

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Cary Engleberg

Trainee Investigator (if any) _____

Application No. 82-012(P)

Supporting Agency (if Non-ICDDR,B) _____

Title of Study Investigations into

Project status:

Depression in Matlab

New Study (pilot 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 NA

(c) Physical risks Yes No NA

(d) Sensitive questions Yes No NA

(e) Benefits to be derived Yes No NA

(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 an overview (all other requirements will be submitted with individual studies).

Protocol (Required)

Abstract Summary (Required)

___ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)

___ Informed consent form for subjects

___ Informed consent form for parent or guardian

___ Procedure for maintaining confidentiality

___ Questionnaire or interview schedule

* If the final instrument is not 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 Committee for review.

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

[Signature]
Principal Investigator

Trainee

15 JUN 1985

REF
WC 280 JB2
E571
1982

82-012(p)
Recd. 25-3-82

SECTION I - RESEARCH PROTOCOL

- 1. Title: Investigations into Dysentery in Matlab
- 2. Principal Investigator: Cary Engelberg
- 3. Co-investigators: Dr. Mitra, Dr. E. Haque, & Dr. R. Glass
- 4. Starting Date: February 24, 1982
- 5. Completion Date: May 24, 1982
- 6. Total Direct Cost: US \$2,722
- 7. Scientific Program Head:

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

*Signature of Scientific Program Head: [Signature]

Date: 22/3/82

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

8. Abstract Summary:

Dysentery remains the second most common identifiable cause of death and the largest single cause of diarrhoeal death in Matlab. This protocol aims at identifying the extent to which dysentery deaths in Matlab could be reduced by community wide interventions, such as earlier referral, field based treatment. In-depth medical histories will be taken from family members of individuals recently diseased with dysentery to determine as far as possible whether dysentery was the primary or secondary cause of death and if a specific intervention might have altered outcome. Patients with chronic dysentery (more than 1 month) and preterminal patients with dysentery in the field will be examined by a physician and the diagnosis of shigellosis, amoebiasis and other treatable causes of dysentery will be sought. This pilot exploration into the cause of fatal, chronic or severe dysentery could lay the ground work and provide directions for further work in trying to reduce mortality from this most important cause of diarrhoea.

9. Reviews: (leave blank)

- a) Ethical Review Committee _____
- b) Research Review Committee _____
- c) Director _____
- d) BMRC _____
- e) Controller _____

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DHAKA 1212

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ABSTRACT SUMMARY - PARTICULAR ITEMS

1. Subjects will be individuals who have been identified by active surveillance as ill with severe dysentery. Subjects will be referred for diagnosis and treatment to Matlab Treatment Centre. A well individual from the same bari will be asked to provide a passed stool as a control specimen.
2. The medical history, physical examination and laboratory examination (of stool) will be conducted in accordance with the routine requirements of good medical care. All information that is collected will be a propos to the need for making an accurate diagnosis and providing an accepted mode of therapy.
3. N/A
4. As for all Matlab Treatment Centre referees.
5. N/A
6. Living subjects: Routine medical history.
Family members of recently deceased subjects: 15-20 mins.
Open-ended interview designed to elucidate the cause of death.
In essence, this will be a post-mortem medical history.
7. Living subjects who are referred, diagnosed, and treated will benefit from state-of-the-art medical care.
8. Death reports will be monitored to identify recent "dysentery deaths" whose next-of-kin may be interviewed re: cause of death.

15 JUN 1998

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objectives:

- A. To examine the extent to which dysentery deaths in Matlab might be reduced by community-wide interventions in the future.
- B. To improve the field diagnosis terms presently used in reporting dysentery deaths.
- C. To identify approaches for further studies and interventions to reduce dysentery deaths in Matlab.

2. Background and Rationale:

The diarrhoeal disease control programs in Bangladesh and in the world-wide program of WHO have been concerned with prevention of death from watery diarrhoeas causing dehydration using oral therapy and now with the dysenteric diarrhoeas which have a high case fatality rate and are not as responsive to oral therapy. After the implementation of a home based oral therapy program and hospital treatment of diarrhoea in Matlab, dysentery remains the largest single cause of diarrhoeal deaths. The exact cause of these deaths is unknown and it is unclear whether (1) Matlab residents are dying with a form of simple dysentery which would be responsive to treatment (e.g. shigella, amebiasis, i.e. primary cause); (2) dysentery is a secondary cause of death among people suffering from other severe disease (e.g. marasmus) in which case treatment of dysentery alone would be ineffectual, (secondary or contributing cause); (3) if dysentery is a misclassification assigned following death to individuals with a host of more severe problems (misclassification), extent to which dysentery is primary and treatable would determine the potential for an effective intervention and would encourage programs: (a) to develop field-based treatment programs and simple discriminating diagnostic criteria for shigella and amebic dysentery; and (b) to deliver short course therapy for both these illnesses in a field setting.

B. SPECIFIC AIMS

In this pilot proposal, we will examine for groups of dysentery patients and try to assess by interview and simple diagnostics (a) whether dysentery was the primary illness or cause of death; (b) the extent or duration of other significant associated illnesses; and (c) if earlier medical intervention for dysentery could have affected the outcome (e.g. if dysentery was abrupt in onset and rapidly fatal).

C. METHODS OF PROCEDURE

The study groups will include deceased individuals chosen from death (1) in the past 6 months (past deaths), and (2) in the past 2 weeks (recent deaths) and individuals chosen by the community health workers complained of dysentery, (3) continuously for more than 4 weeks (chronic dysentery patients), or (4) who are critically or terminally ill (pre terminal dysentery).

The principal investigator will develop a questionnaire and methods of data collection including interviews with family members of the deceased. In families of a recently deceased individual (group 2 above) contacts of the patient and a control patient who died without dysentery will be asked to give a stool specimen to look for ameba or shigella. Children less than 8 will be weighed and measured to see if families with a recent dysentery death were more likely to suffer from malnutrition. Thirty patients in each of the third and fourth groups (chronic dysentery and pre-terminal dysentery) will be identified by field workers and referred to the Matlab field hospital or examined and interviewed in the field to determine a possible agent of dysentery and important associate illnesses.

D. SIGNIFICANCE

This pilot study will provide a first review of this important cause of death and the visiting investigator can help us set up better criteria for dysentery and diarrhoea causes of death as noted on the death certificates. It will also provide medical guidelines for FWs by suggesting improvements in care for chronic and dysentery patients who they now see.

Results of this study will complement the "lay reporting and Matlab DSS cause of death forms" protocol. It will provide physicians' validation of "dysentery" assigned as a cause of death by the lay reporters, may indicate questions that could be included in the lay reporter's interviews to distinguish between various kinds of dysentery, and will provide information useful for developing guidelines for classification of deaths due to multiple causes (e.g. dysentery and marasmus).

E. FACILITIES REQUIRED - None

F. COLLABORATION

The principal investigator will be given support to investigate dysentery causes of death, develop appropriate questionnaires and perform routine diagnostic cultures on people with chronic or preterminal dysentery as part of his field work and as an extension of care provided by FWs. After he reviews the possible avenues of investigation, a more detailed and specific program of investigation will be submitted to the working group with the second co-investigator assuming the role of Principal Investigator. Present review date is expected to be April 23, 1982.

030751

SECTION III - DETAILED BUDGET

1. <u>PERSONNEL SERVICES</u>	<u>Name</u>	<u>Position</u>	<u>% effort</u>	<u>No.of days</u>	<u>Annual Salary</u>	<u>Project Requirement</u>	
						<u>Taka</u>	<u>Dollar</u>
	C. Engelberg	Investigator	100%	-	-	-	-
	Interpreter		60%	2 months	54,500	6,000	-
	Secretary			4 days	36,000	400	-
2. <u>SUPPLIES & MATERIALS</u>						500	-
	Misc. stationeries & office supplies						
3. <u>EQUIPMENT</u> - None							
4. <u>PATIENT HOSPITALIZATION</u> - None							
5. <u>OUT-PATIENT CARE</u>						500	-
	Medications - ampicillin & metronidazole						
	Stool ME - 500, @ Tk.5.00					2,500	-
	Shigella cultures - 500, @					3,000	-
6. <u>ICDDR,B TRANSPORT</u>						2,800	-
	Dacca-Matlab-Dacca - 7 trips, @Tk.400 per trip						
7. <u>TRAVEL AND TRANSPORTATION OF PERSONS</u> - None							
8. <u>TRAVEL AND TRANSPORTATION OF THINGS</u> - None							
9. <u>RENT, COMMUNICATION AND UTILITIES</u> - None							

B. BUDGET SUMMARY

<u>CATEGORY</u>	<u>Taka</u>	<u>Dollar</u>
1. Personnel	6,400	-
2. Supplies & Materials	500	-
3. Equipment	-	-
4. Patient Hospitalization	-	-
5. Out-patient Care	6,000	-
6. ICDDR,B Transport	2,800	-
7. Travel & transportation of persons	-	-
8. Travel & transportation of things	-	-
9. Rent, communication and utilities	-	-
10. Printing and reproduction	300	-
11. Other services	5,000	1,400
12. Construction and renovation	-	-
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	Tk.21,000	\$1,400

= Total US \$2,722

Project Requirements

	<u>Taka</u>	<u>Dollar</u>
10. <u>PRINTING AND REPRODUCTION</u>		
Questionnaire, 150 X 3 pages	300	-
11. <u>OTHER SERVICES</u>		
Guest House - single room, \$35/day in Dacca	-	1,400
Meals Tk.125/day	5,000	-
12. <u>CONSTRUCTION & RENOVATION</u> - None		
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	Taka 21,000	US \$1,400

= Total US \$2,722