

ETHICAL REVIEW COMMITTEE, ICDDR,B.

*b2*

Principal Investigator Dr. S. K. Roy

Trainee Investigator (if any) \_\_\_\_\_

Application No. 81-035(P)

Supporting Agency (if Non-ICDDR,B) \_\_\_\_\_

Title of Study Subsequent Mortality of Hospitalised Children in Relation to Their Nutritional Status.

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

Give 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
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: — *NA*
- (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 overview (all other requirements will be submitted with individual studies)
  - Protocol (Required)
  - Abstract Summary (Required)
  - Statement given or read to subjects of 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 Committee for review.

*No human subject is used. Data only involved.*

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

S.K. Roy  
Principal Investigator

\_\_\_\_\_  
Trainee

Recd 25/8/81

SECTION - I RESEARCH PROTOCOL(LIMITED STUDY)

1. Title: Subsequent Mortality of Hospitalised Children in Relation to their Nutritional Status.
2. Principal Investigator: Dr. S. K. Roy
3. Co-Investigator: :
4. Starting Date: When possible
5. Completion Date: Within three months
6. Total Direct Cost: US \$ 1,510.00
7. Incremental Cost: :
8. Scientific Programme Head:

This Protocol has been approved by the Nutrition Working Group.

\*Signature of the Scientific Programme Head

Date:

*K. S. Aziz*  
17/8/81

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

9. Abstract Summary

Matlab Treatment Centre has been admitting all kinds of diarrhoeal patients with varying level of nutritional status. Case fatality in hospital among the children is high. These children may be more vulnerable when they are severely malnourished. A cohort of such 600 hospitalised children below 5 years of age will be studied to look at their subsequent deaths. Their anthropometry were recorded in patient chart will be used for determining the nutritional status and subsequent mortality after discharge from hospital will be found from Matlab D.S.S. death records. This study will estimate the relative risk of mortality of children according to their degree of malnutrition. this relative risk will also be looked at by controlling age, sex and socio-economic status. The study may reflect some strategies for the care of post discharged malnourished children.

#### ABSTRACT SUMMARY

Matlab Treatment Centre has been admitting all kinds of diarrhoeal patients with varying level of nutritional status. Case fatality in hospital among the children is high. These children may be more vulnerable when they are severely malnourished. A cohort of such hospitalised children below 5 years of age will be studied to study their subsequent deaths. Their anthropometry measurements recorded in patient charts, will be used for determining the nutritional status; any subsequent death after discharge from hospital will be found from Matlab D.S.S. death records. This study will estimate the relative risk of mortality of children according to their degree of malnutrition. This relative risk will also be looked at by controlling age, sex and socio-economic status. The study may reflect some strategies for the post discharge care of malnourished children.

9. Reviews

- (a) Research involving human subject \_\_\_\_\_
- (b) Research Review Committee \_\_\_\_\_
- (c) Director \_\_\_\_\_
- (d) Controller/Administrator \_\_\_\_\_

## SECTION II - RESEARCH PLAN

### A. INTRODUCTION

1. Objectives:
  - (a) estimate the yearly survival rates of the hospitalised children age 0, 1, 2, 3, and 4 yrs. following discharge from hospital;
  - (b) how these estimates differs according to the nutritional status at the time of discharge;
  - (c) determine any causal mechanism of those children who fail to survive.

### 2. Background

It has been a common knowledge that there exists a cyclical association between infection and malnutrition. This phenomena is more common in developing countries. There are some evidences that infection and child nutrition are closely related (1-5) in 3rd world countries. More than 25% of children die before their 5th birth day in Bangladesh. This age group is highly vulnerable because of the lowering of host defence mechanism following repeated infection and the environmental condition which results in a vicious cycle of repeated infection/diarrhoea/malnutrition (6). Investigators have shown a marked impairment of the ability to make specific antibody in malnourished children (7). Lincoln (8) showed that there is a threshold point in PEM expressed by anthropometry beyond which mortality increases by two to four time. Some of our hospitalised data showed that case fatality is very high among 3rd and 4th degree of malnutrition (below 60% of Harvard) among diarrhoeal admission. It is documented by D.C. Dingara et al (9) that moderate to severely malnourished children had a 51.8 percent rate of infection compared to 26.5 percent in normally nourished children during the same period of time P.M. Shah (10) showed that in children from rural community, the mortality rate was 45 percent in children with Kwashiorkor and 42 percent in children with Marasmus.

The observation done by D.L. Palmer and his colleagues (11) shows the malnourished patients traverse a protracted course of diarrhoeal disease than well-nourished hospital patients. Gordon (12) has concluded in his observation that incidence rate and severity in infection is higher in malnourished children than children of normal nutritional status. Samia A Wabba (13) have shown in a rural community of low socio-economic that malnourished children are more 'at risk' than well-nourished because of the cycle malnutrition infection diarrhoea. All these studies reflect the magnitude of health problems in the developing countries especially among the children created by the vicious cycle of malnutrition and infection.

### 3. Rationale

It is generally believed that moderate to severe malnourished children usually died faster and more frequently than normally nourished children. For a better survival rate following diarrhoeal attacks, one shot hospital treatment may not be sufficient for malnourished children and other interventions and follow-up in the home and the community might be necessary. The study intends to identify the pattern and the survival rate with time and other risk factors leading to the nutritional intervention programme.

A diarrhoeal episode might precipitate a child into the cycle of malnutrition and diarrhoeal infection leading to ultimate death. The cycle persists, because of environment condition and deteriorating of host defence mechanism. The findings from the study may be of value (1) developing hospital based strategy when discharging the malnourished child after diarrhoeal recovery; (2) to determine some community strategies like mass immunisation, health education etc. for the improvement of present status of fatality (3) to screen out of risky group for immediate attention at the community level.

## B. SPECIFIC AIMS

1. To ascertain the role of different malnutritional status at the time of discharge on the yearly survival rate of children under 5.
2. To assess the pattern of survival according to age, sex and socio-economic status following a one year period after an attack of diarrhoea.

## C. METHODS OF PROCEDURE

### 1. Sample and Sample Size

Six hundred hospitalised children under 5 years who had been discharged in calender year 1979 (did not die during hospitalisation) would be selected. These children will be matched with birth records to determine age and death records to determine survival status.

### 2. Criteria for Selection

Almost equal number of males and females will be selected from the discharge records of months March through June 1979. Children will be divided in three categories according to their nutritional status. Nutritional status will be determined by WHO recognised indicator weight for age expressed as percent of the median of International reference population (WHO 1980). Nutritional classification will be done as follows:-

Category I - 75 percent and above median of International reference population.

Category II - 61-74 percent of median International reference population.

Category III - Below 60 percent of median International reference population.

Socio-economic status of parents will be available from 1974 Matlab Census Data.

3. Analytical Frame Work

Relative risks of mortality will be calculated for category II and III of nutritional status as defined before. These risks also will be analysed by controlling for age, and sex of the children. Figure 1 showed the dummy tables for analysis.

D. FACILITIES REQUIRED

None

E. COLLABORATIVE ARRANGEMENT

None



SECTION III - BUDGET

A. DETAILED BUDGET

<u>1. Personnel Service</u>		<u>Percent</u>	<u>Annual</u>	<u>Taka</u>	<u>Dollars</u>
<u>Name</u>	<u>Position</u>	<u>No. of days</u>	<u>Salary</u>		
Dr. S.K. Roy Medical Officer	1	20% of 3 months	68,380	3420	
Coding Assistant	1	1 month	24,000	2000	
Computer Programmer	1	10 days	36,990	1030	
<u>2. Supplies and Material</u>					
<u>Items</u>			<u>Unit Cost</u>		
Stationaries				9500*	
3. Equipment - Calculator				500*	
4. <u>Patient Hospitalisation</u>	None				
5. <u>Outpatient Care</u>	- None				
6. <u>ICDDR, B Transport</u>	- None				
Transport - Matlab to Dacca/Matlab				200*	
Per diem expenses - 10 days				1900*	
7. <u>Travel &amp; Transportation of Person</u>	None				
<u>Local Travel</u>					
<u>International Travel</u>	None				
8. <u>Transportation of things</u>	None				
9. <u>Rent, Communication and Utilities</u>	None				
10. <u>Printing and Reproduction</u>					
Publication Cost (ICDDR, B)				4000	
11. <u>Other Contractual Service</u>	- Not required				
12. <u>Other Cost</u>				100	
				<u>22,650</u>	

US \$ 1,510

B. Budget Summary

	<u>Taka</u>	<u>Dollar</u>
1. Personnel	6,450	-
2. Supplies	9,500	-
3. Equipment	500	-
4. Patient Hospitalisation	Nil	-
5. Outpatient Care	Nil	-
6. ICDDR, B Transport	2,100	-
7. Travel & Transportation of persons	Nil	-
8. Transportation of things	Nil	-
9. Rent, car & utilities	Nil	-
10. Printing & Reproduction	4,000	-
11. Other contractual service	Nil	-
12. Other Cost	1100	-

Tk. 22,650

Eqv. US \$ 1,510

DUNGY TABLE  
FOR 12 MONTHS

Status	Age/Sex	Number Children	Number Died	Death Rate	Rel. Risk
I	O M	$n'_1$	$d'_1$	$d'_1/n'_1$	
	O F	$n'_2$	$d'_2$	$d'_2/n'_2$	
	I M	"	"	"	
	I F	"	"	"	
II	O M	$n''_1$	$d''_1$	$d''_1/n''_1$	$d''_1/n''_1 \div d'_1/n'_1$
	O F	$n''_2$	$d''_2$	$d''_2/n''_2$	$d''_2/n''_2 \div d'_2/n'_2$
	I M	$n''_2$	$d''_2$	$d''_2/n''_2$	
	I F	$n''_2$	$d''_2$	$d''_2/n''_2$	

Such table for 1st 3 months, 1st six months  
and 1st year.

References:

1. D.C. Dhingra et al. Interaction of Nutrition & infection in school children. Indian Pediatrics. Vol. XIV No. 3, 189.
2. P.M. Shah, Mortality from severe malnutrition in the rural community. Indian Pediatrics. Vol. XII No. 1. 84.
3. Unpublished analysis by Dr. S.K. Roy of Mortality cases of ICDDR, B Tr. Centre of Matlab.
4. D.L. Palmer. F.T. Koster, A.K.M. Jamiul Alam & M.R. Islam, Nutritional status: A determinat of severity of diarrhea in patients with cholera. The Journal of Infectious Diseases, Vol. 134, No. 1 July 1976.
5. Grodon, J.E. Guzman M, Ascoli W, & Scrimshaw N.S. 1964 La Enfermedad Diarreica en los Paises en Desarrollo. Discusiones technicas XIV Reunion del consejo de la O.P.S. Publicaciones cientificas no 100. 14.
6. Samia A Wahba B.Sc, Osman Galal Ph.D. Laila M. Kamal, M.D., Khairy S. Morsi, Ph.D. and Fathalla A., El. Wakeil Ph.D - Improved feeding patterns in the prevention of childhood Nutrition. Egyptian Journal of Pediatric Association.
7. Dr. Ghush. Feeding and cure of Infants & Young children. Page 49.