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Date 12/7/83

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Bonita Stanton Trainee Investigator (if any) \_\_\_\_\_

Application No. 83-047(P) Supporting Agency (if Non-ICDDR,B) \_\_\_\_\_

Title of Study Pilot Project to follow up on research on health care services in Bangladesh Project status:  
will allow patients to assess impact (X) New Study  
work on health care services ( ) 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).

- 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
- 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
- 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.

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

R. H. [Signature]

SECTION I: RESEARCH PROTOCOL

Title: Pilot Project to Follow-up Surveillance Patients to Assess Impact of Diarrhoea on Loss of Time from Money Generating Activities and other Normal Activity.

Principal Investigator: Bonita Stanton

Co-Investigators: John Clemens, Nigar S. Shahid and Tajkera Khair

Starting Date: 1 December, 1983

Completion Date: 28 February, 1984

Total Direct Cost: Taka 5,500

Associate Director for CSR:

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

\*Signature of Acting Associate Director for CSR. W. B. J. fe

Date: 14/12/83

\*This signature implies that the Associate Director for CSR takes responsibility for the planning, execution and budget for this particular protocol.

Abstract Summary:

While considerable attention has been focused on the medical consequences of diarrhoea in Bangladesh, there has been little attempt to determine the financial consequences of an episode of diarrhoea on the patient and patient's family. The present study plans to evaluate this question in the urban setting. Patients presenting themselves to the ICDDR,B Treatment Centre who are entered in the established in hospital surveillance system will be administered an additional questionnaire setting to determine all costs and losses of income experienced by the family due to the present illness. Two weeks after discharge patients will be home visited by a trained volunteer of the Urban Volunteer Program; a follow-up questionnaire will be administered to ascertain continuing costs and losses of income due to illness in the patient and subsequent illness in other family members.

SECTION II: RESEARCH PLAN

INTRODUCTION

Considerable research has been focused on the medical consequences of diarrhoea on the poor in Bangladesh<sup>1-3</sup>. Some attention has also been given to the costs incurred by a medical centre in treating a diarrhoea patient<sup>4</sup>. However, while there have been approximations of the cost of medical care to families<sup>5</sup>, there are ~~10~~<sup>no</sup> studies estimating the cost of a diarrhoeal episode to the patient and patient's household in Bangladesh.

It is reasonable to hypothesize that even a mild case of diarrhoea that does not result in a prolonged hospital stay may have major economic impact on a family in Dhaka, Bangladesh, because of the marginal financial resources appreciated by these people. Dhaka city has a population of over 3,000,000 of which approximately 1,500,000 earn less than the \$200 per capita annual income cited by the World Bank as the poverty line for developing countries<sup>6</sup>. Less than 5% of this poor population earn the daily 6 Taka per person necessary to achieve minimum nutrition for an adult. Thus any costs due to an episode of diarrhoea may have a profound impact on a family. It is the purpose of this study to quantitate the cost of an episode of diarrhoea incurred by the household.

Such a study requires visiting a household at the end of an illness in order to identify all costs. There is currently no routine follow-up of patients seen at ICDDR,B. This lack of a follow-up system is in part explained by the difficulty and expense involved in sending a centrally located team out into the city to attempt to find persons in unfamiliar areas. The Urban Volunteer Program has 350 trained volunteers located at known

addresses in 14 of Dhaka Metropolitan's 18 thanas. These volunteers are experienced in locating patients in their areas. This pilot study proposes to develop and test this potential follow-up system for patients seen at ICDDR,B to answer the question of the cost of an episode of diarrhoea on a family.

B. SPECIFIC AIMS

1. To assess the overall cost of an episode of diarrhoeal illness on the family of patients seen at the ICDDR,B Treatment Centre.
2. To establish a system for follow-up of patients currently enrolled in the hospital ICDDR,B surveillance.

C. MATERIALS AND METHODS

1. Subjects:

All patients currently in the hospital surveillance at ICDDR,B<sup>7</sup> will be eligible. Patients who deny any other case of diarrhoeal disease in the family in the previous 7 days will be asked if they wish to participate in the study.

It is anticipated that 5-10 patients will be selected per day using this method. Patients will be enrolled for 8 weeks for a total of 250-500 patients.

2. Methods:

Subjects will receive the stool cultures, physical examination and history questionnaire given to all patients in the Treatment Centre surveillance

system. A detailed home address will be taken. In addition, while at the hospital they will be asked to answer questions regarding expenditures to date on the present episode of diarrhoea (see In Hospital Financial Form). The regular surveillance staff will administer this questionnaire. At the time of discharge from the Treatment Centre the patient will be told that a member of the Urban Volunteer Program will be coming to ask more questions on a specific date (2 weeks hence). The nature of these questions will not be further described to the patient.

Daily, the driver from the Urban Volunteer Program will collect all In Hospital Financial Forms and will arrange these forms by thana.

A "post-hospital questionnaire form" for each patient will then be started with the patient's name, age, address, date of discharge from ICDDR,B and date to be visited filled in. At the weekly meeting of the Urban Volunteer Field Supervisors, the field Supervisor-in-charge of that thana will take the questionnaires of patients living in her thana. On her weekly visits to her 40-70 volunteers, she will deliver each questionnaire to the volunteer who lives nearest to the patient. Two weeks post-discharge the volunteer will visit the patient and ask the further questions regarding expenditures on the illness since discharge from the Treatment Centre (see Post-Hospital Financial Form). The volunteer will return the completed questionnaire to the field supervisor at the next scheduled weekly meeting and will receive 5 Taka plus travel expenses. The field supervisor will review the forms for completeness and logic and return them at the weekly field supervisor meeting. If the volunteer is unable to locate the patient after 3 attempts the field supervisor will attempt one time. The volunteer will be reimbursed for her efforts.

D. FACILITIES REQUIRED AND COST

1. No new office
2. No new field worker
3. No new hospital support worker
4. No new equipment
5. Existing hospital surveillance team will be required to administer 1 more questionnaire (3 minutes per patient).
6. Existing driver for Urban Volunteer Program will be required to collect questionnaires daily at 2:00 p.m. and sort by thana.
7. Existing record keeper/administration for Urban Volunteer Program will file questionnaires and establish 5-10 post-hospital questionnaire per day.
8. Existing field supervisors will hand out and collect post-hospital questionnaires and dispense pay to volunteers.
9. Existing volunteers will receive 5 Taka per patient and travel expense (i.e. 10 Taka/patient x 500 patients = 5,000 Taka).
10. Paper and supplies - 500 Taka.

E. RISKS TO PATIENTS: None

F. BENEFITS TO PATIENT

Additional follow-up by volunteer trained in diarrhoeal disease.

## Analysis

The basic purpose of this study is descriptive. We will cost-account the financial burden to a family when one or more members acquire diarrhoea. It will also be of interest to assess variables which may modify this cost, such as the ages and occupations of affected individuals, the etologic pathogens responsible for the diarrhoea, the clinical severity of diarrhoea and therapies (pre-intra- and post-hospitalization) given for diarrhoea. The family costs within categories of lack of these variables will be compared statistically with the student t-test (for variables with 2 categories) or with one-way analysis of variance (for variables with >2 categories). Those variables which are found to be important determinants of cost with these univariate analyses will then be included in a multivariate analysis, using multiple linear regression, to assess the relative program of each variable controlling for all other important variables.

REFERENCES

1. The urban poor in Bangladesh. Centre for Urban Studies, University of Dhaka.
2. Proceedings of the National Workshop on Oral Rehydration. Dhaka, International Centre for Diarrhoeal Disease Research, Bangladesh, Special Publication No.9, October, 1980.
3. Roy, S.K. Mortality after discharge from hospital. British Medical Journal,
4. Oberle, M.W. et al. Diarrhoeal disease in Bangladesh: Epidemiology mortality averted and costs at a rural treatment centre. Indian Journal of Epidemiology, Vol.9, 1980.
5. Slums in Dhaka City. Draft final report, Centre for Urban Studies, University of Dhaka, June 1980.
6. Stoll, B. et al.



ABSTRACT SUMMARY

1. Patients will be in the surveillance system as this group is representative of all patients presenting with diarrhoea. We are limiting the study to "index" cases in the family because we wish to prospectively follow the financial impact on the entire family.
2. No risk.
3. N/A
4. None
5. N/A
6. Interview in treatment center and at residence approximately 10 minutes will be required.
7. Additional follow-up to patient. Establishing that episode of diarrhoea is or is not of significant financial cost to family. If it is, future studies can examine ways to curtail these costs.
8. Hospital records will be used.

FORM TO BE FILLED IN BY CENTRAL STAFF, UVP

Pt's name: \_\_\_\_\_ Pt's # \_\_\_\_\_

Pt's address: \_\_\_\_\_

Pt's legal guardian: \_\_\_\_\_

Date of presentation: \_\_\_\_\_ Date scheduled for field visit: \_\_\_\_\_

Name of Field Supervisor given to: \_\_\_\_\_

Date form given to Field Supervisor: \_\_\_\_\_

Date Field Supervisor return form: \_\_\_\_\_

Date Volunteer paid: \_\_\_\_\_ Amount volunteer paid: \_\_\_\_\_

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Information to be taken from Surveillance Form

# 26-29 - How many persons eat from same pot? \_\_\_\_\_

# 35 - Income of household \_\_\_\_\_

# 36 - Facilities in household \_\_\_\_\_

# 68 - Duration of diarrhoea \_\_\_\_\_

Stool parasites: \_\_\_\_\_

Stool culture: \_\_\_\_\_

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At the time of presentation to ICDDR,B -

Total family income forfeited: \_\_\_\_\_

Total cost to family: \_\_\_\_\_

Two weeks following presentation to ICDDR,B -

Total family income forfeited: \_\_\_\_\_

Total cost to family: \_\_\_\_\_

Additive:

Salary forfeited: \_\_\_\_\_

Cost to family: \_\_\_\_\_

% of total income this month: \_\_\_\_\_

# Take person/day - normal: \_\_\_\_\_

this month: \_\_\_\_\_

POST-HOSPITAL FINANCIAL FORM

Date of field visit: \_\_\_\_\_ Name of patient: \_\_\_\_\_

Address: \_\_\_\_\_

Age of patient: \_\_\_\_\_

(To be completed by Volunteer and Patient)

Date of patient visited: \_\_\_\_\_

How many days did patient spend at ICSDR, B? \_\_\_\_\_

Since returning home -

How many days has patient worked \_\_\_\_\_  
in last two weeks?

How many days would patient normally  
have worked in last two weeks? \_\_\_\_\_

How much salary does patient believe  
forfeited in last two weeks due to  
illness? \_\_\_\_\_

To be crossed out  
by Central staff if  
patient not employed

Did Caretakers stay in hospital with patient?

Yes  
↓

How many days? Caretaker #1 \_\_\_\_\_ Caretaker #2 \_\_\_\_\_

Has Caretaker stayed home with patient in last two weeks?

Yes  
↓

No →

How many days have Caretakers worked in last two weeks?

Caretaker #1 \_\_\_\_\_ Caretaker #2 \_\_\_\_\_

How many days would Caretakers normally have worked in  
last two weeks?

Caretaker #1 \_\_\_\_\_ Caretaker #2 \_\_\_\_\_

How much salary does caretaker believe forfeited in last two weeks due to illness of patient?

Caretaker #1 \_\_\_\_\_ Caretaker #2 \_\_\_\_\_

Is the patient still ill? \_\_\_\_\_

If yes, describe \_\_\_\_\_

Have any other household members contracted diarrhoea in the past two weeks? \_\_\_\_\_

If yes, how many persons? \_\_\_\_\_

How many additional loss of working days was this resulted in? \_\_\_\_\_

How much loss of salary was this resulted in? \_\_\_\_\_

Are some family members still ill? \_\_\_\_\_

Have any members of the household lost their jobs because of this illness? \_\_\_\_\_

How much was spent on -

Travel while patient in hospital or Taka \_\_\_\_\_

Travel due to illness since patient left hospital \_\_\_\_\_

Medicine prescribed at hospital \_\_\_\_\_

Medicine prescribed after leaving hospital \_\_\_\_\_

Visits to medical practitioner since leave hospital \_\_\_\_\_

Other supplies related to illness while patient at hospital and since left \_\_\_\_\_

Presenting: Financial Form

ICDDR,B # \_\_\_\_\_

Name: \_\_\_\_\_

Age: \_\_\_\_\_

Date: \_\_\_\_\_

Detailed address: \_\_\_\_\_

Does patient work to bring in salary?

Yes \_\_\_\_\_ If No \_\_\_\_\_

What job/jobs does patient do?

1) \_\_\_\_\_

2) \_\_\_\_\_

3) \_\_\_\_\_

How many days per week does patient usually work?

How many days this week has patient worked? Has patient missed work because of this illness?

How many days?

What was patient's "net earnings" per day \_\_\_\_\_

or per week \_\_\_\_\_

or per month \_\_\_\_\_

How much salary has patient forfeited due to illness?

Has someone been taking care of patient?

Yes \_\_\_\_\_ If No \_\_\_\_\_

Who? 1) \_\_\_\_\_

2) \_\_\_\_\_

Do Caretakers work to bring in a salary?

Yes

What job/jobs do Caretakers have ?

<u>Caretaker #1</u>	<u>Caretaker #2</u>
1.	1.
2.	2.
3.	3.

How many days per week do Caretakers normally work?

<u>Caretaker #1</u>	<u>Caretaker #2</u>
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How many days this week have Caretakers worked?

Caretaker #1 _____	Caretaker #2 _____
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Have Caretakers missed work because of this episode of illness in patient?

Yes

How many days?

Caretaker #1 _____	Caretaker #2 _____
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What is Caretaker's usual salaries?

Caretaker #1 - per day \_\_\_\_\_  
 or per week \_\_\_\_\_  
 or per month \_\_\_\_\_

How much salary have Caretaker's forfeited due to illness?

Caretaker #1 _____	Caretaker #2 _____
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What is total approximate monthly salary of household? Tk. \_\_\_\_\_

How many people are in household?

Miscellaneous costs due to this illness:

Travel to health care given including  
this trip to ICDDR,B

in Taka \_\_\_\_\_

Cost of health care given

\_\_\_\_\_  
\_\_\_\_\_

Medication cost

Unusual food cost

\_\_\_\_\_  
\_\_\_\_\_

Cost of additional supplies

\_\_\_\_\_  
\_\_\_\_\_

Cost of additional help to family



Form # 1

Presenting: Financial Form

ICDDR,B # \_\_\_\_\_

Name: \_\_\_\_\_

Age: \_\_\_\_\_

Date: \_\_\_\_\_

Detailed address: \_\_\_\_\_  
\_\_\_\_\_

SECTION 1: (To be completed only if patient is normally involved in income generating activities)

What regular employment does patient have

	<u>Type</u>	<u>Income in Taka</u>	
Job # 1	_____	_____	Per month/week
Job # 2	_____	_____	Per month/week
Job # 3	_____	_____	Per month/week

Other sources of income

	<u>Type</u>	<u>Income in Taka</u>	
# 1	_____	_____	Per month/week
# 2	_____	_____	Per month/week

How long have you been ill with this episode of diarrhoea # \_\_\_\_\_ days

How much money have you earned since illness began Taka \_\_\_\_\_

How much money would you normally have earned during this time? \_\_\_\_\_ Tk.

How many days have you worked since illness began? \_\_\_\_\_ days

How many days would you have normally worked during this time? # \_\_\_\_\_ days

1a. How much total income do you estimate has been lost due to illness?

Taka \_\_\_\_\_

SECTION 2: (To be completed only if someone has remained with patient to give care)

Who are the caretakers?

# 1 \_\_\_\_\_

# 2 \_\_\_\_\_

Do caretakers normally work to generate income?

Caretaker # 1 Yes/No

Caretaker # 2 Yes/No

What job/jobs do Caretakers have?

Caretaker #1

	<u>Type</u>	<u>Income in Tk.</u>	
1.	_____	_____	per month/week
2.	_____	_____	per month/week
3.	_____	_____	per month/week

Caretaker #2

	<u>Type</u>	<u>Income in Taka</u>	
1.	_____	_____	per month/week
2.	_____	_____	per month/week
3.	_____	_____	per month/week

How many days have caretakers worked since illness began?

Caretaker #1 # \_\_\_\_\_ days

Caretaker #2 # \_\_\_\_\_ days

How many days would caretakers normally have worked during this time?

Caretaker #1 # \_\_\_\_\_ days

Caretaker #2 # \_\_\_\_\_ days

How much money have caretakers earned since illness began?

Caretaker #1 Tk. \_\_\_\_\_

Caretaker #2 Tk. \_\_\_\_\_

How much money would caretakers normally earned?

Caretaker #1 Tk. \_\_\_\_\_

Caretaker #2 Tk. \_\_\_\_\_

2a. How much total income do you estimate has been lost due to illness?

Caretaker #1 Tk \_\_\_\_\_

Caretaker #2 Tk \_\_\_\_\_

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SECTION 3: (To be completed by all patients )

What is the total approximate monthly income of your household? Tk \_\_\_\_\_

How many people are in your household? # \_\_\_\_\_

What other costs has patient or household had due to this illness before coming to ICDDR,B

Cost of doctor fee Tk \_\_\_\_\_

Cost of homeopath fee Tk. \_\_\_\_\_

Cost of quack fee Tk \_\_\_\_\_

Cost of transport to and from medical care Tk \_\_\_\_\_

Cost of medication Tk \_\_\_\_\_

Type \_\_\_\_\_

Type \_\_\_\_\_

Cost of special food Tk \_\_\_\_\_

Type \_\_\_\_\_

Type \_\_\_\_\_

Cost of other supplies Tk \_\_\_\_\_

Type \_\_\_\_\_

Type \_\_\_\_\_

Cost of additional household help Tk \_\_\_\_\_

Cost of transport today to ICDDR,B Tk. \_\_\_\_\_

Form # 2

FORM TO BE FILLED IN BY CENTRAL STAFF, UVP

Patient's Name: \_\_\_\_\_ Patient's # \_\_\_\_\_

Patient's Address: \_\_\_\_\_  
\_\_\_\_\_

Patient's Legal Guardian: \_\_\_\_\_

Date of Presentation: \_\_\_\_\_ Date Scheduled for Field Visit: \_\_\_\_\_

Name of Field Supervisor Form given to: \_\_\_\_\_

Date Form given to Field Supervisor: \_\_\_\_\_

Date Field Supervisor Return Form: \_\_\_\_\_

Date Volunteer paid: \_\_\_\_\_ Amount Vounteer paid: \_\_\_\_\_

=====

Information to be taken from Surveillance Form

# 28-29 - How many persons eat from same pot? \_\_\_\_\_

# 35 - Income of household \_\_\_\_\_

# 36 - Facilities in household \_\_\_\_\_

# 68 - Duration of diarrhoea \_\_\_\_\_

Stool parasites: \_\_\_\_\_

Stool culture: \_\_\_\_\_

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At the time of presentation to ICDDR,B - (Totals from Form 1)

Total family income forfeited: (Sum of 1a + 2a) \_\_\_\_\_

Total cost to family: (3a) \_\_\_\_\_

Two weeks following preswntation to ICDDR,B - (Totals from Form 2)

Total family income forfeited: (Sum of 1b + 2b) \_\_\_\_\_

Total cost to family: (3b) \_\_\_\_\_



POST-HOSPITAL FINANCIAL FORM

Date of field visit: \_\_\_\_\_ Name of patient: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_ Age of patient: \_\_\_\_\_

SECTION 1: Central staff check here if volunteer to complete this section



Since returning home -

How many days has patient worked in last two weeks? \_\_\_\_\_ days

How many days would patient normally have worked in last two weeks? \_\_\_\_\_ days

1b. How much salary does patient believe forfeited in last two weeks due to illness? \_\_\_\_\_ Tk.

SECTION 2: Central staff check here if volunteer to complete this section



Did Caretakers stay in hospital with patient?

Caretaker #1 Yes/no      Caretaker #2 Yes/no

How many days? Caretaker #1: \_\_\_\_\_ days      Caretaker #2 \_\_\_\_\_

Has Caretaker stayed home with patient since patient returned home?

Caretaker #1 Yes/no      Caretaker #2 Yes/no

How much money has caretakers earned in last 2 weeks?

Caretaker #1 \_\_\_\_\_ Tk.      Caretaker #2 \_\_\_\_\_ Tk.

How much money would caretaker normally have earned in last 2 weeks?

Caretaker #1 \_\_\_\_\_ Tk.      Caretaker #2 \_\_\_\_\_ Tk.

Form # 3

How many days have Caretakers worked in last two weeks?

Caretaker #1 \_\_\_\_\_ Caretaker #2 \_\_\_\_\_

How many days would Caretakers normally have worked in last two weeks?

Caretaker #1 \_\_\_\_\_ Caretaker #2 \_\_\_\_\_

SECTION 3: To be completed by all patients



How much money was spent by family on travel to hospital while patient in hospital?

Tk \_\_\_\_\_

Travel due to illness since patient left hospital

\_\_\_\_\_

Medicine prescribed at hospital

\_\_\_\_\_

Medicine prescribed after leaving hospital

\_\_\_\_\_

Visits to medical practitioner since leaving hospital

\_\_\_\_\_

Other supplies related to illness while patient at hospital and since left

\_\_\_\_\_

3b. Total: \_\_\_\_\_

Is the patient still ill? Yes/no

Have other members of the family contracted diarrhoea in the last 2 weeks?

Yes/no #1

#2

#3