ETHICAL REVIEW COMMITTEE, ICDDR,B.

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Principal Investigator JAMES PHILLIPS

Application No. 81-052

Title of Study The Community Health Services Project, Matlab (The MCH Component)

Trainee Investigator (if any) _____

Supporting Agency (if Non-ICDDR,B) _____

Project status:
( ) New Study
(✓) Continuation with change
( ) No change (do not fill out rest of form)

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

1. Source of Population:
   (a) All subjects — (Yes) No
   (b) Non-MCH subjects — (Yes) No
   (c) Minors or persons under guardianship — (Yes) No
2. Does the study involve:
   (a) Physical risks to the subject — Yes (No)
   (b) Social Risks — Yes (No)
   (c) Psychological risks to subjects — Yes (No)
   (d) Discomfort to subjects — Yes (No)
   (e) Invasion of privacy — Yes (No)
   (f) Disclosure of information damaging to subject or others — Yes (No)
3. Does the study involve:
   (a) Use of records, (hospital, medical, death, birth or other) — (Yes) No
   (b) Use of fetal tissue or gametes — Yes (No)
   (c) Use of organs or body fluids — Yes (No)
4. Are subjects clearly informed about:
   (a) Aims and purposes of study — (Yes) No
   (b) Procedures to be followed including alternatives used — Yes No NA
   (c) Potential risks — Yes No NA
   (d) Sensitive questions — Yes No NA
   (e) Benefits to be derived — (Yes) No
   (f) Right to refuse to participate or to withdraw from study — (Yes) No
   (g) Confidential handling of data — Yes No NA
   (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure — Yes No NA
5. Will signed consent form be required:
   (a) From subjects — Yes (No)
   (b) From parent or guardian (if subjects are minors) — Yes (No)
6. Will precautions be taken to protect anonymity of subjects — Yes (No)
7. Check documents being submitted herewith to Committee:
   ___ Umbrella proposal - Initially submit overview (all other requirements will be submitted with individual studies)
   ✓ Protocol (Required)
   ✓ Abstract Summary (Required)
   ___ Statement given or read to subjects re 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 complete 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 Ctte for review.

It is to obtain approval of the Ethical Review Committee for any changes affecting the rights and welfare of subjects before making such change.

James T. Phillips

Principal Investigator

Trainee

87-052
Rec'd: 14.12.87

SECTION I: RESEARCH PROTOCOL

1. Title: The Community Health Services Project, Matlab (The MCH Component)

2. Principal Investigator: James F. Phillips

3. Co-Investigators: Makhlisur Rahman, P. Claquin and Jalaluddin Akbar

4. Starting date of MCH Component: 1 January 1982.

5. Completion date: December 1983.

6. Total additional cost: US$ 20,500.00

7. Scientific Program Head:

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

*Signature of the Scientific Program Head: _____

Date: 1 Dec 87

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

8. Abstract Summary:

The present protocol develops and amplifies the MCH component of a broader protocol No. 80-042 "The Community Health Services Project, Matlab". Under this protocol it is proposed to implement in staggered phases several elements of an MCH package aimed at a reduction of under-five mortality and maternal mortality. The package includes:

- control of diarrhoeal diseases;
- control of immunizable diseases (namely, measles, whooping cough, tetanus, diphteria);
- reduction of the risks associated with pregnancy and delivery

This programme will be implemented in two of the four blocks of the Matlab study area (population 40,000) using the existing Community Health Workers as the delivery system. The remaining two blocks will be used as control. A surveillance system for measles and whooping cough as well as a careful monitoring of the deaths occurring in the under-five and child bearing age group will allow the collection of data needed.

9. Reviews (leave blank)

a) Ethical Review Committee: _____

b) Research Review Committe: _____

c) Director: _____

d) BMRC: _____

e) Controller: _____

ABSTRACT SUMMARY

1. The protocol is an addendum to an existing protocol. No changes in the study population are proposed.

2.3. Oral packets, if improperly prepared, can be unsafe. A training programme has been instituted and monitoring has shown that packet production is safe. Monitoring will continue.

Pertussis vaccine has risks which have been researched and reviewed in this protocol. We conclude that benefits outweigh risks.

4. Clinical and field records are confidential in Matlab. Confidential records of immunizations will be maintained for service and research in CHW work books now in use.

5. No consent forms are necessary for MCH services.

6. No interviews are proposed.

7. We aim to reduce mortality and morbidity of childhood diseases and reduce maternal mortality.

8. We must maintain service records of immunizations, morbidity records, and clinical treatment records. These records are largely service oriented, bieng designed to facilitate service delivery.

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, Jalaluddin Akbar and personnel in Data Management.

SECTION II: RESEARCH PLAN

A. INTRODUCTION

1. Objectives

The Community Health Services Project (CHSP), Matlab (80-042) is an approved protocol of the ICDDR,B. Its research plan, objectives, specific aims and strategies have been described at length in the protocol document (1). The protocol work plan mentions (p 28): "In addition to the already developed two maternal and child health (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 mangement 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 baris, 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 programme."

The overall objective of this protocol is to specify the MCH service component of the CHSP programme. The present document thus presents the detailed elements of the MCH programme, the rationale for selection of each element, the strategy to be followed for its implementation, the requisite data collection for MCH evaluation, the analysis plan, and the budget. The present document is not a separate protocol: it simply develops areas already identified, largely budgeted, and approved under protocol 80-042. As such, it is not a new project with a new budget code, but an addendum to the CHSP. We nevertheless present this addendum in standard format to facilitate review.

2. Background

Although there is a vast primary health care literature on MCH strategies, relatively little work has been addressed to the critical question of the optimum package of services for Bangladesh given the severe institutional and resource contraints that prevail in this country and the potential benefits that accrue from implementing such a package. We have nevertheless turned to the various WHO guidelines that are available and the limited scientific literature on Bangladesh in order to focus our work on the most critical problems and those that afford the greatest promise for health status improvement. To achieve this,we have followed the methodology recommended by WHO for their Expanded Programme on Immunization (EPI) (2) and their Control of Diarrhoeal Disease Programme (CDD) (3). This entails: (1) assessing the importance of each health problem related to mothers and children under-five years of age, (2) assessing the feasibility of control of each health problem, and (3) reviewing this assessment in order to establish the priorities.

a) Assessing the importance of each health problem

Reliable data on the morbidity and mortality of diseases are scarce in Bangladesh. Our approach has been to review whatever document was available on Bangladesh and Matlab more particularly (4-14).

For each disease or health problem we have attempted to:

i) assess the incidence of the disease,
ii) assess the mortality effects,
iii) assess the severity by considering the case fatality rate, the extent of disability and the average duration of the health problem, and
iv) assess the perception the community has of the importance of each disease. This forth criterion has been problematic because little information has been collected on the subject of perceptions of health problems.

b) Assessing the feasibility of control

For the existing Matlab MCH project we have examined the following factors:

i) The technical capability of the project to undertake new activities with particular attention to the following questions:

- Do control measures exist?
- How effective are they?
- What are the special equipment or supplies required?
- What training is needed for the staff?
- What coverage can reasonably be expected?

ii) The cost of existing and prospective services:

Since WHO is assisting the programme and since there is already a delivery system which is part of research in Matlab, the question of cost might not be considered a priority. However, since the ICDDR,B intends to test the replicability of the Matlab experience in other parts of Bangladesh, an assessment of the capital and recurrent costs is relevant.

iii) The public response to the MCH services provided:

Although there is a long history of collaboration between the Matlab station staff and the Matlab thana people, it is important to be aware and document the villager's beliefs on each health problem, their usual practice in handling it and the cultural acceptance or resistance to the control strategies proposed. M. Rahman et al. (15) alluded to the subject for tetanus toxoid immunization.

c) Assessing priorities: The package

After reviewing the available literature, following the above described steps we decided on priorities and have identified the following elements to be part of the MCH package:

i) Control of Diarrhoeal Diseases by use of ORS Packets. In rural Bangladesh and in Matlab particularly, diarrhoeal diseases is a significant cause of death among children (80 per 1,000 among children under-5 years of age) (4). In an unpublished study, Black et al. (5b) report that the annual incidence of diarrhoea was highest in children two to eleven months old and declined progressively with age from seven to four episodes per child per year. Clearly, diarrhoeal disease treatment has to be a priority component of any MCH programme.

The specific intervention to be employed is a somewhat more difficult issue. A voluminous literature exists on the efficacy of various means of treatment and prevention of dehydration in diarrhoeal diseases in general and on oral rehydration, in particular (18).

Matlab station has been associated with oral rehydration research for more than 15 years. In 1979-1980 a field trial of home prepared oral rehydration solution (ORS) was carried out, comparing two methods: (1) WHO-formula packets, and (2) local sugar and salt measured with a special spoon. Expert "bari mothers" were trained to prepare the solution and were supplied with ingredients as well as a used intravenous fluid bottle to measure water. Analysis to date shows:

- No difference between the two methods in reported use rate (a).
- Slightly more variation in glucose and electrolyte concentrations for the lobon-gur than for the packet solutions, but very acceptable accuracy of solution preparation by both methods (b,c).

- No difference in the hospitalization rate of patients from the two areas, though overall both ORS areas provided slightly fewer hospital patients than a third area, where ORS was not provided. (An earlier, small ORS project had reported a 29% decrease in hospitalisation associated with home distribution of ORS (16). Thus result has not been duplicated.)

- With time, an increasingly disproportionate amount of sugar has been supplied (d). Most of this represents "leakage", but some has apparently been used to prepare sweeter, more palatable solutions.

These findings have led to CHSP policy decisions which are being implemented in the field. Because packets, although more expensive, are easier to distribute, do not offer the same potential for "leakage" as supplying sugar and salt, and may eventually be supplied by the Bangladesh Government National Oral Rehydration Programme, all mothers in the treatment areas with initially be trained to make ORS using packets and water measured household containers. Eventually all will also be trained to make ORS by the sugar-salt method and provided with a special spoon. Packet production will be increased and decentralized. A quality control system has been instituted to insure safety of preparations. Preliminary evidence from this system has shown that the decentralized system is safe.

ii) Control of Immunizable Diseases. There are six major immunizable diseases known to be endemic in Bangladesh. They are:

a. Measles
b. Diphteria
c. Whooping cough
d. Tetanus
e. Poliomyelitis, and
f. Tuberculosis

ii.a) Measles

ii.a.i) Introduction: Published data on the epidemiology of measles in Bangladesh are scarce. What is presently known come from two sources: (1) The list of reportable diseases of the Bangladesh Government (GOB) and (2) The Matlab Measles Surveillance System.

Measles was first included on the list of reportable diseases in October 1975. This weekly reporting system was set up as a part of the notification of rash with fever and rash deaths in the context of Smallpox Surveillance and discontinued in January 1978. As such, the data collected during that period may reflect some of the epidemiological features of the disease in Bangladesh, but it does not accurately indicate the magnitude of the problem, and thus cannot provide adequate guidance for health planners.

In Matlab, measles surveillance was undertaken between August 1975 and July 1976 in 12 villages. Following a measles outbreak in March 1980, measles surveillance was resumed on the entire DSS population of 160,000 people. That project is in progress and data have yet to be analysed.

ii.a.ii) Epidemiology: annual and seasonal variations. Although an annual variation of the measles incidence is known in other countries it has not been sufficiently documented in Bangladesh. From the available data, it appears that there is typically a seasonal variation which appears to be related to temperature, rainfall and humidity. In Bangladesh measles incidence begins with a gradual upswing in early October, peaks in February, March and April, then declines before the first rains, remaining at the lowest level through the monsoon season — July to September. As with any other highly communicable diseases, measles incidence is likely to be distributed uniformly throughout Bangladesh because the combined effects of high population density and high mobility exacerbate transmission from locality to locality.

Morbidity. Since, to this date, no measles immunization programme has yet been developed in Bangladesh, it may be admitted that 90% or more of persons surviving to 20 years of age have had measles a great majority of them having contracted the disease during their childhood. Calculated over several years so as to minimize the effects of annual variations, the number of cases should approximate to the number of live births and on that basis, is probably over 3 millions every year in Bangladesh. This is speculative, however.

F.T. Koster et al. (9) in Matlab have shown that the attack rate of measles is uniform among children aged 1 and 6 years; while 97% of cases recorded from selected villages during a 12 month period of surveillance occurred in children between the ages of 7 months and 10 years.

ii.a.iii) Mortality: case fatality rate. F.T. Koster et al. (9) in Matlab have shown that "the most common complication accompanying fatal measles was diarrhoea. Pneumonia appeared to be less common as a lethal complication." The same study estimates the case fatality rate to be approximately 4 percent for the 0-6 year age group and 1.6 percent for the 7-10 years of age group.

Mujibur Rahaman in Teknaf found case/fatality figures of 8.3 percent for all age groups, ranging from 10.7 percent for the 0-6 month group to 1.4 percent for 3 years and 0 and 4 years and above (personal communication).

Table 1: Age-specific measles attack and mortality rates (12 Matlab villages) August 1975 - July 1976[a]

Age (months)	1-23	24-47	48-71	72-120	1-120
Population (N)	1421	1369	1148	1837	5775
Measles:					
Number of cases	202	307	193	193	896
Attack rate per 1,000	143	224	168	105	155.2
Number of deaths	9	13	8	3	22
Case fatality rate per 1,000	44.3	42.4	41.5	15.5	36.8
Mortality rate (per 1,000)					
All cases	18.3	27.0	23.5	3.3	21.1
Measles-associated[b]	5.6	9.5	7.0	1.6	5.7
All gastro-intestinal[c]	2.1	8.0	7.8	0.5	5.6
Pneumonia	1.4	2.9	1.7	0.5	1.6
Other	9.0	6.6	7.0	0.7	8.2

[a] Source: Koster, et al. (9).

[b] Deaths occurring within one month of rash onset.

[c] All diarrhoea and dysentery, acute and chronic, not following measles.

The complications of measles have been extensively described (21). As in many other developing countries, measles in Bangladesh is often complicated by pneumonia, diarrhoea and malnutrition. One out of a thousand cases will be complicated with encphalities which may lead to permanent brain damage and mental retardation.

Mortality: death rate. The reported cause specific death rates from measles in Matlab are shown in the following table:

Table 2: Matlab age specific measles mortality rates from three sources, 1975-1978.

Mortality rate per 1,000 in the age group	0-1	2-3	4-5	6-10	0-10
Koster et al., 1975-76 Matlab	56	95	70	16	57

	1st Year	1-4 Year	5-9 Year
L. Chen et al., 1975-77 Matlab	31	45	-
DSS 1978, Matlab	16	20	4

There are marked discrepancies between the reported age specific/mortaltiy rate due to measles for the studies cited in Table 2. Several factors could account for this: the sampling errors associated with the size of the population studied, the differences in the quality of the surveillance, true differences in the occurrence of epidemics during certain years, and the difference in extent of error in classification of deaths due to measles or indirectly related to measles. Despite this marked variation between reported rates, it is clear that measles constitutes a serious threat to child health. The available data suggest that measles is at least third ranking cause of death among the under-five Bangadeshi children and possibly the leading cause if the Koster et al. (9) data apply to the present situation. The role of measles in the morbidity and mortality of the under 5 years of age is therefore significant and control of measles is thus a high priority component of an MCH programmes.

Measles vaccine. Live freeze-dried measles vaccine is widely used by the WHO Expanded Programme on Immunization. However, this vaccine is heat instable and a cold chain is an essential element of a successful programme. Studies have shown that vaccine when kept at $4^{o}C$ for 7 months retains its potency. This level of cold chain maintenance is possible in the context of the Matlab service system.

ii.b) Diptheria

ii.b.i) Epidemiology: Very little is known of the epidemiology of diptheria in Bangladesh. The only information available on the disease is based on the admission records of the Infectious Diseases Hospital, Dacca. The unknown catchment area of IDH makes interpretation of results difficult. From 1973 to 1975, the hospital admitted, on the average 758 cases annually. Case fatality rate was 9.7%. Peak incidence occurs from March to May, but actual rates are unknown. Control will occur as an additional benefit of whooping cough control by the diptheria component of DPT vaccine.

ii.c) Whooping cough (pertussis)

ii.c.i) Epidemiology: Whooping cough is a disease which is prevalent in Bangladesh (6, 24). However, its significance as a cause of mortality is underestimated. It is highly communicable (22), particularly in situations like Bangladesh, where children are carried around by elder siblings and crowding is common place. Pertussis is also believed to have an adverse effect on the nutritional status of patients (23), although further research on the pertussis - nutritional status issue is warranted.

(a) Table 3 presents the results of a 1977 survey conducted by WHO in randomly selected clusters of houses, throughout Bangladesh (6).

Table 3: Age specific attack and case fatality rates for whooping cough

Age Group & Sex	0-1		1-4		5-9		10-14		0-14	
	M	F	M	F	M	F	M	F	M	F
Morbidity	40	52	303	308	309	301	78	59	730	720
Mortality	1	3	1	0	0	0	0	0	2	0
Total cases	41	55	304	308	309	302	78	59	730	720
Total deaths both sexes	4		1		0		0		5	
Total cases both sexes	96		612		610		137		1450	
Expected age group population	3219		9125		12937		10723		96004	
Age specific attack rate (per 1,000)	29.28		67.07		47.15		12.78		40.27	
Age specific fatality rate (percent)	4.17		0.16		1.0		1.0		0.34	

The attack rate for whooping cough was found to be 40.27 per 1,000 for the 0-14 age group, peaking in the 1-4 age group (67 per 1,000). Although the case fatality rate is reportedly low (0.34%), it is likely to be under estimated.

(b) The Country Health Programming reports a 1976 incidence rate for pertussis of 18 per 1,000 in the less than one year age group and a mortality rate of 0.2 per 1,000 in the 1-4 year age group (source not mentioned)(24).

ii.c.ii) Control: Pertussis vaccine is part of DPT. It has been labelled as a controversial vaccine owing to its side effects. However, the conclusions of a recent review paper (25) was that: "with a vaccination programme in a cohort of one million, there would be five cases of post-vaccination encephalitis and 0.1 case of pertussis-associated encephalitis; without a programme there would be 2.3 cases of pertusis associated encephalitis. We predict 0.3 death from pertussis and 1.7 deaths from post-vaccination encephalitis with a vaccination programme as compared with 7.6 deaths from pertussis without a vaccination programme" (25). Koplan (25) added: "In the UK, controversy about pertussis vaccination over the past few years has led to a considerable decrease in immunisation of newborns. A 10 fold to 16 fold increase in pertussis cases has been reported from some regions of the country, and is leading to recommendations that immunization be reinstituted vigourously."

ii.d) Tetanus

In Bangladesh, tetanus, particularly tetanus neonatorum is clearly, identified as a leading cause of infant deaths (see, for example, 4,11,14).

ii.d.i) Epidemiology: Several studies have contributed to our knowledge of the epidemiology of tetanus in Bangladesh.

- A national survey conducted by WHO in 1977 (6) found the following age specific attack rate and case fatality rate.

Table 4: Age specific attack rates and case fatality rate from tetanus 1977.

	AGE GROUP									
	0-11 m		1-4 y		5-9 y		10-14 y		0-14 y	
	M	F	M	F	M	F	M	F	M	F
Attack rate (per 1,000)	29.8	18.0	0.65	1.31	0.92	0.31	0.75	0.18	3.39	2.11
Case fatality rate (percent)	91.6	96.5	33.3	50.0	0	0	50.0	0	77.5	81.6
Total cases	48	99	3	6	6	2	4	1	61	68
Total deaths	44	28	1	3	0	0	2	0	47	31
Pop. at risk (as calculated)	1609	1610	4562	4563	6468	6469	5361	5362	18002	18002

- In Teknaf, Shafiqul Islam et al. (14) found an attack rate 27.4, 6.7 and 34.1 (per 1,000 live births) for the neonatal, post-neonatal and infant deaths respectively. Since tetanus is almost always fatal in these 3 age groups, these rates could also be considered as incidence rate per 1,000 live births.

- Chen et al. (4) found tetanus to be responsible for 9.9% of deaths for all age groups (death rate of 1.6 per 1,000 population). In the under-5 age group, the death rate of tetanus per 1,000 was found to be 37.4, 0.6 and 39.4 for the infant, 1-4 and 0-4 year age groups.

- Analysis of the DSS results for 1978 shows that 96% of the deaths due to tetanus occurred during the first year of life. The attack rate for tetanus death for the first year of life was found to be 58.8 per 1,000. There is, therefore, no doubt that tetanus is a significant cause of death among infants.

ii.d.iii) Control: Three strategies are available:

- Tetanus toxoid immunization can be administered to women of child-bearing ages. This strategy has been already implemented in the MCH intervention area in Matlab and within a year (1978-79) was able to produce a reduction of 47.7% in the neonatal deaths (12). This strategy has been now extended to all married women between 15-45 years of age.

- The tetanus vaccine can be administered to children as a component of DPT.

- The incidence of tetanus can be reduced by improving the safety of delivery practices.

ii.e) Poliomyelitis

Evidence is mounting that the importance of the neurological complications of poliomyelitis in developing countries has been underestimated (27,28). It was believed that infants were exposed to the virus during the first 6 months of their life, a time during which they were thought to be partially protected by maternal antibodies in the breast milk. Recent studies in several countries have shown that prevalence of lameness due to polimyelitis was higher than expected (29-35).

In Bangladesh, two studies have attempted to document the prevalence of lameness due to poliomyelitis (6, 13). A WHO study found a prevalence rate of residual paralysis due to poliomyelitis to be less than 1.64 cases per 1,000 children in the 0-14 years age group. A study by Snyder (13) in Matlab found an overall prevalence of 1.05 per 1,000 children in the 5-14 years age group. This implies that an immunization programme for the 40,000 residents of the MCH-FP blocks would prevent less than a case a year.[1] Poliomyelitis does not appear an immediate priority for the MCH programme.

[1] Both studies have assumed that the case fatality ratio is low and that the cases did not migrate out of the villages(for begging, for example).

ii.f) Tuberculosis

Tuberculosis, particularly pulmonary tuberculosis, is believed to be prevalent in Bangladesh. The only study available (41) estimated the prevalence of open pulmonary tuberculosis to be 7 per 1,000 in the more than 10 years age group in 1965. A study is presently being undertaken to measure the prevalence of open pulmonary tuberculosis and the age specific BCG vaccination rate in the project population (80,000). The results of this study will be used to decide whether to include BCG in our MCH package or not.

iii) Achieving a reduction in the risks associated with pregnancy and delivery. In Bangladesh, as in most developing countries, almost all deliveries in rural areas take place at home assisted by female relatives or Traditional Birth Attendants (TBA). WHO has defined the TBA as "a person (usually a woman) who assists the mother at childbirth and who initially acquired her skills delivering by herself or by working with other Traditional Birth Attendants." Descriptions of the TBAs educational background and pattern of practices have been provided by Croley (36), Shushum Bhatia (37), Islam (38), and Claquin (39). The TBAs generally have little knowledge of asepsis, safe delivery techniques and are often guided by misinformation. A study by Croley (36) reported that only 30 percent of all delivery cases were attended by a TBA with the remaining 70 percent delivered by close female relatives.

These factors undoubtedly contribute to the high maternal mortality rate (7.1 per 1,000 pregnancy terminations), and the high neonatal mortality rate of 78.3 per 1,000 live births, due essentially to tetanus neonatorum.

In their review of "Maternal and abortion related deaths in Bangladesh 1976-1979" Rochat et al. found that eclampia was responsible for between 26 percent and 30.3 percent of pregnancy related deaths (40).

It it therefore reasonable to expect that a simple programme of antenatal care encompassing (1) means of identifying high risk pregnancies and referral, and (2) health education for pregnant women on hygienic practices at the time of delivery could contribute significantly to a reduction of mortality. Such programmes have been successful in Africa, in India and Indonesia (42).

iv) Nutrition health intervention. Many organizations have been working in Bangladesh since 1972 and several had had a continuing commitment to nutrition programmes for some time.

Relief and rehabilitation work has been found to be temporarily effective. However, it is less clear what an isolated nutrition health programme can achieve in rural Bangladesh, considering the extreme poverty level of most people. An hypothesis to be considered is that malnutrition is not the reflection of cultural practices or lack of adequate knowledge but a symptom of extreme poverty and of inequitable distribution of wealth. In such a situation, the most effective strategy of nutrition programme should be either to increase the production of consumable items

(duck raising, vegetable gardens, etc...) or increase the net income of households to levels which permit them to up-grade their diets. Cottage industries have been the traditional answer in Bangladesh, but such activities are often not nutrition programmes per se.

Before the above mentioned issues are clarified, the relevance of a nutrition education package is questionable to us. Under the present programme we are proposing:

1) To review the experience gained from a rural based development programme with a nutrition component in Bangladesh.

2) To identify feasible strategies resulting in a significant improvement of the nutrition of under-five children and/or pregnant and lactating women.

Thus we propose to address the nutrition issue in separate protocols. See, for example, Wilson (1981) (43).

v) Summary: In Bangladesh, the deaths rates have been estimated for 1978 to be at least 74.1 per 1,000 live births in the neonatal period, 125 per 1,000 live births in the first year of life and 28 per 1,000 in the 1-4 year of age period. In the first year of life tetanus, diarrhoea respiratory disease and "fever" are respectively responsible for 50.7, 6, 4.7 and 4.7 percent of all deaths. In the 1-4 year age group, the distribution become 1.8, 35.9, 4.7 and 11.6. In addition measles was responsible for 6.7 percent of deaths.

Most of the leading causes of deaths in the 0-4 year age group could be prevented or controlled if the technology available was properly implemented.

3. Rationale

Results from more than ten projects associating various components of primary health and nutrition care "suggests that mortality declines were notably more rapid in a clear majority of the project sites than would have been expected in the projects' absence ..... infant and child mortality can be reduced by 1/3 - 1/2 or more within 1-5 years, at a cost of under of 2 percent of per capita incomes" (42).

As yet there has been no comprehensive test of the overall morbidity and mortality effects of MCH services in rural Bangladesh. The Matlab setting affords a unique opportunity to examine the efficacy of specific MCH strategies and the potential for improving overall maternal and child health. The other elements of the rationale have been clearly stated in the 80-042 protocol document, pp.18-19.

B. SPECIFIC AIMS

- to increase the utilisation of ORS packets for each episode of diarrhoea affecting the under-five age group. By the end of 1982, it is expected that in 50 percent of all episodes having occurred in this age group, at least two packets of ORS will have been utilised.

- to decrease the incidence of measles in the 0-5 years of age group by 50 percent by December 1982 in blocks A and C.

- to decrease the incidence of tetanus particularly tetanus neonatorum by 50 percent of its 1981 rate in blocks A and C by December 1982.

- to decrease the death rate of respiratory disease from its present rate. Specific targets will be not be set until cause specific mortality instruments are developed.

- to decrease the incidence of diphteria, whooping cough and tetanus by 50 percent of their 1981 rates in blocks A and C by December 1982.

- to decrease the maternal mortality by 25 percent by December 1982.

- to adress the following issues in the field of MCH:

  i) what modification in the pattern of morbidity and mortality of diseases have the implemented interventions brought?

  ii) what is the role of each strategy and intervention in the observed change?

  iii) is there any synergistic effect of interventions?

  iv) what are the operational problems associated with the strategies implemented?

C. METHODS AND PROCEDURES

1. Strategies

The CHSP MCH programme will be implemented in only two blocks of the protocol's intervention area, namely blocks A (Bordia) and C (Nayargaon) for a total population of 40,000. The proposed activities will be implemented by the Community Health Workers after training and under their present supervisors. The surveillance activities, however, will take place in the totality of the protocol area (80,000 population).

a) Promotion of oral rehydration therapy for CDD

Our service strategy for MCH has 7 components:

i) To train each housewife in all blocks (A to D), in the knowledge and utilisation of ORS packets.

ii) To train each village practitioner of blocks A and C in the knowledge and utilisation of ORS packets.

iii) To have ORS packets distributed in each household of all blocks (A to D) by the CHWs using a "pull" system.

iv) To enforce a stricter system for diarrhoeal cases referred or coming spontaneously to Matlab hospital by emphasising the role of the CHWs in screening and in attempting ORS for at least 24 hours for cases without or with mild and moderate dehydration.

v) To decentralize the ORS packet production at subcentre level.

vi) To implement a quality control system for ORS production in all blocks maintaining:

- the ORS packet production at subcentre level;
- the preparation of ORS solution at the household level by housewives.

vii) To organise treatment centres accessible to people. In one block (Bordia) the proximity of the Matlab Treatment Centre makes this provision unnecessary. In the case of the second block (Nayargaon), land has been donated for that purpose and a Centre may start functioning by 1982.

b) Control of measles

The strategy for the control of measles consists of 5 elements:

i) The installation of an efficient cold chain with an adequate monitoring system.

ii) The development of Community Health Worker training material.

iii) The training of the trainers in the management of the cold chain, in the techniques of immunization and in the diagnostic and surveillance of the disease.

iv) The training of the Community Health Workers in the technique of immunization and maintaining of vaccine potency with the cold chain; to train them in measles diagnostic (positive and differential) and surveillance.

v) To immunize every child of more than 9 months of age after an initial round for the 9 months to 5 years groups (back log).

c) Control of tetanus

Our strategy for the control of neonatal tetanus consists of 5 elements:

i) Continuing the present new strategy giving tetanus toxoid to all women between 15 and 45 years of age, whether married or not. Married and menstruating women of less than 15 years of age will also be included. Males between 15 and 45 years of age are also strongly encouraged to join the vaccination programme.

ii) Training the CHWs on the safety of delivery practices.

iii) Distributing after some health education to each pregnant women a small sterile kit to be used at the time of delivery.

iv) Implementing DPT vaccination in the under-five years of age old groups.

v) Participating in the second training session of TBA organised by the thana authorities.

d) DPT immunization

Our strategy for the control of diptheria, pertussis, and tetanus in under-5 children consists of:

i) Installing an efficient cold chain with adequate monitoring system.

ii) Developing training material.

iii) To train trainers in the management of the cold chain, in the technique of immunization and in the diagnostic and surveillance of diptheria and whooping cough.

iv) To train the community health workers in the technique of immunization and maintain of vaccine potency with the help of cold chain; to train them in whopping cough and diagnostic and surveillance. Diptheria, a relatively rare disease of difficult positive diagnostic is not intended to come under surveillance.

v) To immunize every infant by three injections, spaced by at least 30 days, the first injection being started in the third month of life.

e) Reduction of the risks associated with pregnancy and delivery

In order to improve the safety of delivery practices the following strategy is proposed:

i) Identification of high risk pregnancies by CHWs and SHAs. Each pregnant woman will be visited twice during her pregnancy (first, as soon as the pregnancy is recognized, and subsequently during the 7th month). A simple questionnaire and physical examination will identify indicators of high risk pregnancy, such as severe anemia, toxoemia gravida, vaginal bleeding, extreme age or parity, short interval between pregnancy, and concomitance of pregnancy with disease. In each case, pregnant women will be informed about the possible risk involved in her condition and whenever possible, complications of pregnancies will be treated or referred.

ii) Improvement of the asepsis during delivery. The CHW will stress upon pregnant women and their monther-in-law the necessity of using a sterile thread to tie the cord, and the importance of dressing the umbilical cord. The CHW will strongly discourage the use of harmful practices (as described in (37) and (39)). A sterile kit containing those items will be provided and women will be trained in its appropriate use.

iii) Complication of deliveries. It is proposed to train the CHWs to identify early enough a delivery which does not progress normally in order to suggest adequate handling or early referral through government channel. A labour chart or check list will be taught to TBAs, dais, etc. of the area where each CHW works (1,000 population). In addition, a special effort will be done to implement the government raining programme of TBAs in the 2 blocks area.

iv) Post delivery. Perineum tears, placenta retention and puerperal sepsis should be referred to the subcentres and treated or referred to a hospital.

f) Control of respiratory diseases

Respiratory disease has been found to be the second cause of death among infants (4). Most of the causes of respiratory infection will be controlled by the EPI intervention (measles, whooping cough, diptheria)

2. Surveillance and Data Collection

In order to implement the objectives of the present protocol routine data must be made available to the investigators on a fortnightly basis. These information will not only be used for data analysis but also for the monitoring of the operational aspects of the programme. For example, there is little benefits to be gained by discovering 2 years after vaccination that the cold chain in one block must have been deficient. This will require aggregation and scrutiny of data at the block level in a largely non-computerized system, in analogy with the family planning data system. While field use of data will be independent of the computer, there must nevertheless be provision for computerization and analysis.

The following data will be collected in all 4 blocks and submitted (fortnightly) to the protocol investigators:

i) Death reports for children under 5 years of age.

ii) Death reports for each woman between 10 and 45 years of age.

iii) Measles morbidity.

iv) Respiratory diseases morbidity.

v) Diarrhoeal diseases morbidity.

vi) Menstrual status.

vii) Outcome of pregnancy status.

Under the existing system, all above mentioned information except respiratory diseases morbidity is already collected by the CHWs and submitted either to DSS or to the on-going CHSP protocol. Such channels will still operate. In addition, the investigators of the present protocol will receive the information directly from the CHWs. This data collection system will be developed in detail in a separate protocol.

3. Agenda

The implementation of the present protocol is determined by two factors:
1) The existence and proper functioning of the various components of a delivery channel: for example, the cold chain for EPI, the proper training of the CHW for the surveillance of a particular group of diseases, the availability of

vaccines and other supplies. 2) The research paradigm: for example, if one wants to measure the impact of measles vaccine on the morbidity and mortality of diarrhoeal and respiratory diseases one might want to delay the DPT immunization? How would one measure the effectiveness of the training of dais or of the use of safer deliveries or of TT immunization if these three interventions are implemented simultaneously in the same area?

With these considerations in mind and taking into account the fact that as of 1981 November:

- the mothers of all 4 blocks have all been trained in two successive training sessions in the use of ORS.

- the ORS packet production has been decentralized in the four subcentres and the quality and safety of the packets has been evaluated in the Dacca laboratory and found acceptable,

- the cold chain is in place in Matlab and functioning with an adequate monitoring system,

- training material for EPI has been developed, and

- the trainers have been trained in the management of the cold chain, in the techniques of immunization, and in the surveillance of diseases, we propose the following agenda:

a) Control of diarrhoeal diseases. Beginning on November 1st, in all four blocks.

b) Control of immunizable diseases.

i. Tetanus:

- to continue the present strategy for TT immunization. (a different approach between blocks A-C and B-D.);
- to start DPT in block C in May 1982;
- to participate in the training of TBAs under the government scheme early 1982;
- to supply the delivery kit in block A and B in March 1982.

ii) Measles:

To start immunizations in blocks A-C by December first, by handling first the backlog[a] during the following three months and then using a routine procedure for the 9-12 months of age group.

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[a]Children between 9 months and 5 years of age, non immunized and for whom the mother does not recall an episode associating symptoms clearly related to measles.

iii) Diptheria and pertussis:

- to start whooping cough surveillance in January 1982 in the four blocks by using simple algorithms to be used by the CHWs for positive and differential diagnosis;
- to start DPT in block C in May 1982.

c) Improvement of the risks associated with pregnancy and delivery. The programme should start in blocks A and C in May 1982 after proper training of the trainees and development of training material and algorithms.

D. SIGNIFICANCE

The implementation of the MCH-FP project represents an initial step in a research agenda related to preventive and curative 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. Is is not envisaged that ICDDR,B will provide for primary health care instead or in addition of government health services but rather to show which and how specific curative and 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.

It is expected that this protocol will bring significant contributions to a better implementation of mother and child health in national programmes.

E. FACILITIES REQUIRED - none

F. COLLABORATIVE ARRANGEMENTS

WHO has been supplying cold chain and immunisation material for an approximate value of US $3,000, free of cost through the GOB EPI programme. In addition measles, TT and DPT vaccines as well as nylon syringes and electric sterilizers have been supplied free. Assurance has been received that more material will be supplied on request.

SECTION III - BUDGET

The budget mentioned here is incremental to the one already presented in the protocol 80-042.

1. Control of Diarrhoeal Diseases.

Although it is too early to know exactly, each ORS packet is expected to cost Taka 1.50 instead of the present Taka 1.75 and the cost for the 4 blocks will be charged to the MCH-FP protocol instead of being changed to the ORS study or the DSS. Considering an average incidence of 4 episodes per year in the under-five years of age group and an average consumption of 2 packets per episode, the yearly requirement for this age group in a 20,000 population block would be 32,000 packets.

A daily production of 100 packets would cover the needs and allow for wastage. The 1982 yearly budget required for this operation is 1.92 takas. To decrease our costs it is proposed to obtain some packets from the office of the Civil Surgeon through the Thana Health Administrator (THA) Office. Preliminary contacts have already taken place and a favourable answer has been received.

For 1983 it is proposed to obtain 50 per cent of the required supplies from the government.

For quality control it is considered to have a flame photometer set in Matlab and a worker/trained for its use (non incremental).

2. Control of Immunizable Diseases.

A cold chain is presently working in Matlab. It is made of one deep freezer, four cooling boxes, four cold boxes, twelve vaccine carriers.

3. Incremental Budget.

	1982	1983*
CDD		
Production of ORS	192,000	106,000
Reagent for F.P.	5,000	5,500
IID		
Delivery kits	9,000	8,000
Syringes glass	8,000	3,000
Total Taka:	214,000	132,500
1 US$ = 17 Taka; US$:	12,590	7,800

*10% inflation is included.

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