

22

Principal Investigator SHUSHUM BHATTAR Trainee Investigator (if any) nil  
 Application No. 85-014(P) Supporting Agency (if Non-ICDDR,B) \_\_\_\_\_  
 Title of Study Patterns & Causes of Neonatal & Post-neonatal mortality in Malabar Project status: PILOT PROTOCOL  
 New Study ✓  
 Continuation with change  
 No change (do not fill out rest of form)

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

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

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

Shafia  
Principal Investigator

\_\_\_\_\_  
Trainee

00.25/4/85

SECTION I: RESEARCH PROTOCOL

1. Title: Patterns and Causes of Neonatal and Post-neonatal Mortality in Matlab
2. Principal Investigator: Shushum Bhatia
3. Starting Date: As soon as possible
4. Completion Date: 3 months after approval
5. Total Direct Cost: US\$ 2,355
6. Scientific Program Head:

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

Signature of the Acting Assoc. Director for CSRWC: M. Chandra

Date: 2.4.85

7. Abstract Summary:

In order to evaluate the impact of a health intervention strategy on its related mortality it is essential to have reliable information regarding the causes of mortality in the area. The Matlab Demographic Surveillance System which was initiated approximately two decades ago has been involved in collecting mortality information in the area. Over the years however, the intervention programs in the Matlab station have expanded but refinement of the mortality related information collected through DSS was not simultaneously undertaken. Therefore, attempts to evaluate the health interventions in Matlab cannot be accomplished with the data derived from the DSS mortality records. This study aims to examine the symptoms leading to death among neonates and post-neonates in the Matlab DSS area. This task will be accomplished by interviewing mothers who experienced a neonatal death in 1982 and 1983. The pregnancy and labour history of the mother and physiologic status of the new born will be considered when arriving at a diagnosis. The "refined" cause of death information will be used to assess the impact of the health intervention programs in Matlab and also to develop guidelines for improving the DSS mortality information system.

8. Review:

a) Ethical Review Committee:

b) Research Review Committee:

c) Director:

## SECTION II: RESEARCH PLAN

### A. INTRODUCTION

#### 1. Objectives:

✓ The overall aim of this protocol is to know the patterns and causes of neonatal and post-neonatal mortality in the Matlab field area in order to

- ✓ a) evaluate the impact of various health interventions particularly tetanus toxoid immunization in the area;
- ✓ b) improve the compilation of cause of death information collected by the DSS workers.

#### 2. Background:

The Matlab MCH/FP Project has, as one of its activities, made available tetanus toxoid immunization for eligible women since June 1978. Two doses of tetanus toxoid spaced 4-6 weeks apart were given to women during pregnancies, the first dose being initiated at 5 months of pregnancy. Since 1982 all eligible women, irrespective of pregnancy were given two doses of tetanus toxoid in two (Blocks A & C) of the four blocks of the MCH/FP treatment area. The remaining two Blocks (B & D) adhered to the regimen of immunizing women during pregnancy. The new campaign like approach in Blocks A & C aimed to increase the proportion of women immunized against tetanus <sup>since</sup> the earlier approach of immunizing women during pregnancy could achieve only a 35 percent coverage<sup>2</sup>. An evaluation of the two approaches particularly in terms of assessing the impact of each approach on tetanus neonatorum related mortality in the two areas has not been undertaken. An examination of the DSS data indicates that 40.3 percent and 49 percent each of all infant deaths in 1982 in the Matlab MCH/FP area and in the comparison area respectively were attributed to tetanus neonatorum. The proportion of deaths reported to be due to tetanus neonatorum were 43/1000 livebirths and 57/1000 livebirths in the MCH/FP area and comparison area respectively. A further examination of the deaths due to tetanus neonatorum in the MCH/FP area split by the two tetanus t-oxoid immunization strategies, indicates that in Blocks A & C,

where all eligible women were immunized against tetanus and where 80 percent coverage is estimated deaths attributed to tetanus neonatorum were 48.8/1000 livebirths. In Blocks B & D, where approximately 35 percent of the women who gave birth were immunized with tetanus toxoid, 59 deaths (i.e. 34.9/1000 livebirths) were listed as being due to tetanus neonatorum.

An examination of the Death Forms collected and completed by the Demographic Surveillance System workers indicates that in general, tetanus was assigned as the cause of death if the relative of the deceased neonate reported that the child was unable to breastfeed, or if the death was described as being due to Takuria, alga and dhanushtonkar etc.. Needless to state that not all neonates who are unable to breastfeed have tetanus, and that the terms takuria, alga and dhanushtonkar denote several symptom complexes.

### 3. Rationale:

Tetanus toxoid immunization has been shown to be an effective means of combating tetanus neonatorum<sup>3</sup>. Despite the fact that between 80-85 percent of women in Blocks A & C were immunized against tetanus a large number of neonatal deaths were reported to be due to tetanus neonatorum in that area. As mentioned earlier the death reports do not provide adequate information to assess whether these deaths were actually due to tetanus neonatorum. Assuming that mortality due to tetanus mainly occurs between days 4-14, in 1982 only 27.2 percent of the deaths reported to be due to tetanus neonatorum in the MCH/EP area occurred within these days. In the comparison area villages, of the total "Tetanus" deaths 43.6 percent occurred during days 4-14.

In order to assess the impact of tetanus toxoid immunization it is important to get correct information on the causes of neonatal mortality. However, a substantial number of the so-called tetanus neonatorum deaths have been reported during the post-neonatal period. An examination of the deaths that took place during infancy is therefore warranted.

B. SPECIFIC AIMS

1. ✓ To investigate the symptoms leading to death of infants who were reported to have died from tetanus neonatorum in the years 1982 and 1983 in both MCH/FP and Comparison areas.
2. ✓ To arrive at a probable diagnosis based on the above and on the pregnancy and labour history of the mother.
3. ✓ To assess the impact of the two strategies used to provide tetanus toxoid to pregnant women in the MCH/FP area by examining the proportion of deaths due to tetanus neonatorum in each area and in the comparison area.
4. ✓ To develop guidelines to improve the lay reporting system for neonatal and post-neonatal infant deaths.

C. MATERIAL AND METHODS.

Information on the socio-demographic characteristics and the pregnancy history of the women who had an infant death for the two study years i.e. 1982 and 1983 will be extracted from the DSS records. Information on the duration of pregnancy and on tetanus toxoid immunization status will be taken from the CHW register books. Where possible and if available, information on the exact symptoms leading to death recorded in the CHW registers will be utilized. In all other cases women will be interviewed to seek information on the duration of pregnancy, on problems and complications during pregnancy and labour, on breastfeeding and other physiologic status of the livebirth, and on symptoms leading to death of the new born.

Based on this information a probable diagnosis will be assigned in each case. The "refined" cause of death will be used to assess the impact of the two tetanus toxoid immunization strategies. Since the interval between immunization and the outcome of pregnancy and also the number of doses received prior to the delivery may influence the protection imparted by the vaccine, these variables will be accounted for during the analyses.

*informal  
new  
H.W. reg.  
mler and  
of women*

D. SIGNIFICANCE

✓ The study will indicate the patterns and causes of neonatal and infant deaths which will be important for formulating intervention strategies. The Demographic Surveillance reports are circulated internationally and ✓ the information in them is referred to and quoted extensively. An examination of the data collection system and improvement of the routine reporting of cause of death information will be useful for more than ✓ just the Center.

REFERENCES

1. Bhatia, S. et al. The Matlab Family Planning Health Services Project. Studies in Family Planning, 11: 191-201 (1980).
2. Rahman, M. et al. Use of Tetanus Toxoid for the Prevention of Neonatal Tetanus I. Reduction of Neonatal Mortality Immunization of Non-pregnant Women in Rural Bangladesh. Bulletin of World Health Organization, 60(2): 261-267 (1982).
3. Newell, K. W. et al. The Use of Toxoid for the Prevention of Tetanus Neonatorum: Final Report of a Double Blind-Controlled Field Trial. Bulletin of the World Health Organization, 35: 863-871 (1966).

BUDGET

1. PERSONNEL SERVICES:

<u>Name</u>	<u>% effort</u>	<u>Monthly Salary</u>	<u>Project Requirement</u>
Dr. Shushum Bhatia Scientist	50 x 3 mths	- -	-
4 Field Interviewers	100 x 3 "	Tk. 2175	Tk. 26,100
1 Sr. Health Assistant	50 x 3 "	" 3058	Tk. 4,587
		Subtotal:	Tk. 30,687

2. SUPPLIES AND MATERIALS

None

3. EQUIPMENT

None

4. ICDDR,B TRANSPORT:

Speedboat 60 hours @ Tk.350/hr.	Tk. 21,000
4 Country Boats @ Tk.30/day x 2 months	" 7,200

Grand Total: Tk. 58,887

= US\$ 2,355.48



ABSTRACT SUMMARY FOR ETHICAL REVIEW COMMITTEE

1. The subject population will be mothers who have experienced an infant death in the years 1982 and 1983.
2. No risks.
3. Not applicable.
4. Coded identification numbers are used for each person.
5. There are no potential risks to the interviewee and neither is there any involvement of privacy of the individual. The interviewee is just required to narrate the symptoms experienced by the child prior to death.
6. In the deceased infants home. Approximately 10-15 minutes.
7. Knowledge of the patterns and causes of infant deaths in the community will be important for formulating health intervention strategies which will benefit the communities.
8. The following records will be used:

Birth  
Death  
Community Health Worker's Note Book

STATEMENT TO BE READ TO MOTHER PRIOR TO INTERVIEW

Before the mothers are asked to impart any information they will be explained the following:

We are trying to establish the patterns and causes of infant deaths in the Matlab area, so that we can plan appropriate health intervention strategies to prevent such deaths in future. We understand that you lost an infant in 1982 and/or in 1983. We would like you to describe all the problems and symptoms the infant had prior to death and also whether you had any problems during pregnancy and childbirth. All the information we will get from you, will be handled confidentially.

You may voluntarily participate in this research and if you don't wish you may not participate.

ମାମୁଲିତର ଅବସ୍ଥା କରୁନି ଏକ ଦିନର ଭେଦ  
ଦେଖିବି- ବିକଳତା- ମାତ୍ର ଶାନ୍ତତା ଦିଅ।

କେବଳ କା-ରା- କରୁଥିଲା କେବଳ ତେଣୁ କେବଳ- ଭେଦ  
ଭେଦର ବିକଳତା- ବିକଳତା- କ୍ରମେ କର  
ଦିଅ, ସମା:

ଭେଦର ଅଂଶ- ଏକାକୀ- ବିକଳ- କ୍ରମେ  
ଦିନ 3 କରନ ଅଧିକାର ବିକଳତା- କେବଳ- କେବଳ  
କର- କର- ଭେଦ- 3 ବିକଳ- ଏ ବିକଳ-  
କି-<sup>କେବଳ</sup> କର- କର- କର- ମାମୁଲିତର- ବିକଳ-  
କ୍ରମେ 3 ମାମୁଲିତର- କେବଳ- ମାମୁଲିତ,

ଭେଦର ଦିନ- 2022/2026 ଅଂଶ

ଭେଦର ମାମୁଲିତ ବିକଳ- କର- କେବଳ। ଭେଦ-  
କି- ବିକଳ- କ୍ରମେ- ଅଧିକାର- ଏକ ବିକଳ-  
ଅଧିକାର 3 କେବଳ- ଏକ ଭେଦର- କେବଳ- କ୍ରମେ  
ଅଧିକାର- କେବଳ- ଅଧିକାର- ଅଧିକାର- ବିକଳ-  
କେବଳ- କେବଳ- କେବଳ- କେବଳ- କେବଳ- କେବଳ-  
ଅଧିକାର- କେବଳ- କେବଳ

ଭେଦର ବିକଳ- କେବଳ- ଏକ କେବଳ- କେବଳ-  
କେବଳ- କେବଳ- କେବଳ- ଏକ କେବଳ- କେବଳ-  
କେବଳ- କେବଳ- କେବଳ- କେବଳ,