Library

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Date 1/15/84

ncipal Investigator STANTON

Trainee Investigator (if any) —

lication No. 84-003(P)

Supporting Agency (if Non-ICDDR,B) —

e of Study POST-DISCHARGE MORTALITY OF Children ... Presenting Diarrhoea

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

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

Source of Population:
(a) Ill subjects — (Yes) No
(b) Non-ill subjects — Yes (No)
(c) Minors or persons under guardianship — (Yes) No

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)

oes 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)

re 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? NA — Yes No
7. Check documents being submitted herewith to Committee:
   - ___ Umbrella proposal - Initially submit a 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)
   - N/A Informed consent form for subjects
   - N/A 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.

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

Principal Investigator

16 JAN 1984

Trainee

Abstract Summary

1. All children ages 2 years to 5 years enrolled in the ongoing surveillance system from September 1 to October 15, 1983 at ICDDR,B will be included. We are looking at this age group for the highest mortality associated with malnutrition was noted in children of this age in previous study.

2. No risk.

3. N/A.

4. None

5. N/A.

6. Interview at residence - approximately 10 minutes.

7. Refer 1 to ICDDR,B if child is not thriving.

8. Hospital records will be used.

SECTION I: RESEARCH PROTOCOL

1. Title: Post-discharge mortality of children less than 6 years of age presenting with diarrhoea.

2. Principal Investigators: Bonnie Stanton & John Clemens

3. Co-investigator: Nigar S. Shahid

4. Starting date: January 15, 1984

5. Completion date: April 15, 1984

6. Total direct cost: $2,240

7. Scientific Program Head:

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

Acting Associate Director for CSR W.B.

Date: 15/1/84

8. Abstract Summary

Severe malnutrition has been demonstrated to be a sign of poor prognosis for children 2 years to 5 years of age presenting for treatment of diarrhoea in a rural Bangladesh setting. Little is known about the post-discharge outcome of children presenting from an urban environment for treatment of diarrhoea. This study proposes to evaluate the overall mortality of young children in the 4 months after presentation to ICDDR,B Dhaka and to identify potential prognostic indicators, evident before discharge, that might be used to target special intervention toward high-risk children.

INTRODUCTION

Roy et al[1] demonstrated that during the year following discharge from a rural Bangladeshi clinic severely malnourished, 2- to 5-year old children have a 13 times higher risk of dying than do comparatively aged but adequately nourished or minimally malnourished children. Seventy percent of this mortality occurred in the first 3 months after discharge. Cause of death studies for children under 5 years in the some rural area have demonstrated dysentery to be responsible for 17% of all deaths with other diarrhoeas responsible for only 7%[2].

For logistical reasons follow-up studies have been difficult to perform in urban areas of Bangladesh. Thus, little is known about post-discharge mortality patterns or prognostic factors for mortality for children living in cities. Because of potential differences in access to medical care[3], "safe" water sources, levels of sanitation and family support systems there is reason to believe that mortality patterns and prognostic indices may differ in rural and urban settings.

The present study proposes to determine mortality rates in urban children under the age of 6 years during the four months after receiving care and being discharged from ICDDR,B. Signs, symptoms and laboratory findings will be evaluated for their importance in predicting post-discharge mortality.

MATERIALS AND METHODS

All children who were enrolled in the diarrhoeal surveillance study from September 1 to October 15, 1983 will be eligible for this study (approximately 5-10/day or 200-400 patients).

Two cards will be constructed for each subject. This first card will consist of information obtained from the ICDDR,B surveillance forms 1-3 (see Card #1) and will be completed by an urban volunteer senior field researcher and kept in a central file. The second card will consist of the patient's name, age, father's name and a detailed address (all from the surveillance registry book) and then several outcome questions (see Card #2). This second card will be given by the senior field reseacher to an urban volunteer living in the closest ward to the patient. The urban volunteer will seek out the family to administer the questionnaire. Upon returning the completed form to the senior field researcher the volunteer will be given a stipend of Taka 5.00 and reimbursed for travel costs upto Taka 7.00

Analysis

Single univariate analysis will examine the impact of the following factors upon risk of death: age, gender, clinical type of diarrhoea (watery vs. non-watery), surviving of diarrhoea, clinical signs of malnutrition, anthropometric indices, and complications. Significant univariate prediction will be fitted into a multiple logistic equation. This equation will permit elucidation of which predictors, remain important even when all other predictors are controled, and will permit estimation of the relative and absolute risk of death among patient, with various combinations of predictors.

BIBLIOGRAPHY

1. Roy, S.K. et al. Mortality after discharge from rural hospital. Bangladesh Medical Journal.

2. Slums in Dhaka city. Draft final report. Centre for Urban Studies, University of Dhaka, June 1980.

3. Dhaka Metropolitan Area Integrated Urban Development Project. Working Paper; Population, Dec. 1979.

BUDGET

Personnel:	
Principal Investigators, 20% x 2 months	US $1,400
Sr. Field Researcher, 20% x 3 months	200
Computer	500
Other Contractual services	
Reimbursement for Urban Volunteer, 400 x Tk.12/-	240
	US $ 2,440

Card #1

DATA FROM
ICDDR,B FORM #1

Name _____ Father's name _____

Address _____

Study # _____ Case No. _____
(# from surveillance form)

Date of presentation	12-17
Age	18-23
Sex	24
Wt on admission	39-71
Wt on discharge	42-44
Height	

(Completed Wt/Ht nutritional status _____)

Character of stool: /1/ watery /2/ non-watery 52

Content of stool: /0/ none /1/ mucous /2/ blood /3/ not blood 53

For Children with Form #5

List associated complication:
(questions 58-69)

Form #2

Stool parasite (question 17-25)

Stool culture (question 26-43)

Treatment received (question 59-71)

ICDDR,B CARD #2

To be completed by Senior Field Researcher

Name: _____ Father's name _____

Study # _____ Case# _____ Hospital date _____

Today's date _____

Detailed address: _____

Is Child Still Alive?

Yes/__/ /__/No

Does child appear in good health to parents?

Yes/__/ No/__/

When did child die?

Does child appear poorly nourished to parents?

Yes/__/ No/__/

Of what illness did child die?

Does child appear poorly nourished to volunteer?

Yes/__/ No/__/

Did volunteer refer patient to clinic?