

ETHICAL REVIEW COMMITTEE, ICDDR,B.

A.H. Baqui, K. Zaman

Principal Investigators P. Claquin

Trainee Investigator (if any) x 22

Application No. 81-023(P)

Supporting Agency (if Non-ICDDR,B) _____

Title of Study Limited study for the dehydration status of Matlab patients

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

(3,000) (1 September to 15 November 1980)

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)
 - ___ 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 Cttee. for review.

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

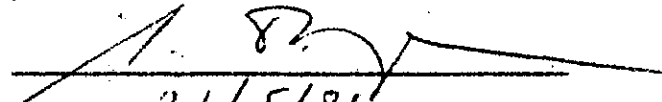
[Signature]
Principal Investigator

[Signature]
Trainee

SECTION I - RESEARCH PROTOCOL

1. Title: Limited study for the dehydration status of Matlab patients (3,000)
(1 September to 15 November 1980)
2. Principal Investigators: Dr. A.H. Baqui, Dr. K. Zaman, Dr. P. Claquin
3. Starting Date: 1st May 1981
4. Completion Date: 1st June 1981
5. Total Direct Cost: US \$ 310.00
6. Scientific Programme Head:

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

*Signature of Scientific Programme Head 
Date 21/5/81

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

7. Abstract:
The aim of the protocol is to compare the dehydration status of 3,000 patients as assessed by the paramedics and by the weight gain at the time of discharge. In addition, the correlation between dehydration as assessed by the paramedic and treatment given in the first 2 hours will be assessed.

8. Reviews:
 - a) Research Involving Human Subjects:
 - b) Research Review Committee: (only CSRWG approval is needed)
 - c) Director:
 - d) BMRC:
 - e) Controller/Administrator:

Abstract Summary - Particular Items

This study is a systematic retrospective review of hospital records. The review is anonymous the variables studied: age, sex, dehydration status and treatment given are not confidential data. No consent form is therefore required.

* The study will benefit all future patients as they will be given a better care as a result of the study.

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objectives

- To assess the type of patient admitted in Matlab treatment centre
- To assess the level of competence of paramedics in
 - assessing correctly the type of dehydration
 - promoting correct therapy

2. Background

Matlab treatment centre treats a yearly average of 13,025 patients as in-patients since 1975. Normally only diarrhoeal diseases patients with moderate to severe dehydration should be admitted.

Upon patient's admission, trained paramedic immediately assess his/her dehydration and start rehydration therapy. A physician may or may not be present at this phase of treatment although the physician on duty always see the patient soon after his admission and prescribe additional therapy if needed (like antibiotics).

Recently, there has been some concern about the proportion of patients admitted to Matlab treatment centre with no diarrhoea, no dehydration or mid dehydration. In addition an assessment of the knowledge of the paramedic in assessing the degree of dehydration as well as of the type of oral rehydration prescribed was felt to be useful.

3. Rationale

- a) Matlab treatment centre claims to be a treatment of diarrhoeal diseases.
- b) Matlab treatment centre claims to be promoting ORT and as such is a "show place" all over the world.
- c) Matlab TC is promoting the clinical management of diarrhoeal diseases by trained paramedics and has been promoting this approach outside Matlab bazar (Sataki).

B. SPECIFIC AIMS

1. To study the correlation between the degree of dehydration as assessed by the paramedics and as measured by the weight gain at the time of discharge.
2. To study the correlation between the degree of dehydration as assessed by the paramedics and the type of rehydration therapy given in the first 2 hours.
3. To study the distribution of the type of dehydration among 3,000 patients admitted to Matlab treatment centre in a 2½ months period.
4. To study the percentage and type of complications observed upon admission on 3,000 patients admitted to Matlab TC in a 2½ months period.

C. METHODS AND PROCEDURES

September to November is traditionally a period of high incidence of diarrhoeal diseases and consequently admissions to Matlab TC are plenty. All admissions to Matlab TC having occurred between September 1 and November 15 (about 3,000 patients) will be reviewed from the hospital charts for

1. Age
2. Sex
3. Type of dehydration as assessed by the paramedic upon admission (none, mild, moderate, moderate/severe, severe)
4. Dehydration as measured by:

$$\text{Dehydration} = \frac{\text{Weight at discharge} - \text{Weight at admission}}{\text{Weight at discharge} \times 100}$$

5. Type of rehydration therapy ORS and IV administered in the first 2 hours.
6. Type of complication observed upon admission and during the stay in the hospital.
7. Particular paramedic involved (not mentioned by name).
8. The length of stay in the hospital (in hours).

After listing the information for 3,000 patients, punch cards will be used. Computer analyses will involve simple distributions of variables; two and three-way cross-tabulations with appropriate statistics; calculation of correlation coefficients; and multiple regression and/or multiple classification analyses.

D. SIGNIFICANCE

1. To document the pattern of practices in Matlab TC.
2. To assess the necessity of a refresher course to medical and paramedical staff of Matlab TC.

B U D G E T

Project Requirements
Takas Dollars

1. Personnel Services

Position

% Effort or Annual
No. Days Salary

1 Coding Assistant (Matlab)	14 days	Tk.21,350	822	-
2 Coding Assistant (Dacca)	8 days	21,350	411	-
1 Data Entry Personnel	4 days	21,350	206	-
1 Senior Programmer	5 days	34,728	668	-
1 Secretary	5 days	45,000	950	-

Sub-total = 3,057 -

2. Miscellaneous

2,100 -

Total Tk. 5,157 -