recognize that the supervisory structure in Matlab cannot be replicated nationally, we expect to gain insights into the practical field problems of conducting such a programme under optimum administrative conditions.

3. Rationale

When so much commitment exists among international agencies and Asian Governments to improve health and well being of rural people through family planning and MCH, the general question of whether to integrate or to operate separate vertical programmes represents an important policy issue. The Matlab station and its demographic data represents an unparalleled resource for addressing this issue. Five factors account for this:

- 1) The long term demographic data from the demographic surveillance system provide powerful insights into the fertility and mortality levels and trends prior to the introduction of contraception and MCH intervention in a rural Bangladesh population. Thus field experimentation can be conducted in the context of a thorough understanding of the recent demographic history of the population.
- 2) Data are of excellent quality and it is possible to designate trial and comparison areas. Thus results can be readily interpreted and scientifically validated.
- 3) Rural Bangladesh does not have a recent history of rapid socio-demographic change. While recent political events and economic crisis have effected natural fertility, it is widely believed that social structure, aspirations and reproduction motives have not changed systematically overtime. We thus have a unique resource for observing what programs can achieve under the difficult conditions prevailing in a rural traditional society.
- 4) No rural area in the developing world has vital data of comparable quality. Although other MCH experimental studies have been fielded, none has compiled data of a level of quality

that permits unambiguous interpretation of results¹,

- 5) Owing to the excellent demographic resources for MCH and family planning (as in 1-4 above) the joint effects hypothesis can be tested in Matlab with a degree of rigor that is not possible elsewhere.

It is nevertheless reasonable to ask if the issues of this study can be addressed in other special research areas of Bangladesh. During the post-liberation period, a number of research and special health care services projects have undertaken different innovative programmes to fulfill demand; create greater demand for contraceptives, and deliver services. The more important projects are as follows:

- 1) The Savar Gano Shasta Kendra (People's Health Centre at Savar) is a community health project in Savar thana of Dacca district with emphasis on family planning and primary health care. Its main features are (a) paramedical, clinical and surgical functions including sterilization under the guidance of physicians, and (b) low cost services.
- 2) The Bangladesh Rural Advancement Committee Project (BRAC) at Sulla Thana. The project is situated in a remote rural area in Sylhet district. The project provide family planning within a community based integrated development context. The core persons of the programme are the locally recruited village based lady family planning organisers (LFPO).
- 3) Companiganj Health Project, Noakhali is an integrated project with MCH, health, nutrition, education and family planning. The project is a joint venture between the Bangladesh Ministry of Health and Population Control and Christian Community for Development in Bangladesh (CCDB). Its main objective is to establish a model for the National Integrated Health and Family Planning Programme in a single thana, Companiganj,

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See, for example, Williamson (1979). An important limitation of international studies is the absence of a comparison area. See, for example, the design for an international study in Taylor and Laphan (1974).

with a population of 120,000. In addition to utilize the services of all the Government Health and Family Planning personnel available in the thana, the project recruited and trained health auxiliaries from the locality for more effective service delivery. Data collection and research on this project have stopped.

- 4) The Concerned Women for Family Planning project is a voluntary organization of women that offers family planning information and services to the women in the slum households and poor-income areas of the city of Dacca.
- 5) Integrated Family Planning Project at Rangunia Thana is an integrated MCH, health and family planning programme in a community of about 5,000 people.
- 6) The Zero Population Growth Project in 5 selected areas covering a population of about 400,000 and the Intensive Family Planning Programme in Self Reliant Villages, are two pilot projects sponsored by the Government with a view to experimenting with close community involvement and MCH-based family planning programme as a part of total village development.

These six projects have developed innovative programmes in response to local needs that reflect the objectives of the sponsoring organizations. A review of the progress reports of these projects reveals that all these projects have attained a level of contraceptive practice among their study population that are significantly higher than levels attained by the National Family Planning Programme. However, due to non-uniformity of data collection instruments, it is difficult to compare the degree of success of these projects. More importantly, non-availability of a vital registration system or adequate comparison areas represents an important barrier to measuring the demographic effect of family planning and MCH efforts. Thus none of the existing studies permit rigorous examination of either the independent or joint effects of MCH and family planning.

We conclude, in summary, that important issues are unresolved in the health policy literature that can be addressed by research on existing Matlab data. But we conclude, as well, that new questions and issues arise that can only be addressed by further service work in the Matlab field trial area.

B. SPECIFIC AIMS

1. To determine the long term fertility impact of intensive contraceptive services and to examine the correlates of demographic transition in Matlab. A corollary aim is to investigate the determinants of the plateau in contraceptive prevalence.
2. To determine the impact of a comprehensive MCH programme on maternal and child mortality.
3. To research and examine operational questions in family planning and MCH, namely:-
 - a) the determinants of effective contraceptive method selection, use effectiveness, and re-acceptance with emphasis on determining the role of services and information on effective contraceptive practice.
 - b) the appropriate mix of MCH strategies, their relative effectiveness, and acceptability in rural Bangladesh.
4. To determine if fertility and mortality effects of family planning and MCH are enhanced by integration.
5. To identify, document, and clarify the operational problems that accrue from integration of family planning and MCH.
6. To determine the mechanisms, if any, are found to exist, of the synergism between MCH and family planning. In particular we aim to determine if fertility control motives are effected by MCH services.
7. To examine in detail the quality of longitudinal family planning data already collected, to provide comparison data for the non-treatment areas, and to establish baseline attitudinal and health practice data for future MCH and family planning work.

C. METHODS AND PROCEDURE

This protocol is primarily a service protocol, in that services are established for research purposes that are more general than we specify here. We outline below the study design and core research could be implemented with the Community Health Services Project as their core resource. A list of a few such studies with a capsule description of each appears in Appendix A. Each study could not be fully supported by the research design below, but could utilize data or services from this project, and could thus be implemented with minimal incremental costs.

1. Sampling and Treatments

The sampling for this study will bring into account for the CDP and the modified CDP which was as follows:

At the sampling phase of the modified CDP study of four celled design was specified with each cell comprising approximately 40,000 people. Cells were designated on the basis of the contraceptive distribution project (CDP) versus the modified design as follows:

Figure 2

CDP

		<u>Present</u>	<u>Absent</u>
<u>Modified CDP</u>	<u>Present</u>	A	B
	<u>Absent</u>	C	D

The cells were subsequently merged across CDP columns, however, because investigators had reason to believe that modified services would be more effective than the CDP. While the elimination of cell from the study achieved certain economies it greatly complicates the task of comparing the efficacy of the two approaches. For this reason current research focuses solely on the modified treatments, and we have no further analytical interest in the CDP apart from its contaminating effect on the present study. To control for the contaminating effect treatments for this study (as shown in Figure 1) will overlap with

the former CDP treatments as shown in Figure 3,

Figure 3

		Family Planning (modified CDP)	
		Present	Absent
Intensive MCH	Present	I (AB)	III
	Absent	(AB) II	(CD) IV

As shown in Figure 3 positions of cells A,B,C and D (Figure 2) will be allocated to cells (I,II and III) so that any lasting CDP effects are distributed across treatments.

Note that cell III has no components from the previous studies and that cell IV is the previous comparison area (population 80,000). We will not implement a cell in the comparison area because we intend to preserve the position of the DSS. Past studies of fertility and mortality in Matlab have provided Bangladesh with valuable insights into rural population dynamics. That role of the DSS could be compromised if this representative area were greatly diminished in size.

It is important to note that in the past allocation of villages to treatments was based more on administrative considerations than on scientific sampling, and that practical problems will undoubtedly compromise the design somewhat. Present treatment villages were selected for their accessibility to river transport in order to minimize logistic costs. Similar constraints may affect allocation of village in this study.

Sample size in the previous study was addressed to an overall objective that required a large population of contiguous villages, but previous documents have never fully justified the size of this study. This sample was nevertheless fortuitous. If the

true birth rate in a low fertility cell is 35/1000, then a fluctuation in the birth rate of 1 birth per 1000 per year will occur at random at a probability of less than 0.001. Thus the size of the sample is more than adequate for assessing overall annual fertility change. Our objectives, however, call for assessing the pattern and dynamics specific fertility rates by quarter over time. A population of 40,000 per treatment is adequate for that purpose, as there is more than a 5 percent chance of a random fluctuation of .1 birth in a given quarter, and sufficiently low random variation in ASFRs as to permit comparison between treatments. If the criterion for accepting a difference is a 0.01 probability that an observed difference is attributable to chance, a mortality intervention effect is established for effects that exceed a 13 points difference in neonatal rates in this population. Effects of less than that magnitude are conceivable and a smaller sample might therefore impair our interpretation of results. We therefore argue that 40,000 is the minimum population of a cell.

Finally, we note that contraceptors represent a third of the 14,000 women in the combined family planning areas. This affords an adequate but not an unduly large sample of contraceptors. As of August 1980, we have 2093 DMPA users, 582 pill users, 164 condom users, 399 copper-T users, and 966 sterilized women. We can thus study long term use effectiveness and safety of all the major methods offered by the Bangladesh Government Program. Use effectiveness research on specific methods would be impaired if a smaller population was used.

The final treatment designation and population sizes are shown in Figure 4.

Figure 4

		Family Planning	
		Present	Absent
Intensive MCH	Present	Former modified program (40,000)	Expanded DSS area (40,000)
	Absent	Former modified program (40,000)	Existing Comparison area (80,000)

2. Services

In the family planning treatments cell, the existing family planning and selected maternal child health services developed by the modified CDP will continue unchanged,

- a. Services in the Family Planning Treatments: The modified CDP programme is currently operating in 70 villages containing approximately 80,000 persons. In these 70 villages, 80 female village workers (FVW) were recruited in October 1977, to replace the demographic surveillance female village workers. The qualifications of these workers are 7th grade pass, all are married, and most have children and 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 people, or 200 families, visiting each family every fortnight, or about 20 families per day¹.

In November 1977, the FVWs were trained to (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 refer those with complications to the central facility.

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Feasibility studies in 1981 may show that family visitations may be less frequent in the MCH-FP treatment, depending upon the additional time invested in new MCH activities. It is our intention to preserve the fortnightly frequency of visitation, if possible.

The FVWs are supported and supervised by 4 male senior field assistants (SFA) and 4 lady health-family planning visitors (LFPV) residing and operating out of 4 subcentres dispersed in the area. The subcentres, opened in February-March 1978, primarily operate as support and training facilities. SFA's supervise the work of FVWs and in addition discuss health and family planning with community leaders, head of households, and male spouses. Since males play a dominant role in decision-making processes (many women regarded husband objection as a reason for non-acceptance of family planning), special activities will be initiated in the first year of the project period to inform males about family planning methods and the rationale for considering family planning.¹ The work of LFPVs primarily involves technical back-up of the work of FVWs. In addition, LFPVs provide IUD services at the clinic and back-up the use of long-acting hormonal contraception by FVWs. The village-level and sub-centre workers are supervised by an overall supervisor. Technical back-up, moreover, is provided by physicians stationed at the Matlab Centre, who are also responsible for the technical support of the subcentres.

Staff and facilities for delivering the full range of FP services were 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 removals; (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. The activities are operated under the jurisdiction of the Government Thana FP Officer. Detailed medical procedures for contraception are set forth in Appendix B.

By June 1978, after the FVWs had become trained and the supervisory structure was operating smoothly, vaccination of pregnant women with tetanus toxoid was introduced. Initially, those who agreed to accept were given 1-3 injections of an aluminium-phosphate-absorbed tetanus toxoid on a schedule of .5 ml at 6 month, a second .5 ml at 7 month, and a third .5 ml at 7 month of pregnancy. Effective July 1979, the three doses schedule was, however, modified,

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Husband-wife interaction regarding contraception will be addressed in a separate protocol.

to a two dose schedule as .5ml any time after the 5th month and another .5 ml at a minimum of 4 weeks apart, preferably by the 7th or 8th month of pregnancy.

The supply of vaccine is procured from the Bangladesh Government with the assistance of the World Health Organisation (WHO) office in Dacca. WHO guidelines on "cold-chain" procedures for storage, transport, and delivery of the vaccine are followed. Vaccine stock is stored in a refrigerator in Dacca and shipped monthly to the Matlab field station in specially designed cold thermos. At the field station, the vaccine is stored in a refrigerator; the electric power is often maintained by a generator during power failures. Vaccines are consistently stored and transported at 4.8°C, and are discarded if the temperature exceeds 8°C for accumulative period of 72 hours. At fortnightly meetings at the subcentres, the FVWs submit lists of pregnant women willing to accept the vaccine. Accordingly, vaccines are despatched from Matlab Centre to the subcentres for distribution among the FVWs. Since the subcentres have no electricity, cold boxes with re-freshed freezer packs are rotated to the subcentres every two days. Moving from the subcentres, the FVWs carry the vaccine to the homes of pregnant women and deliver the vaccine using ice. Injections are applied with disposable needles and syringes. All unused vaccines left over at the end of the day are discarded.

Field records of eligible women and vaccines are maintained by the FVW. Each FVW maintains a field register which contains an up-to-date list of all currently married women (age 15-44 years), supplemented with information on their current reproductive status, use of contraception, expected date of termination of pregnancy, schedule of tetanus vaccination, and dates and number of immunizations given. The information is continuously up-dated by the FVW during her routine fortnightly home visits.

As mentioned earlier, the field trial of home-based oral therapy for diarrhea using labon-gur and the WHO glucose electrolyte packets began in January 1979, after seven months of the initiation of the tetanus immunization programme. The 80 FVWs trained 1,400 women (bari mothers) to prepare, distribute, and manage the use of oral fluids within their baris and neighbourhood. The ingredients are supplied to bari mothers without charge. The bari mothers also advise on diet during and after diarrhea and keep record of all diarrhea patients they treat. The FVWs visit the bari mothers once every fortnight and check their supplies and records. Further training on preparation and administration of the oral fluid is also provided during the visit.

b) Services in the MCH Treatments: In addition to the already developed two MCH components (tetanus immunization and oral therapy), the MCH services under this protocol will include:

- (i) Identification, surveillance and care of high risk pregnancies (bleeding during the last months of pregnancy, diabetes, severe anemia, eclampsia, first pregnancy, high parity, short interval during pregnancy, extreme age of child bearing).
- (ii) Improvement of the safety of delivery practices through training of the individuals who play a significant role as birth attendants, e.g. dais. Particular emphasis will be given to the management of the cord of the placenta and the ability to refer complicated cases at an early stage.
- (iii) Nutritional surveillance of under-5 children to include monitoring of weight through monthly "weight clinics". Such meetings, grouping several bars, will seek an active participation of the mothers in order to improve the welfare of their children. Advice on breast-feeding, weaning practices, additional food supplement, alternate sources of foods, gardening, sanitation and food handling etc. will be extended whenever it is appropriate to do so.
- (iv) DPT immunization and mass treatment of parasitic infections.
- (v) Referral services for children under-5 to include care for respiratory diseases, scabies and diarrhoeal disease.

A comprehensive MCH programme with the above components raises operational questions about task structure, training, recruiting, supervision, and routine data collection. The detailed operational strategy will be developed in the first six months of the program. We seek a mandate in this protocol to develop 5 MCH component programme for subsequent review.

3. Data Collection

Family Planning data collection: The data collection procedures

for the family planning component are substantially revised under this protocol. The purpose of revision is to eliminate administrative work so that time is available for service and research activities. The data system has the following elements:

- (a) Record book and service statistics. Each FVW maintains a register book. We propose to use books as they are now prepared for following research information:
- (a) a list of all eligible women in the area was recorded by the FVW in the beginning from the DSS record, since then the list is updated by FVWs whenever a change in eligibility status occurred;
 - (b) a list of all contraceptive adoptors by type of method. The date of acceptance, the date of termination and the switchers of methods is also noted. The reason for dropping or switching is also recorded;
 - (c) a list of all pregnant women with the date of last menstruation, dates on which tetanus toxoid immunization and iron folic acid tablets are provided is recorded for each women. The date of delivery and outcome is also recorded.
 - (d) a list of all "Bari Mothers" who have been trained by the FVWs to dispose oral rehydration solution for treating diarrhoeas is maintained along with the information of number of diarrhoea patients treated by them.

The record book enables the FVWs to keep all information about the eligible couples in her area in one place. The book also helps the FVWs to keep track of all the re-supply schedule of various contraceptives and immunizations (specially DMPA and tetanus toxoid).

The listing of the "Bari Mothers" who provide oral rehydration solution and the supplies they receive help the

FVWs estimating the extent of diarrhoeal illness in the different "Baris." The record book is thus helpful for service.

Modifications proposed in this protocol involve adding a simple system on recording changes of reproductive status to include information on menstruation, pregnancy and lactational amenorrhoea, and the breast-feeding status of each eligible woman. This entails coding identification data and the contraceptive, reproductive, and lactation status for all eligible women (already completed under the modified CDP) and all status changes over time.

- b) Vital registration. The FVW maintain a record by date of all births, deaths, and migration occurring within their area. These records are verified and collected from the FVWs by the DSS field worker. The detailed procedures for DSS data collection have been described elsewhere (See the DSS protocol).
- c) Proposed couple visit record (Exhibit 1). As experience with the DSS has shown, checking on data quality is greatly simplified if data checkers know the status of women. In the present system it is not possible to know the content of records without the help of the FVWs, as all the records are held by them.

The card will be recorded in code to ensure confidentiality, and left with the DSS record in the household.

- d) Status change forms. A computerized system of monitoring contraceptive status will be developed. Field assistants will attend subcentre meetings to record status changes on a standard computer form. This form will be sent to Dacca for data entry and longitudinal file building (Exhibit 2 and 3). We expect the project to generate an average of 500 status change records per cell per month, based upon our experience with the modified CDP.
- e) Comparison area family planning surveillance. Plans call for the designation of a non-family planning MCH area in which pregnancy surveillance is a vital research and service component. At present DSS workers record pregnancies in village register books as an aid to their routine birth reporting activity. With minor modifications this ad hoc practice can be used for the MCH activities and for monitoring pregnancy and family planning practice in non-family

planning areas. We propose to reassign two workers from the present family planning coding scheme to the comparison area. Simplification of the family planning record system will free these workers for coding record book data. We thus propose a standard record book system (as discussed above) and computerization of pregnancy contraception and lactation histories.

MCH Data Collection:

For development of appropriate composition of services and operational strategies of MCH programme the following special surveys and analyses will be undertaken in the first year of the project.¹

- a) (i) Maternal mortality rates will be analysed through
 - a review of existing literature, and
 - tabulation of existing DSS data from the period after 1974;
 - (ii) Causes of maternal mortality will be examined by means of an exploratory investigation of the circumstances surrounding the death of the past 50 maternal deaths. This will provide insight into how the recording of cause of deaths could be improved.
 - b) (i) Neonatal and infant mortality rates will be analysed through
 - a review of the existing literature, and
 - tabulation of existing DSS data from the period after 1974;
 - (ii) Causes of neonatal and infant mortality by means of an exploratory investigation of the circumstances surrounding the deaths of the last 50 neonatal and infant deaths in the comparison area.
- These studies will provide insight into how the recording of causes of deaths could be improved.
- c) Identification of the proportion of deliveries assisted by dais and of their beliefs, knowledge and practice of delivery

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Each MCH data collection and analysis project will be the subject of a separate protocol, and is not included in the budget below.

care. This will involve,

- (i) Compiling a list of the past 6 months deliveries having occurred in a limited area. From this list a sample will be drawn and the mothers will be asked who played an active role in their deliveries. The individual respondents will be interviewed about their beliefs and knowledge regarding pregnancy and birth delivery.
- (ii) From the general listing of deliveries having occurred in the MCH-FP and comparison area over the past 6 months, a sample will be drawn and the mothers will be asked who played the most active role in assisting during the delivery. The individual identified will be interviewed about their beliefs, knowledge and practice regarding pregnancy and delivery.

These studies will document the proportion of deliveries attended by trained dais, will ascertain the current status of their knowledge and practices, and will contribute to an assessment of the feasibility of the possible participation of dais in activities aimed at improvement of the safety of delivery practices.

It is recognized that the objectives of this protocol require routine MCH data collection. Detailed MCH data collection procedures will be specified in the MCH Addendum to be submitted in Calendar 1981.

4. Analysis Plans

Family planning research: The following represents a research plan for family planning:

- a) Our first priority is to fully implement record keeping systems to include (a) training of comparison area FVWs (b) coding of baseline data from comparison areas; (c) finalizing computer programs for data editing, file building, and reporting.
- b) Second we intend to issue the first of a series of quarterly reports on contraceptive prevalence, use-effectiveness, and user characteristics by cell. These reports will be simple and routinized. Special studies of the covariates of contraceptive efficacy will be conducted under separate protocols to be developed later on.
- c) Third, we intend to issue the periodic reports on trends, levels and patterns of fertility and mortality by cell.

The first report will be written in calendar 1980, the second in late 1981.

- d) We will conduct a logistic regression analysis in which the dependent variable is used or non-adoption of contraception and tetanus toxoid in which predictors are bari and village identifiers. This analysis of variance-like study will ascertain whether clustering exists. Given the detailed contraceptive history data, it may be possible to elaborate on the analysis in order to examine specific methods and contraceptive use dynamics. A possible outcome of this research will be a special study on the determinants of contraceptive behaviour (see Appendix A, item 8).

Bari and village characteristics are also of interest. The health behaviour of bari members, for example, may be influenced by whether or not at least one member has some education. If intervention's adoption clusters by bari, then the views of bari leaders and features of bari economics are of interest. Caldwell (1979) has hypothesized that the size of extended families affects their security, and that receptiveness to contraceptive use is determined by inter-generational flows of wealth and by power relationships in extended families and villages. We will address, in short, hypotheses which could explain: (1) the plateau in contraceptive use and (2) the variation in contraceptive efficacy among individuals, baris, and villages.

A central hypothesis of this study is that MCH will have family planning effects through the effects of perceived improvements in child survival on reproductive motives. In this survey we will address questions to perceived risks of mortality, attitudes towards health care, and other MCH matters to determine if mortality experiences, beliefs, and attitudes affect contraceptive dynamics.

D. SIGNIFICANCE

1. Fertility Implications

Determining the level of demand for contraception and meeting such demand with appropriate, safe, and effective contraceptive technologies with a low cost delivery system constitutes one of the most important health issues in developing and developed countries alike. Findings from this study should contribute some information towards meeting the knowledge required, particularly those of immediate relevance and applicability for Bangladesh and other similar poor countries. An important policy issue is determining whether meeting this stated demand through MCH services, has any effect on fertility, and whether additional demand can be generated by effective mortality control.

2. Mortality Implications

The implementation of the MCH-FP project represents an initial step in a research agenda related to preventive services related to maternal and child welfare.

Research will provide the rationale for specific health related interventions. The strategy is to integrate these not only in the work plan of the field staff but also into life of the community and into the plan for evaluation of the health impact. It is not envisaged that ICDDR,B will be providing comprehensive sickness care but rather that specific preventive measures will be selectively applied in the context of a critical research agenda to assess their overall health impact. Primary efforts will be directed toward introducing preventive measures that the villagers can effectively implement themselves.

3. MCH-FP Implications

The integration of MCH and FP has long been a recommended

strategy of WHO and is recently official policy of the Bangladesh Government. Achieving any comprehensive understanding of the health benefits of integration thus represents an important research issue.

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SECTION III BUDGETA. DETAILED BUDGET*

1. PERSONNEL SERVICES	Percent of Effort	Annual Salary (one person)	1981	1982	1983
1. Investigator(Phillips)	40%	381600	152640	152640	152640
2. Investigator(Claquin)	40%	620100	242040	248040	248040
3. Investigator(Rahman)	40%	53600	21400	21400	21400
4. Acting Head,Matlab Station	20%	87500	17500	17500	17500
5. Field Research Officer, I(1)	100%	58900	58900	58900	58900
6. Assistant Supervisor(4)	100%	44800	179200	179200	179200
7. Senior Field Assistants(5)	100%	38880	194400	194400	194400
8. Lady Health Visitors (9)	100%	21883	16947	16947	16947
9. Female Village Workers(120)	75%	10503	945270	945270	945270
10. Female Village Workers(30)	25%	10503	78773	78773	78773
11. Clinic Attendant(Contract)					
	(4)	100%	10500	42000	42000
12. Health Assistants (6)	100%	27233	163398	163398	163398
13. Ward Cleaner (1)	100%	10500	10500	10500	10500
14. Chowkidar (6)	100%	10500	63000	63000	63000
15. Data entry (2)	100%	21350	42700	42700	42700
16. Statistical Assistant (2)	100%	37500	75000	75000	75000
17. Computer Programmer (1)	100%	34728	24728	34728	34728
18. Typist (Matlab) (1)	25%	21528	5382	5382	5382
19. Secretary (Dacca)	50%	34728	17364	17364	17364
20. Medical Officer. I(1)	100%	43800	43800	43800	43800
21. Field Research Officer II					
	(1)	100%	44800	44800	44800
Taka sub-total					
US \$ sub-total**			2635782	2635782	2635782
			165773	165773	165773

* An adjustment for inflation is at the end of the budget

**Assuming 1US\$ = 15.9 Tala. Costs include known MCH personnel expenses for the cost of expanded area, but include all DSS costs.

2. SUPPLIES

a) Pharmaceuticals*

Item	Unit Cost	Required Annual Quantity	Total Annual Cost		
			FY 1981	FY 1982	FY 1983
Tab. Falfetab	Tk. 35 per 1000	2,88,000	10,081	10,081	10,081
Tab. Multivitamin	Tk. 47 per 1000	2,16,000	10,152	10,152	10,152
Tab. Sulphadiazine	Tk. 200 " "	72,000	14,400	14,400	14,400
Tab. Oracyn K (125mg)	Tk. 30 per 100	54,000	16,200	16,200	16,200
Tab. Aspirin	Tk. 90 per 1000	72,000	6,480	6,480	6,480
Tab. Calcium	Tk. 15 per 100	36,000	5,400	5,400	5,400
Tab. Baralgin	Tk. 100 per 100	8,000	8,000	8,000	8,000
Tab. Flagyl 200 mg	Tk. 80 per 100	7,000	5,600	5,600	5,600
Tab. Ananoxyl	Tk. 100 per 100	2,000	2,000	2,000	2,000
Tab. Mycostative	Tk. 1.50 each	2,000	3,000	3,000	3,000
Cap. Ampicilin	Tk. 1.70 each	10,000	17,000	17,000	17,000
Inj. Ampicilin(250mg)	Tk. 12.50 each	1,500	18,750	18,750	18,750
Inj. Penicillin	Tk. 1.50 each	7,000 amps	10,500	10,500	10,500
Distilled water	Tk. 60 per 100	6,000 vials	3,600	3,600	3,600
Syr. Ascapar	Tk. 32 each lb.	300 lbs.	9,600	9,600	9,600
Ascobiol (4 ozs. bottles)	Tk. 7.50 each	300	2,250	2,250	2,250
White filled ointment	Tk. 50 each lb	30 lbs	1,500	1,500	1,500
Neo-bacterine ointment(20 gr/ tube)	Tk. 5 each	400	2,000	2,000	2,000
Chloromycetin eye drops	Tk. 9.60 each	250	2,400	2,400	2,400
Cough Syrup (4 ozs bottles)	Tk. 6 each bottle	350	2,100	2,100	2,100
Tixylix	Tk. 7 per bottle	175 bottles	1,225	1,225	1,225
Phensidyl	Tk. 10.75 per bottle	100 bottles	1,075	1,075	1,075

*Pharmaceutical costs budgeted here do not include costs of the "MCH only" cell. Incremental MCH pharmaceutical costs will be budgeted in the MCH addendum to be submitted in 1981.

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2. SUPPLIES AND MATERIALS (Contd.)

a) Pharmaceuticals (contd.)

<u>Item</u>	<u>Unit Cost</u>	<u>Required Annual Quantity</u>	<u>Total Annual Cost</u>		
			<u>FY 1981</u>	<u>FY 1982</u>	<u>FY 1983</u>
Vullex	Tk. 8.50 per bottle	50 bottles	425	425	425
Vitamin A & D Cap.	Tk. 70 per 1000	30,000	2,100	2,100	2,100
Syp. vitamin (4025 bot.)	Tk. 8 each	2,000	16,000	16,000	16,000
Vitamin C Tab.	Tk. 36 per 100	5,000	1,800	1,800	1,800
Antacid Tab (Gelucil)	Tk. 150 per 1000	7,000	1,050	1,050	1,050
Cap. Tetracycline	Tk. 55 per 100	16,000	8,800	8,800	8,800
Syrup Tetracycline	Tk. 8.50 per bottle	300 bottles	2,550	2,550	2,550
Inj. Vitamin A	Tk. 5 per vial	100 amp.	500	500	500
Infusion set 2l	Tk. 6.75 per Pkct.	24	116	116	116
Inj. Dextrose (25%) 500 ml/bot.	Tk. 19 each	100	1,900	1,900	1,900
Lotion Benzyl Benmonti	Tk. 8 each gl.	1 gl.	8	8	8
Inj. Baralgin	Tk. 2 each amp.	100 amp.	200	200	200
Tab. Methergin	Tk. 1.35 each	2,000 amp.	2,700	2,700	2,700
Inj. Methergin	Tk. 6.25 each	200 amp.	1,250	1,250	1,250
I.V. Normal Saline 500cc	Tk. 30 each bottle	100 bottles	3,000	3,000	3,000
Inj. Xylocaine (Plano Cain) 50 ml./vial	Tk. 19 each	100 vial	1,900	1,900	1,900
Inj. Phenergon 50 mg	Tk. 1.25 per amp.	1,000 amps	1,250	1,250	1,250
Inj. Antropene 6 mg	Tk. 0.50 per amp	1,000 amps	500	500	500
Inj. Seduxon 10 mg	Tk. 2 each amp	1,000 amps	2,000	2,000	2,000
Inj. Pathedine 100 mg	Tk. 11 each amp	1,000 amps	11,000	11,000	11,000
Lysol	Tk. 69 each lb	20 lbs	1,380	1,380	1,380
Benzoin (Joy)	Tk. 65 each lb	20 lbs	1,300	1,300	1,300
Phenyl	Tk. 14 per gl	200 gl	2,800	2,800	2,800
Dettol	Tk. 1.20 per gl.	300 lbs	2,880	2,880	2,880

2. SUPPLIES AND MATERIALS (Contd.)

a) Pharmaceuticals (contd.)

<u>Item</u>	<u>Unit Cost</u>	<u>Required Annual Quantity</u>	<u>Total Annual Cost</u>		
			<u>FY 1981</u>	<u>FY 1982</u>	<u>FY 1983</u>
Dettol	(Tk. 9.6 per lb)				
Spirit (Methylated)	Tk. 3.88 each lb.	200 lbs	776	776	776
Spirit (Rectified)	Tk. 11.31 each lb.	200 lbs	2,262	2,262	2,262
Inj. Combiotics	Tk. 5.50 each lb	3,000 vials	16,500	16,500	16,500
Tab. St 5 mg tab	Tk. 26 per 100	200	5,200	5,200	5,200
Tab. Laxena	Tk. 18 per 100	1,000	180	180	180
Tab. Terbolan	Tk. 60 per 100	500	300	300	300
Venopak	\$ 288.40 per box	1 box	4,268	4,268	4,268
Sub total (Take)			2,50,208	2,50,208	2,50,208
Sub total (Dollars)			15,737	15,737	15,737

EXPENSES (Cont'd)

b) Stationeries*

<u>Item</u>	<u>Unit Cost</u>	<u>Required Annual Quantity</u>	<u>Total Annual Cost</u>		
			<u>1981</u>	<u>1982</u>	<u>1983</u>
Aerosol/insecticide	Tk. 50/- Each	192	9600	9600	9600
Felt tip marker	Tk. 25/- "	200	5000	5000	5000
Cloth, Duster	Tk. 2/- "	300 pieces	600	600	600
*Paper Weight	Tk. 6/- "	20	120	-	-
Thread, Ball	Tk. 2/- "	100	200	200	200
Stamp, pad	Tk. 50/- "	100	5000	5000	5000
Register book 500 pages	Tk. 75/- "	20	1500	1500	1500
Register book 200 pages	Tk. 15/- "	300	4500	4500	4500
*Basket	Tk. 15/- "	16	240	-	-
Erasor	Tk. 7.00	100	700	700	700
*Scissors, household ordinary	Tk. 60/- "	24	1400	-	-
*Tray 12" x 18"	Tk. 18/- "	12	696	-	-
Bucket, plastic	Tk. 42/- (local with lead)	48	2016	2016	2016
Vim powder	Tk. 4/- "	400	1600	1600	1600
Washing soap	Tk. 3.50 "	500	1750	1750	1750
Toilet soap	Tk. 4/- "	500	2000	2000	2000
Match	Tk. 0.25 "	900	225	225	225

* Stationery and equipment budgets include projected costs of the MCH addendum.

2. SUPPLIES (Contd.)

b) Stationeries (contd.)

<u>Item</u>	<u>Unit Cost</u>	<u>Required Annual Quantity</u>	<u>Total Annual Cost</u>		
			<u>1981</u>	<u>1982</u>	<u>1983</u>
Razor Blade	Tk. 7/- pk. Each	1000	7000	7000	7000
Towel	Tk. 25/- each	200	5000	5000	5000
Masking Tape	Tk. 12.72	50	636	636	636
Torch cell	Tk. 5/- each	400	2000	2000	2000
Torch light, cells (2)	Tk. 70/- "	12 (1981)	840	280	280
Octave pad, small	Tk. 3.50 "	600	1892	1892	1892
Ballpoint pens	Tk. 6.00 "	750	4500	4500	4500
Exercise Book No. 4	Tk. 6.00 "	600	3600	3600	3600
Wooden pencil	Tk. 4.13 "	600	2478	2478	2478
Chalk	Tk. 2.50 " box	120 boxes	300	300	300
Pad, foolscap	Tk. 7.16	300	2148	2148	2148
Scotch tape	Tk. 2.23	120	268	268	268
Envelope (ICDDR, B)	Tk. 0.55 each	900	495	495	495
Ruler*	Tk. 3.25 "	120	390	390	390
Staples	Tk. 10.00	60	600	600	600
*Stapler	Tk. 35/- each	60	2100	-	-
*Staple remover	Tk. 2.80 each	20	-	-	-
*Clip board	Tk. 7.20 each	183 (1981)	1800	-	-
Miscellaneous Office (supplies (paper, stencils carbon etc.)			10000	10000	10000
Sub total (Taka)			83234	76278	76278
Sub total (Dollars)			5235	4798	4798

* Once only expense.

3. EQUIPMENT

a) Medical Instruments

<u>Item</u>	<u>Unit Cost</u>	<u>Required Annual Quantity</u>	<u>Total Annual Cost</u>		
			<u>1981</u>	<u>1982</u>	<u>1983</u>
Silk Thread	Tk. 15/- each roll	4 Roll	60	60	60
White cloth gauze	Tk. 75/- each yd.	50 yds.	3750	3750	3750
Surgical sponze brush(2"x2")	\$ 60 per 200 pkts.	6	190	190	190
Gauze bandage	Tk. 8/- per dozen	1 doz.	8	8	8
Gauze Than	Tk. 50/- per than	5 than	250	250	250
*Thermometer	Tk. 15/- each	48	720	720	720
Blood Pressure Instrument	Tk. 500/-	4	2000	2000	2000
Pan with lid ordinary	Tk. 60/-	12	720	720	720
Karman syringe & Cannulae	Tk. 239/-	12	2868	2868	2868
Catheter, rubber No. 12	Tk. 7/- each	24	168	168	168
*Kidney dish,cage	Tk. 200/-	16	3200	1980	1980
*Stethoscope	Tk. 275/- each	8	2200	-	-
Lifter	Tk. 110/-	18	1980	-	-
Directing forcep (non-tooth)	Tk. 28/- each	48	1344	1344	1344
" " (tooth)	Tk. 35/- each	48	1680	1680	1680
Catgut chromic 00	Tk. 12/- "	20	240	240	240
Catgut plain 0	Tk. 12/- "	20	240	240	240
Needle straight	Tk. 15/- "	12	180	180	180
" Cutting round	Tk. 15.8 "	72	1138	1138	1138
Needle holder 8"	Tk. 95/- "	48	4560	4560	4560
Scissor, blunt, medium	Tk. 35/- "	48	1680	1680	1680
Artery forcep, medium	Tk. 35/- "	75	2625	2626	2625
" " , large	Tk. 155/- "	18	2790	2790	2790
Vulsellum forcep	Tk. 145/- "	18	2610	2610	2610
Vaginal speculum,small	Tk. 125/-	4	500	500	500
" " medium	Tk. 175/- "	24	4200	4200	4200
Sponge holding forcep	Tk. 145/-	48	6960	6960	6960

* Once only expense.

3. EQUIPMENT (contd.)

a) Medical Instruments (contd.)

<u>Item</u>	<u>Unit Cost</u>	<u>Required Annual Quantity</u>	<u>Total Annual Cost</u>		
			<u>1981</u>	<u>1982</u>	<u>1983</u>
Cotton Absorbant	Tk. 21/- per lb.	450	9450	9450	9450
Adhesive tape 1" x 5 yds.	Tk. 16/- each roll	750 rolls	12000	12000	12000
Syringe (plastic) with needle (1)	Tk. 2.54	60,000	45760	45760	45760
1CC . 3CC 5CC (2)	Tk. 1.89	30,000	56700	56700	56700
(1) (2) (3) (3)	Tk. 2.23	30,000	20020	20020	20020
Needle 20 x 1"	Tk. 0.80	27,000	21600	21600	21600
Gloves 7½ = 15 pair	Tk. 15/- per pair	16 doz.	240	240	240
<hr/>					
Sub total			215631	209231	209231
Sub total (US Dollars)			13562	13159	13159

3. EQUIPMENT** (Contd.)

b) Other Equipments

<u>Item</u>	<u>Unit Cost</u>	<u>Required Annual Quantity</u>	<u>Total Annual Cost</u>		
			<u>1981</u>	<u>1982</u>	<u>1983</u>
*Table 4' x 3'	Tk. 400/- each	8	3200	-	-
*Chair	Tk. 200/- each	48	9600	-	-
Kerosene stove	Tk. 35/- each	8	280	280	280
*Bench (7' x18') for sitting	Tk. 150/- each	16	2400	-	-
*Drum 9" (waste paper basket)	Tk. 12/- each	8	96	-	-
*Chalk board	Tk. 250/- each	10	2500	-	-
*Examination Table	Tk. 250/- each	4	3000	-	-
*Instrument Table	Tk. 250/- each	4	1000	-	-
*Calculator	Tk. 480/-	2	960	-	-
*Suction machine	Tk.	3896	3896	-	-
<hr/>					
Sub total			26932	280	280
Sub total (US Dollars)			1694	18	18

* Once only expense.

** Equipment for new subcentres as well as replacement equipment for existing subcentres.

4. TRANSPORTATION

<u>Item</u>	<u>Unit Cost</u>	<u>Required Annual Quantity</u>	<u>Total Annual Cost</u>		
			<u>1981</u>	<u>1982</u>	<u>1983</u>
48 Country Boatmen	Tk. 500/- per 6 months	48	12,000	12,000	12,000
Dacca-Matlab-Dacca	Tk. 3/- per mile	15,000 miles	45,000	45,000	45,000
Matlab Field work	Tk. 3/- per mile	5,000 miles	15,000	15,000	15,000
Speedboats 6 hrs run/day	Tk. 105/hour	936 hours	98,280	98,280	98,280
International travel	Tk. 123000 per trip		246,000	246,000	246,000
Sub total			416,280	416,280	416,280
US \$ Sub total			26,181	26,181	26,181

5. PRINTING AND REPRODUCTION

Item	Unit Cost	Required Annual Quantity	Total Annual Cost		
			1981	1982	1983
Paper Printing	TK. 0.13/- copy	50,000	6,500	6,500	6,500
Photocopying	Tk. 0.80/- copy	5,200	4,134	4,134	4,134
Sub total			10,634	10,634	10,634
Sub total (US Dollars)			669	669	669

6. MISCELLANEOUS

Maintenance fo Sub-Centres*		15,000	15,000	15,000	15,000
Computer time (Engineering University)		1200/hr 100 hrs	120,000	120,000	120,000
Diskettes	TK. 130/ diskette	50	6,500	6,500	6,500
Cables	Tk. 100/cable	24/year	2,400	2,400	2,400
Sub total			143,900	143,900	143,900
Sub-total (US Dollars)			9,050	9,050	9,050

7. ADJUSTMENT FOR INFLATION (US Dollars)

Unadjusted total (US Dollars)		237,901	235,385	235,385
Adjustment (20%)		-	47,077	56,493
US Dollar total		237,901	282,462	291,878
3 year total	\$ 827,104			

*Excluding special costs of opening 4 new centres. Estimate includes routine maintenance for all Centres, including new ones to be opened.

SECTION III BUDGETB. SUMMARY BUDGET

	1981	1982	1983
1. Personnel Services	165773	165773	165773
2. Supplies and Materials			
Pharmaceuticals	15737	15737	15737
Stationeries	5235	4798	4798
3. Equipment (Medical)	13562	13159	13159
(Other)	1694	18	18
4. Transportation	26181	26181	26181
5. Printing	669	669	669
6. Miscellaneous	<u>9050</u>	<u>9050</u>	<u>9050</u>
Sub-total	237901	235385	235385
7. Adjustment (20%)	-	<u>47077</u>	<u>56493</u>
US Dollar Total	237901	282462	291878

3 year total: \$ 827,104

APPENDIX A

POSSIBLE SPECIAL STUDIES

In the Community Health Services Project we have emphasized services and general research objectives to which those services are addressed. However, we view this project as a continuing resource for ICDDR,B scientists who are engaged in a wide variety of community health services research or special studies on longitudinal demographic data. We therefore list a sample of such studies as an invitation to further inquiry:

1) Oral therapy and Mortality

As yet no conclusive evidence exists that the Matlab oral therapy project has reduced mortality or that it has improved nutritional status. Given the service and data systems of this project, the study could be extended or modified at marginal incremental costs to investigate these important issues.

2) Fertility Control and Morbidity

One possible mechanism for the mortality effects of birth planning is that morbidity of certain diseases are reduced if births are spaced or if dependency ratios are low. One might argue, for example, that the incidence of diarrhoeal disease would be greatly reduced if the proportion of young children in the population were to decline. This effect would not be confined to children, as overall disease transmission would be affected. Other relationships have been posited for nutrition and childhood diseases.

3) Special Studies of Contraception

This project generates a unique resource for the study of the safety and effectiveness of the contraceptive methods used in the Bangladesh National Programme. For example DMPA cases now number over 2000, so that questions concerning the effects of DMPA or lactation, the return to fertility or other issues can be studied

in a carefully controlled environment. The Matlab DMPA sample is the largest and oldest cohort of DMPA adopters in Bangladesh.

4) Studies of Medical Procedures

It has been noted by physicians in Matlab that certain questions can be raised about commonly used contraceptive medical procedures in Bangladesh, most notably the widespread use of prophylactic antibiotic injections. It may be possible to conduct a medically supervised study to determine if medical benefits accrue from prophylaxis. A study of vasectomy cases has shown that no benefits accrue from prophylactic antibiotic injections (Khan and Biswas, 1978).

5) Special Studies of Fertility Limitation

It is widely assumed that socio-economic factors have effects on reproductive motives that, in turn, reduce family size. Some recent comprehensive reviews of this literature, however, suggest that many of the posited relationships are not so axiomatic as it once seemed (See, for example Cochrane, 1979). It is thus important to investigate the role of socio-economic correlates of birth planning behaviour in Matlab, and to examine in detail the mechanisms through which differentials arise.

6) The Analysis of Demographic Model

In this protocol we have said that we will monitor changes in fertility and mortality levels and trends, but little mention was made of fertility and mortality patterns. A traditional avenue of demographic research has been the study of historical data and the development of fertility and mortality models (see for example, Coale and Trussel, 1973 and Coale and Demeny, 1969). The models have wide utility in the estimation of mortality, fertility and population dynamics in situations where demographic data are complete. Matlab is the only situation in rural area where the performance of the Coale Trussel estimation technique can be rigorously examined in the face of transition from low to high fertility control.

7) Studies of Morbidity

A wide range of special studies could benefit from the involvement

of the large cadre of community health workers and longitudinal data from this study.

8. The Determinants of Contraceptive Behaviour

We aim to conduct a survey early in 1981 addressed to the determinants of contraceptive behaviour. Our dependent variables will be:

- a) Adoption/non-adoption of contraception
- b) Attrition among adopters (obtained by linking longitudinal contraceptive history data with sample data)
- c) Contraceptive dynamics (changes of methods)
- d) Onset of pregnancy (again provided by record linkage)
- e) Method failure (limited to methods with high failure rates)

Our predictors will be intentions, attitudes and characteristics of adopters, their husbands, and (depending upon the outcome of preliminary research) characteristics of bars and villages. Interview schedules will focus on a social network rather than individual women. Thus we aim to ascertain the attitudes, beliefs, and characteristics of individual women, as well as complementary information from spouses, mother-in-laws, and respected opinion leaders (Matabars) in order to understand the diffusion of healthy innovation and village decision-making processes.

APPENDIX B

DETAILED DESCRIPTION OF MEDICAL PROCEDURES

Procedures in this study are intended to conform with methods and guidelines of the Bangladesh Draft 5 year plan. None of the methods or procedures in this study are experimental. However, the procedural details are not specified in the 5 year plan. Therefore we describe each of the procedures 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 will be done by the Mini Laparotomy method. The procedure has been done by the Lady Family Planning Visitors (Female Paramedic) under the supervision and presence of a trained physician. The L F P V's 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 FVW during their fortnightly lists will discuss sterilization with potential clients. Discussion will emphasize the permanence of the procedure and its inversibility. The FVW's 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 incision about 1" in length in the lower abdomen. The consenting women will be sent 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 obstetrical history of the clients. Then she will perform a physical examination of the clients to include pulse, respiration, temperature, anaemia etc. After that, an internal (P/V) examination will be done by the LFPV to determine the position of uterus and to identify patients with contraindicating infections or tumors. Laboratory tests such as routine urine examination for albumin and sugar and haemotocryt percentage will also be done in the same afternoon. LFPV will then present the findings of history, physical examination and laboratory tests to the assigned physician. Based on these findings,

the physician will screen the clients for surgery. In case of any doubt, the physician will make a physical examination. After final inclusion signed consent form will be obtained from each client (Exhibit p-1). The consent forms will be kept in a locked cabinet.

Preparation: On the day before the operation, preoperative measures such as cleaning and shaving of the lower abdomen will be done. Also LFPV's will autoclave instruments and prepare linens. Prophylactic antibiotic (Injection Combiotic or Inj. Procaine Penicillin) will be applied.¹ In the evening, a light meal will be provided to the clients. A laxative tablet will be given at bed time for bowel clearance.

On the morning of the operation, Injection Phenargon (50 mgm intramuscular and Inj. Pathedine (100 mgm intramuscular) will be given about one half hour before the general surgery.

Surgical Procedure: The LFPV's perform the surgical procedure by Mini-Laparotomy method under the direct supervision of the physician². During the entire period of surgery, the physician will remain in the operation room. If physicians cannot attend throughout the procedure it will be postponed or cancelled.

Post Operative Care: After the operation, the clients will be provided a cot in the post operative room which is isolated for the purpose of sterilization recovery. 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 two consecutive 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

/1

We plan to conduct a medically supervised study of antibiotic use in which prophylactic antibiotics will be withheld among some patients. This will require a separate protocol and is not authorized at present. One study of vasectomy patients has showed that routine use of prophylactic antibiotics has no medical advantages (Khan and Biswas, 1978). We will replicate that study for labaroscopy. This study is cited briefly in Appendix A item 4.

/2

This role of LFPV's 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.

the specified post operative standards cannot be met, the procedure will be postponed or cancelled.

Field Follow-up: After the clients go home, the FVW's will make daily follow-up visits to the clients and provide antibiotic injections for two days. During the follow-up visits, the FVW's will also enquire about any difficulties. The incision site will be examined for evidence of swelling or infection. If there is complaint of pain or evidence of any problem, the LFPV at the appropriate sub-centre will be informed, who will take necessary measures such as cleaning and dressing of the incision site or referral to a physician

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

Depo Provera (DMPA)¹:

Depo Provera is provided to women in the village at the time of consent. Injections are given by the FVW 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.

Contraindicating conditions are as follows: 1. High blood pressure; 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. any 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

/ 1

Owing to the recent controversy surrounding DMPA in the popular press, the safety of DMPA is addressed in Appendix C.

adopters (see McDaniel, 1974). No nulliporous women will be given DMPA.

LFPV's are trained to care for side effects. FVWs have been trained to recognize problems and refer clients with side effects to the LFPVs.

The consent form appears in Exhibit B-2.

Menstrual Regulation (MR): MRs are performed by LFPVs in the subcentres. MR is not promoted by the program and is performed on only those women who have experienced six weeks or less of amenorrhea since the beginning of the last menstrual period. A consent form appears in Exhibit B-3.

MR is performed by the Karmon Carnula method. All cases are followed up at home by FVWs. All clients receive family planning consultation at the time of the procedure, and subsequently by the FVWs.

Oral Contraception: Oral contraception is provided by FVWs to women in their homes. Contraindicating conditions are specified above for DMPA.

Exhibit B1

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: _____

International Centre for Diarrhoeal Disease Research, Bangladesh

Community Health Services Project, Matlab

(Community Health Services Project, Matlab)

Date: _____

Letter of Consent

Signature of Physician

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.

Exhibit B1

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

অস্বাস্থ্য

- ১। আমি অবগত আছি যে আমাৰ যাতে আমাৰ অন্তৰ না হয় তাৰ জন্য ইচ্ছা কৰে আমি অপাৰেজন কৰিব লাগিব। এই অপাৰেজন অস্ত্রোপচাৰ নিম্নলিখিত অস্ত্র কৰে এ স্থান কেটে কৰা হয় থাকে। অপাৰেজনে দৰ অস্ত্রতা কৰাৰে কাটা স্থানে ব্যথা অনুভব হয়।
- ২। আমি এও জানি যে কোন কোন অস্ত্র কাটা স্থানেৰে চৰ্দাৰে ঘা হতে দাৰে এবং অন আমি আই, ডি, ডি, ডি, আমা, বি'ৰ নিৰ্কাৰে চিকিৎসা সুবিধে লৈতে দাৰি।
- ৩। আমি আমাৰও জানি যে অপাৰেজন কৰাত হলে কমপক্ষে দুটি জীৱিত অন্তৰ থাকতে হবে এবং অৰ্ধকনিষ্ঠ অন্তৰেৰে বহু কম কম পক্ষে দাঁচ কৰাৰ হতে হবে।
- ৪। আমাৰ অস্ত্র এ অপাৰেজনে অস্ত্র অন্তৰ আমাৰ।

আমি/বৃন্দা কুমলী চান্দ
আমি

আমি/বৃন্দা কুমলী

Exhibit B2

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: _____

Exhibit B2

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

অন্বেষণ পত্র

আমি জানতে পেরেছি যে গর্ভধারণ বিনামূলিত অথবা বন্ধ করার জন্য আই, ডি, ডি, আর, বি এর কর্মীরা ডিলো-প্রভেরা ইনজেকশন দিচ্ছেন। এ ইনজেকশন গ্রহণের ফলে স্বাধিক অনিয়মিত হতে পারে। অধিকাংশ স্বহিমা গর্ভধারণকর্তা উপভোগ্য স্বত আর্থিক কিছু উপার্জন আশুভব করে থাকেন। স্বাধারনতঃ ডিলো-প্রভেরা ব্যবহারকালীন অন্বেষণ স্বাধিক বন্ধ থাকে এবং ব্যবহার ছেড়ে দি দেয়তে স্বাধিক সুর হয়। কিছু কিছু স্বহিমা ব্যবহার ছেড়ে দেয়ার পর অনেক দেয়তে গর্ভধারণ করে থাকেন। আমি স্মনেছি যে ডিলো-প্রভেরা ব্যবহারে কে কোন স্বহিমার সুরের দুর্ঘটনা ঘটে যায়। তবে আমি এও জেনেছি যে এ স্বতস্বত অন্বেষণ গ্রহণও অধিকভাবে প্রমোদিত হয়নি।

আমি এও জেনেছি যে ডিলো-প্রভেরা ইনজেকশন সুর মাত্র জন্মনিয়ন্ত্রণে জন্য ব্যবহার হয়ে থাকে এবং প্রতে অন্য কোন বোজ মাঝে না। আমি জানি যে আমি ইচ্ছা করলে যে কোন অন্বেষণ গ্রহণ ব্যবহার বন্ধ করে দিতে পার বা গ্রহণ ব্যবহার কনিত কারলে কোনরূপে আমুর্বিধা দেখা দিলে আই, ডি, ডি, আর, বি এর কর্মীদের কাছ থেকে উপদেষ্টা এবং মন্ডুব চিকিৎসাদা দেতে পারি

স্বাক্ষর/বৃদ্ধাঙ্গুলীর ছাপ
তারিখ

Exhibit B3

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

Letter of Consent

My menstruation has been delayed for days. I have learned that it is possible to have menstruation resumed in cases when the delay is 45 days or less. I understand that a syringe will be used to remove material from the uterus and that this will cause pain and discomfort. The procedure may be followed by bleeding and, in rare cases, by infection. If bleeding or infection related to this procedure occurs I can seek advice and available treatment from the ICDDR,B.

I have received permission from my husband for having this procedure.

Signature or thumb impression

Date: _____

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

অনুমতিপত্র

আমার মাসিক দিন স্থল বন্ধ রয়েছে ।
আমি কুলেছি যে, ৪৫ দিন বা তার কম
অময়ের জন্য মাসিক বন্ধ থাকলে তা
আমার চান্দু করানো যায় । আমি
এও জানি যে, জরায়ু থেকে কিছু জিনিস
বের করার জন্য সিকিউ ব্যবহার করা
যায় এবং এতে ব্যাথা অনুভূত হতে পারে ।
ব্যবস্থা নেয়ার পরে যত্নসহ বা স্থান
স্থলে আমি আর্, মি, ডি, ডি, আর্, বিঃ
কাজ থেকে উদ্বোধন এবং এখানে সম্ভাব্য
প্রয়োজনীয় চিকিৎসা দিতে পারি ।

মাসিক চান্দু করানোর জন্য আমি
আমার স্যামীর অনুমতি নিয়েছি ।

অর্চি/সুধাকুমলীর চান্দু
তারিখ

APPENDIX C

THE SAFETY OF DMPA

Recent publicity in the Bangladesh popular press has been critical of the Government decision to add DMPA to the battery of methods offered by the national program. While DMPA is approved for general distribution in Canada, Western Europe, the United Kingdom, and much of Asia, it has only conditional approval by the U.S. Food and Drug Administration (FDA), wherein, DMPA can be used only in large scale clinical or field trials.

Trials of DMPA have not produced evidence of detrimental effects in humans (see Nash, 1975) although one animal trial demonstrated an association between DMPA and breast nodules in beagle dogs (Finkel and Berliner, 1973).

Human studies as well as studies of rodents, rabbits and monkeys have failed to corroborate the beagle studies (McDaniel and Pardhiason, 1973) most probably because the metabolism of steroid hormones in beagle dogs appears to be dissimilar to that in the human (Goldzeider et al, 1977). Nevertheless, USFDA approval was delayed pending further trial of DMPA on both animal and human subjects. DMPA was approved by the International Planned Parenthood Federation (IPPF) on the basis of overwhelming evidence that DMPA is both safe and dependable (IPPF, 1975). After a careful review of DMPA research the World Health Organisation (WHO) cleared DMPA for distribution by UN agencies such as UNFPA (WHO, 1977). Moreover, a panel of independent FDA experts recommended general FDA approval of DMPA for U.S. distribution despite the beagle findings (see Rosenfield, 1974 and Baldwin, 1978). DMPA is approved for distribution in Bangladesh and is actively promoted by the Government program. It is approved for general use in 69 other countries.

Questions nevertheless persist about the fertility and health effects of DMPA. Given the Bangladesh Government approval of DMPA in the face of such questions, it is important to maintain a site in the country such as Matlab where effectiveness and safety can be carefully monitored. One issue is whether discontinuers return to fertility as rapidly as discontinuers of other contraceptives. A Thai study has shown that 82 percent of all DMPA discontinuers who desired pregnancy became pregnant within 14 months of termination of DMPA (McDaniel, 1974), but this study lacked comparable data from other types of

contraceptors or data on non-contraceptors and it is thus difficult to precisely assess the implications of this finding. If use durations are extended, data from Matlab, however, will be well suited to testing the hypothesis that DMPA has an effect on post use fertility. Data also permit research on the interaction of lactation and DMPA. Our population is too small, however, to permit research on questions about carcinogenic effects.

A careful and comprehensive review of the DMPA safety literature appears in Nash (1975).

APPENDIX D

Table D-I

Tentative Time Table for Adjunct Research
Activities During Calendar Year 1981¹

	Proposed Dais Study	Study of Causes of Death among Infants & Mothers	Proposed Study of Birth Practices	Survey Research on Contraceptive Behaviour	Expansion of DSS
Dec. 80	a) Develop- ment of Protocol			Preliminary areal study of contra- ceptive prevalence	Printing forms, recruitment' supervisor training
Jan. 81	b) Pretest, printing training	a		a	
Feb.	c) Survey	b	a	b	Recruitment fielding, training of surveillance workers
March		c	b	c	
Apr.	d) Coding, Editing		e		Census planning
May	e) Punch, Tabulation	d		d	
June	f) Analysis, report	e	d	e	
July		f	e	f	
August			f		Census in the expanded area to accompany SES study in Matlab at large
Sept.					
Oct.	Consolidation of findings of all surveys, development and processing of an addendum to the Protocol for MCH activities.				
Nov.					
Dec.					

65

/1

These studies will be supported under future protocols. It is hoped that the pace of MCH work can be greatly accelerated. That is, we view this schedule as a "worst case" time table. Our objective is to implement MCH services as early as July of 1981.

Exhibit 2

Baseline form (to link the new system with the RKS II System)

Village: _____ Name of Family: _____

Family Number					Ind.No.					
1	2	3	4	5	6	7	8	9	10	11

Sex name: _____

Age number:			FVWs name: _____			Coder's name: _____	
12	13	14				15	16

Report for _____ day month year

17	18	19
----	----	----

1A Reproductive status	2A Contraceptive Status	3A Lactation status
1 <input type="checkbox"/> Pregnant	00 <input type="checkbox"/> No method	0 <input type="checkbox"/> Not breast-feeding
2 <input type="checkbox"/> Late menstruation pregnancy suspected <input type="checkbox"/>	01 <input type="checkbox"/> Oral pill <input type="checkbox"/>	1 <input type="checkbox"/> Breastfeeding, no other feeding <input type="checkbox"/>
3 <input type="checkbox"/> Eligible to child-bearing 20	02 <input type="checkbox"/> IUD <input type="checkbox"/>	2 <input type="checkbox"/> Breastfeeding providing all other food
4 <input type="checkbox"/> Amenorrheic (post partum)	03 <input type="checkbox"/> 3 month injection 27 28	8 <input type="checkbox"/> Temporarily absent
5 <input type="checkbox"/> Amenorrheic (menopause)	04 <input type="checkbox"/> 6 month injection	9 <input type="checkbox"/> Moved
7 <input type="checkbox"/> Divorced, separated widowed (NE)	05 <input type="checkbox"/> Condom	
8 <input type="checkbox"/> Temporarily absent	06 <input type="checkbox"/> Sampooon	
9 <input type="checkbox"/> Moved out (NE)	07 <input type="checkbox"/> Tubectomy	
	08 <input type="checkbox"/> Vasectomy	
	09 <input type="checkbox"/> Other: _____	
	77 <input type="checkbox"/> No longer eligible	
	88 <input type="checkbox"/> Temporarily absent	
	99 <input type="checkbox"/> Moved out (NE)	

Is the eligible Woman's current status a change from her status in the previous month?

1B	2B	3B
1 <input type="checkbox"/> No <input type="checkbox"/>	1 <input type="checkbox"/> No <input type="checkbox"/>	1 <input type="checkbox"/> No <input type="checkbox"/>
2 <input type="checkbox"/> Yes (as 1C & 1D) 21	2 <input type="checkbox"/> Yes, new user 29	2 <input type="checkbox"/> Yes 35
9 <input type="checkbox"/> Unknown (moved)	3 <input type="checkbox"/> Yes, repeat use ask 2C	9 <input type="checkbox"/> Moved
	4 <input type="checkbox"/> Yes, switched ask 2C &	
	5 <input type="checkbox"/> Yes, stopped 2D	
	9 <input type="checkbox"/> Unknown (moved)	

Exhibit 2 cont'd.....

If yes, record the day, month and year of the most recent status change.

1C day month year	2C day month year	3C day month year																		
<table border="1" style="width: 100%; height: 20px; margin: 0 auto;"> <tr> <td style="width: 33%;"></td> <td style="width: 33%;"></td> <td style="width: 33%;"></td> </tr> <tr> <td style="text-align: center;">23</td> <td style="text-align: center;">24</td> <td style="text-align: center;">25</td> </tr> </table>				23	24	25	<table border="1" style="width: 100%; height: 20px; margin: 0 auto;"> <tr> <td style="width: 33%;"></td> <td style="width: 33%;"></td> <td style="width: 33%;"></td> </tr> <tr> <td style="text-align: center;">30</td> <td style="text-align: center;">31</td> <td style="text-align: center;">32</td> </tr> </table>				30	31	32	<table border="1" style="width: 100%; height: 20px; margin: 0 auto;"> <tr> <td style="width: 33%;"></td> <td style="width: 33%;"></td> <td style="width: 33%;"></td> </tr> <tr> <td style="text-align: center;">36</td> <td style="text-align: center;">37</td> <td style="text-align: center;">38</td> </tr> </table>				36	37	38
23	24	25																		
30	31	32																		
36	37	38																		

If yes, record the reason for the change at that time.

<p>ID Pregnancy</p> <p><u>Change of status:</u> <input type="checkbox"/> 2D</p> <p>01 <input type="checkbox"/> Live birth 25 26</p> <p>02 <input type="checkbox"/> Twin birth</p> <p>03 <input type="checkbox"/> Triplet or more</p> <p>04 <input type="checkbox"/> Still birth</p> <p>05 <input type="checkbox"/> Miscarriage(spontaneous)</p> <p>06 <input type="checkbox"/> Miscarriage(induced)</p> <p>07 <input type="checkbox"/> Menstrual regulation</p> <p><u>Change of amenorrhea status:</u></p> <p>08 <input type="checkbox"/> Pregnant(no PP menses)</p> <p><u>Change of reproductivity status:</u></p> <p>09 <input type="checkbox"/> Pregnant</p> <p><u>Change of eligibility status:</u></p> <p>10 <input type="checkbox"/> Newly eligible</p> <p>11 <input type="checkbox"/> Divorce, separation, widowed</p> <p>99 <input type="checkbox"/> Moved</p>	<p style="text-align: right;"><input type="checkbox"/> 3D</p> <p>1 <input type="checkbox"/> Drop-out 33</p> <p>2 <input type="checkbox"/> Conceived while using</p> <p>7 <input type="checkbox"/> No longer eligible</p> <p>9 <input type="checkbox"/> Moved</p> <p>Age of wife</p> <table border="1" style="width: 100%; height: 20px; margin: 0 auto;"> <tr> <td style="width: 50%;"></td> <td style="width: 50%;"></td> </tr> <tr> <td style="text-align: center;">40</td> <td style="text-align: center;">41</td> </tr> </table> <p>Occupation of Husband</p> <table border="1" style="width: 100%; height: 20px; margin: 0 auto;"> <tr> <td style="width: 50%;"></td> <td style="width: 50%;"></td> </tr> <tr> <td style="text-align: center;">44</td> <td style="text-align: center;">45</td> </tr> </table> <p>No. of living children</p> <table border="1" style="width: 100%; height: 20px; margin: 0 auto;"> <tr> <td style="width: 50%;"></td> <td style="width: 50%;"></td> </tr> <tr> <td style="text-align: center;">47</td> <td style="text-align: center;">48</td> </tr> </table> <p>Date of termination LLB</p> <table border="1" style="width: 100%; height: 20px; margin: 0 auto;"> <tr> <td style="width: 33%;"></td> <td style="width: 33%;"></td> <td style="width: 33%;"></td> </tr> <tr> <td style="text-align: center;">51</td> <td style="text-align: center;">52</td> <td style="text-align: center;">53</td> </tr> </table>			40	41			44	45			47	48				51	52	53	<p style="text-align: right;"><input type="checkbox"/></p> <p>1 <input type="checkbox"/> Started 39 breastfeeding</p> <p>2 <input type="checkbox"/> Began artificial feeding while breastfeeding</p> <p>3 <input type="checkbox"/> Terminated breastfeeding</p> <p>4 <input type="checkbox"/> No longer eligible (divorced or widowed)</p> <p>9 <input type="checkbox"/> Moved</p> <p>Age of husband</p> <table border="1" style="width: 100%; height: 20px; margin: 0 auto;"> <tr> <td style="width: 50%;"></td> <td style="width: 50%;"></td> </tr> <tr> <td style="text-align: center;">42</td> <td style="text-align: center;">43</td> </tr> </table> <p>Education of wife</p> <table border="1" style="width: 100%; height: 20px; margin: 0 auto;"> <tr> <td style="width: 50%;"></td> <td style="width: 50%;"></td> </tr> <tr> <td style="text-align: center;">46</td> <td style="text-align: center;">46</td> </tr> </table> <p>Living sons</p> <table border="1" style="width: 100%; height: 20px; margin: 0 auto;"> <tr> <td style="width: 50%;"></td> <td style="width: 50%;"></td> </tr> <tr> <td style="text-align: center;">49</td> <td style="text-align: center;">50</td> </tr> </table> <p>LLB still living</p> <table border="1" style="width: 100%; height: 20px; margin: 0 auto;"> <tr> <td style="width: 50%;"></td> <td style="width: 50%;"></td> </tr> <tr> <td style="text-align: center;">54</td> <td style="text-align: center;">54</td> </tr> </table> <p>Yes=1 No=2</p>			42	43			46	46			49	50			54	54
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