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Date 29-3-82

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator R. Banerji Trainee Investigator (if any) _____
 Application No. 82-018(P) Supporting Agency (if Non-ICDDR,B) _____
 Title of Study Dynamics of Nutrition Project status:
Dramatic Diets and Mortality (✓) New 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) Family or personal 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.

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

R. Banerji
Principal Investigator

REF

W1 407 JB2

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1982

82-018(P)
Recd. 28/4

SECTION I - RESEARCH PROTOCOL

- 1. Title: Dynamics of Nutrition, Diarrhoeal Diseases and Mortality of Children in Rural Bangladesh.
- 2. Principal Investigator: Radheshyam Bairagi
- 3. Co-investigator: Mridul K. Chowdhury
- 4. Starting date: 15 August 1981
- 5. Completion date: 30 September 1982
- 6. Total direct cost: \$2,818
- 7. Scientific Program Head:

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

*Scientific Program Head: [Signature]

Date: 25/3/82

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

8. Abstract Summary:

This protocol proposes an analysis of the longitudinal data on water use, diarrhoeal diseases, anthropometry, and mortality collected for two calendar years since January 1975 on about 7,000 children under 10 years from a rural area of Bangladesh. It aims to investigate (1) the sensitivity and specificity of different anthropometric indices based on weight, height, and age for screening and surveillance of children at risk of diarrhoeal diseases and mortality, and (2) the relationship between water use, diarrhoeal diseases, nutritional status, and mortality. Socio-economic variables will be controlled for investigating this relationship, and their effects as independent variables on diarrhoeal diseases, nutritional status, and mortality also will be investigated.

9. Review:

Ethical Review Committee: _____

Research Review Committee: _____

Director: _____

BMRC: _____

Controller: _____

15 JUN 1982

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ABSTRACT SUMMARY - PARTICULAR ITEMS

1. Not applicable.
2. Not applicable.
3. Not applicable.
4. Data will be analyzed and published in aggregate and there is no possibility of identifying individuals.
5. Not applicable.
6. Not applicable.
7. No direct benefit to individuals but this study will provide a better understanding of the relationship between nutritional status, diarrhoeal disease and mortality; which, may be an aid to the planners for a better health planning.
8. Not applicable.

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SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objectives: The following hypotheses will be tested:

1) Growth rate is a better prognosticator of mortality than attained growth:

a) for all age groups

b) for all measures (weight, height)

c) for all periods (long and short)

2) Growth rate in weight is a better predictor of mortality than growth rate in height for all ages for short term periods but the two rates are equally good for long term periods.

3) As cross-sectional measures:

a) Weight-for-age is a better indicator than height-for-age for a short term period but both are equally good for long term periods.

b) Weight-for-height is as good as weight-for-age and better than height-for-age as an indicator for success over a short term period but it is inferior to the other two for long term periods.

All the above hypotheses and the following hypotheses will be tested for diarrhoeal diseases:

4) The rate of growth will be more affected in cases of initially malnourished children.

5) The average duration of diarrhoea is longer for initially malnourished children.

6) Duration affects nutritional status more than incidence of episodes.

To study the relationship between anthropometric indices and socioeconomic variables, the following hypotheses will be tested:

7) As age increases, the relationship between different indices and socioeconomic status will be more apparent.

- 8) In a cross-sectional study, weight-for-age and height-for-age are equally related to different socioeconomic status after 5 years of age, but before five, weight-for-age is more related.
- 9) Weight-for-height is not strongly related to socioeconomic status.
- 10) Seasonal effects of nutritional status will be manifest in changes in weight-for-age and weight-for-height more than in height-for-age.

2. Background

Malnutrition and diarrhoeal disease are two major health problems of children in developing countries where 30 to 50 percent of children die before their fifth birthday and more than 50 percent of these deaths may be directly or indirectly related to malnutrition (FAO 1970, Puffer and Serrano 1973). The relationship between infectious disease and malnutrition is well recognized (Behar 1968, Scrimshaw, et al. 1969, DeSweemer 1973), and diarrhoeal diseases are both the cause and effect of malnutrition in lesser developed countries (Mata, 1980).

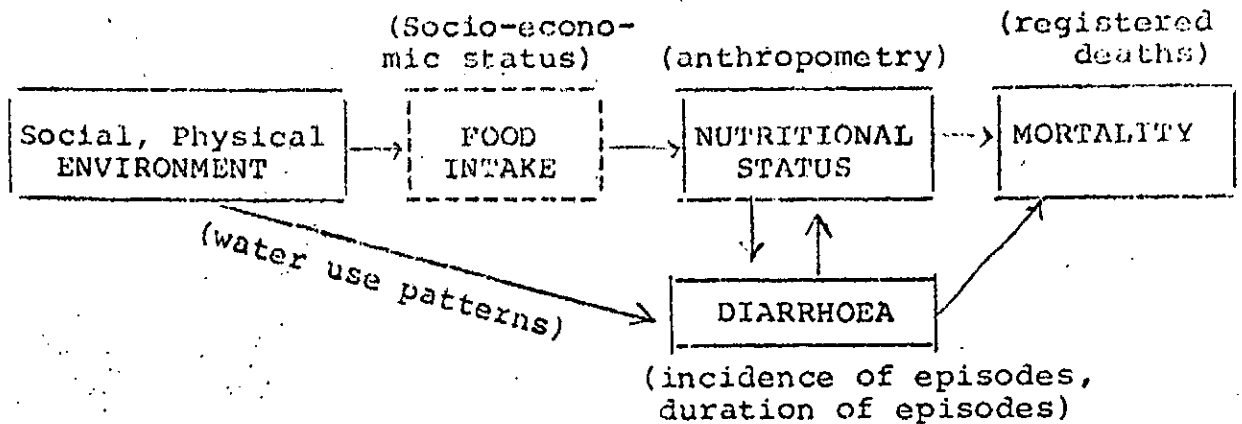
In a rural area of Bangladesh which has been under intensive surveillance for diarrhoea and vital events, diarrhoea and malnutrition appeared as two major causes of death of children (Chowdhury 1980); however, the precise nature of the interrelationship of these two causes of death is not well understood where seasonal variation of each is noted. Accurate assessment of nutritional status is necessary to study the interrelationship of these two factors, and anthropometric indices are an essential field tool in quantification of nutritional status. Many anthropometric indices are described in the literature but it is only recently emerging which of these indicators of nutritional status are most appropriate in a given situation. Recently investigators at the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) demonstrated among the same field population proposed for this study that simple arm circumference for age was the most sensitive screening indicator for predicting subsequent mortality although it performed less well in following changes in nutritional status (Chen 1980). A consensus is developing that the ultimate value of an anthropometric measure lies in its capacity to identify individuals and population at high risk to adverse functional

consequences of malnutrition such as mortality or morbidity (Habicht et al. 1978, Trowbridge and Stochling 1980, Chen et al. 1980).

Recently this investigator compared the validity of several anthropometric indices for screening and for surveillance of malnutrition where mortality of 1 year old children was used as the validating criterion (Pairagi 1981). However, the result obtained in that study may not be generalized to other age groups because the change in anthropometric variables is not independent of age (Anderson 1979).

The first part of the proposed study is to compare the sensitivity (proportion at risk of diarrhoeal diseases and deaths correctly identified) and specificity (proportion identified as without diarrhoeal disease and alive) of the indices composed of age, height and weight. From this analysis the appropriate index or indices will be selected as a measure of nutritional status for investigating the dynamics of the relationship between nutritional status, diarrhoeal disease and mortality as the second part of the proposed study.

Diarrhoeal diseases and nutrition result from several physical and cultural factors in the environment. The relationship between diarrhoeal disease, nutrition and mortality may be illustrated by the following simplified schematic diagram:



The analysis will be done following the path of this diagram concentrating on how diarrhoea affects malnutrition and in turn is affected by malnutrition and how each or both affect

mortality. We shall also note how domestic water use patterns (sources of water for drinking and for all other domestic uses) influence diarrhoea rates and how socioeconomic status (size of dwelling, occupation and education of the head of household, etc.) influence nutritional status as a surrogate for food availability.

J. Rationale

It has already been mentioned that malnutrition and diarrhoea are two major health problems of children in developing countries. This study is aimed at investigating the interrelationship between these two, their causes and effects.

B. SPECIFIC AIMS

- 1) Establish a cleaned primary data set at the ICDDR,B for future use by investigators consisting of files of nutritional, diarrhoeal incidence, mortality; socioeconomic information and water use patterns for 7033 Bangladesh children under 10 years of age. Data files will be constructed to facilitate use of computerized NCHS/CDC nutritional standard data analysis.
- 2) Tabulations and analysis, to be published as ICDDR,B reports, of sensitivity and specificity for anthropometric indices constructed from age, weight and height in predicting diarrhoeal disease morbidity and mortality from all causes among the children in the study.
- 3) Univariate and multivariate analysis of the interaction among the following variables: age, nutritional status, diarrhoea morbidity, and socioeconomic status and water use patterns on mortality and other selected dependent variables. These analysis will be published first as ICDDR,B research reports.

C. METHODS AND PROCEDURES

1) Field Work

These observations were made by the Matlab field staff of the International Diarrhoeal Disease Research Centre, Bangladesh (ICDDR,B: formerly the Cholera Research Laboratory). Matlab, the field research station of the ICDDR,B since 1964, is located in rural Bangladesh approximately 30 miles from Dacca. At the time these studies were conducted approximately 260,000 persons were included in and demographic surveillance area in 126 villages. The original

villages of the Matlab area were first censused in 1964 and in those villages surveillance of births, deaths, immigration and migrations was begun in 1966. An additional 100 villages were added to the area in 1968 with an initial census and institution of vital events registration. In April 1974 a population census was made in the total Matlab field surveillance area, including and update of socioeconomic data. Registration of vital events continued.

The hub of the ICDDR,B activity is a diarrhoeal disease treatment centre located in the centre of the area in Matlab Bazaar. A transportation network of speedboats located strategically throughout the field area serves as ambulances to bring patients to the hospital and to assist with transport of the large field staff who are engaged in village based studies and demographic surveillance. The field staff are experienced in working in vaccine field trial campaigns, routine demographic surveillance and special field surveys including administration of questionnaires and nutrition surveys. Each resident is identified by a unique identification (VIS) number to facilitate matching of clinical and demographic records.

In January 1975, investigators at the ICDDR,B undertook a prospective study of the influence of domestic water use patterns on diarrhoeal disease in 12 villages. Central to the study were determination of diarrhoeal disease morbidity as detected by weekly household surveys and sources of water for four domestic uses as determined once each month.

Diarrhoeal morbidity data were obtained on all village residents; parents responded for children. Field workers uniformly defined diarrhoea as two or more loose or liquid bowel movements in a day. Distinctions were noted between watery diarrhoea and dysentery, characterized by passage of blood and mucus. Microbial cultures were not taken and antibiotic therapy was not administered although seriously ill patients were referred to the hospital where they were treated according to the judgment of the Matlab physicians. An episode of diarrhoea was defined as diarrhoea beginning after a minimum of two days without diarrhoea.

Once each month, each member of the family was also queried about the source of water (tubewell, river, canal, tank or flooded surface water) used for drinking, bathing, cooking and washing.

Socioeconomic information on each family was abstracted from a complete census which was completed in April 1974. Information coded on this set of data included: religion, articles (possession of five household and personal items thought to be reflective of wealth and modernity), area of the family dwelling (previous analysis of the 1974 Matlab census demonstrated this to be an easily measured, censured, sensitive and accurate estimation of wealth), occupation and education of the head of household, education of the mother, number of cows and boats owned by the family and distance from the nearest tubewell (as part of this study, all the tubewells were maintained in functioning order).

The date of birth was coded on the data set as were the dates of death. Dates of birth are known for approximately 70% of the children who comprise this data set; dates of birth of the remainder were estimated at the time of the first census when they were young infants, and errors in the resulting estimated age are thought to be small.

Beginning in July 1975, additional teams of field workers measured every two months the height of each child in the study who could stand in a measuring box and weighed on a Salter scale each child who was less than 25 kg in weight. These teams operated independently of the diarrhoeal surveillance teams. Arm circumference measurements were not taken. Heights were recorded to the nearest 1/10 cm; weights were recorded to the nearest 50 grams. The same scales were used throughout in the study.

Diarrhoea morbidity, water use, and nutritional data were abstracted onto annual summary sheets (Appendix A). At the conclusion of the study these data were coded and punched onto 80 column IBM cards. For each child who completed the study, 8 cards were required. A total of 56,264 cards were punched for the 7033 children in the study.

The cards were read onto a 9 track tape which is now at The Johns Hopkins University Computer Center under the sole care of Dr. Radheshyam Bairagi. Preliminary runs of this tape indicate the cards were read onto the tape completely and in the proper sequence, but the data have not been thoroughly cleaned. It is estimated that the cleaning of the data and the creation of files for analysis will take three months' time after which the final analysis will begin.

Analysis

Both nutritional status as reflected by an anthropometric index and diarrhoeal diseases are related to age, and analysis will be done separately for different age groups. The main age groups will be: 0-5, 6-11, 12-23, 24-35, 36-59, and 60+ months.

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Weight-for-age, height-for-age, and weight-for-height for each child will be calculated with reference to National Centre for Health Statistics (NCHS) standard (Waterlow et al. 1977). A subroutine to compute percentiles, percent of standard median, and z-scores indices for NCHS/CDC standard is available at the Johns Hopkins University Computing Centre and at ICDDR,B. Files of research data will be constructed to facilitate use of NCHS standards in analysis. Bimonthly increments in weight and height will be obtained and will be expressed in standard terms. All indices will be related in the sensitivity and specificity analysis to the subsequent diarrhoeal diseases for 0-3 and 3-6 month periods and to mortality for 0-6 and 6-12 month periods. For diarrhoeal diseases, both the duration of diarrhoea in number of days and the number of episodes will be used as dependent variables. Simple cross classification and regression analysis (Snedecor and Cochran, 1974) will be used for investigating the relationship between water use, diarrhoeal disease, nutrition and mortality.

D. SIGNIFICANCE

We have mentioned earlier that malnutrition is a major health problem in the developing countries. It is, therefore, very important to an agency, national or international, to know which index or indices should be used for screening malnutrition, and which one should be used for surveillance of nutritional status. Anthropometric indices have several advantages over clinical and biochemical methods (Shakir 1975). Our proposed sensitivity and specificity analysis is expected to give answers to the above queries for Bangladesh and for similar other developing countries. Our proposed investigation into the relationship between socioeconomic condition, diarrhoeal diseases, nutrition, and mortality is expected to provide a quantitative measure of evidence of the risk of diarrhoeal diseases and mortality associated with different nutritional status of children in a setting like rural Bangladesh. It will also help to understand the vicious cycle of two major killers of children, diarrhoea and malnutrition, and related factors. This understanding should help the policy makers in breaking this cycle.

E. FACILITIES REQUIRED

This project will not involve any cost for data collection.

1. Office Space: If the work is undertaken in ICDDR,B then existing office of Statistics will be used.

2. Laboratory Space: Not needed.
3. Logistri Support: For data processing and analysis the facilities of Statistics, CSI and SPSS in BUET will be required.

F. COLLABORATIVE ARRANGEMENT

This project is expected to be done on a grant from USAID. If the work is done at ICDDR,B, the SPSS package facility of Bangladesh University of Engineering and Technology will be used for analysis.

References

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- Chen, L. C., Chowdhury, A.K.M., and Huffman, S.L. 1980. Anthropometric Assessment of Energy-Protein Malnutrition and Subsequent Risk of Mortality among Preschool Aged Children. Am. J. Clin. Nutr. 33: 1836-1845.
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- Puffer, R. R. and Serrano, C. V. 1973. Patterns of Mortality in Childhood. Pan American Health Organization. Regional Office of the World Health Organization, Washington, D.C. 20037.
- Shakir, A. 1975. The Surveillance of Protein-Calorie Malnutrition by Simple and Economical Means. In: Priorities in Child Nutrition, Vol. III, Health Services and Education in Relation to Nutrition. Harvard University of Public Health.
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- Waterlow, J.C., Buizina, R., Keller, W., Lane, J. M., Nichaman, M. Z., and Tanner, J.M. 1977. The Presentation and Use of Height and Weight Data for Comparing the Nutritional Status of Groups of Children under the Age of 10 Years. Bull. WHO 55(4): 489-498.

SECTION III - DETAILED BUDGET

1. PERSONNEL SERVICES

<u>Name</u>	<u>Position</u>	<u>% effort</u>	<u>No. of days</u>	<u>Annual salary</u>	<u>Project Requirements</u>	
					<u>Taka</u>	<u>Dollar</u>
*R. Bairagi	Investigator	33	410	104,000	38,551	-
M.K. Chowdhury	Co-investigator	2	410	78,000	1,755	-
Statistical Officer		2	410	49,000	1,102	-
Typist		5	410	27,000	1,518	-
Programmer		5	410	50,000	2,813	-
				Sub-total	Tk. 45,739	-

2. SUPPLIES & MATERIALS

1 tape					400	-
Stationeries					350	-
Diskette					250	-
				Sub-total	Tk. 1,000	-

3. EQUIPMENT - None

4. PATIENT HOSPITALIZATION - None

5. OUT-PATIENT CARE - None

6. ICDDR,B TRANSPORT - None

* Dr. R. Bairagi is in the faculty of the University of Dacca, and he has approval from the University to work at the ICDDR,B.

	<u>Project Requirements</u>	
	<u>Taka</u>	<u>Dollar</u>
7. <u>TRAVEL & TRANSPORTATION OF PERSONS</u> - None		
8. <u>TRANSPORTATION OF THINGS</u> - None		
9. <u>RENT, COMMUNICATION AND UTILITIES</u> - None		
10. <u>PRINTING AND REPRODUCTION</u>	1,000	-
11. <u>OTHER CONTRACTUAL SERVICES</u>		
Computer at BUET	2,000	-
12. <u>CONSTRUCTION, RENOVATION & ALTERATION</u> - None		
13. <u>MISCELLANEOUS COMPONENTS</u>		
Overhead	1,000	-

B. DETAILED BUDGET

<u>Category</u>	<u>Taka</u>	<u>Dollar</u>
1. Personnel Services	45,739	-
2. Supplies and Materials	1,000	-
3. Equipment	-	-
4. Patient Hospitalization	-	-
5. Out-patient Care	-	-
6. ICDDR,B Transport	-	-
7. Travel & Transportation of Persons	-	-
8. Transport of Things	-	-
9. Rent, Communication and Utilities	-	-
10. Printing and Reproduction	1,000	-
11. Other Contractual Services	2,000	-
12. Miscellaneous Components	1,000	-
Total	Tk. 50,739	\$ -
	= US\$2,818	

