Attachment 1. 6 Date 22th August 85

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator A. BRIEND Trainee Investigator (if any) _____

Application No. 85-029 Supporting Agency (if Non-ICDDR,B) _____

Title of Study OPTIMISATION OF SCREENING TECHNIQUES FOR SELECTING MANOURISHED... Project status:
( ) 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) 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 NA
   (b) Procedures to be followed including alternatives used Yes No NA
   (c) Physical risks Yes No NA
   (d) Sensitive questions Yes No NA
   (e) Benefits to be derived Yes No NA
   (f) Right to refuse to participate or to withdraw from study Yes No NA
   (g) Confidential handling of data Yes No NA
   (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure. Yes No NA
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.

(PTO)

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

A. Briend
Principal Investigator

Trainee

85-029
22/8/85

SECTION I : RESEARCH PROTOCOL

Title:

OPTIMISATION OF SCREENING TECHNIQUES FOR SELECTING MALNOURISHED CHILDREN WITH A HIGH RISK OF DEATH

Principal Investigator: A. Briend

Co-investigator: A. Bari.

Consultant: M.G.M. Rowland

Starting date: 1st october 1985

Completion date: 1st october 1987

Total cost: $ 83,681

Scientific Programme Head: MGM Rowland

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

Signature of the Scientific Programme Head:

Date: 15.8.85

ABSTRACT

The relevance of the "Road to Health" growth chart in its present form to select malnourished children with a high risk of death will be tested on a sample of approximately 1800 under 5 children. Its efficacy will be compared to monthly measurement of arm circumference which will be done simultaneously on the same group of children. This study will be carried out in a rural community where the age of every child is known with precision. Weight will be taken monthly with high accuracy scales and arm circumference will be measured by plastic insertion tapes. The relevance of variations of nutritional status to estimate the risk of death, the usefulness of high precision measurements for screening purposes, the adequacy of the generally accepted age limit for growth monitoring will also be tested.

Reviews:

Ethical Review Committee: _____

Research Review Committee: _____

Director: _____

SECTION II : RESEARCH PLAN

A. INTRODUCTION

1. Objectives

- To compare the selection of malnourished children with a high risk of death obtained by measurement of weight for age and arm circumference.

- To determine whether defining malnutrition from the variations of a nutritional indicator over time improves the selection of 'at risk' children compared to what is obtained by taking into account just one measurement.

- To determine what degree of accuracy is needed for measuring nutritional status to select 'at risk' malnourished children.

- To determine to what extent the risk of death associated with the same degree of malnutrition varies with age.

- To determine whether the usual limit of 5 years for nutritional screening is optimal or whether a limit based on weight or arm circumference would not be more appropriate.

2. Background

Regular growth monitoring with the use of weight chart is usually considered as a prerequisite to reduce infant and child mortality in under 5 children (1). UNICEF presents it as a priority and put growth monitoring at the top of the list of actions to be implemented to produce a spectacular reduction of infant and child deaths in the years to come (2). All around the world, many poor countries spend a substantial proportion of budgets available for nutrition programmes to buy scales, to design and to print various models of growth charts and to teach people how to use them.

There are many reasons to be sceptical about the relevance of all these actions. First, charting growth by itself is unlikely to help in preventing death if it is not associated with an adequate programme to treat 'at risk' children (3). Growth charts used without an attached intervention programme are so inadequate that some refer unkindly to them as the "road to death" charts. The complexity of the origin of growth faltering suggests that vague nutritional advice and support will not be enough in most cases. This means that nutritional screening should be simple and cheap enough to leave resources available for a suitable intervention. It is doubtful that the "road to health" growth chart fulfills this criteria for countries with limited health budgets. In addition, its superiority in its present form to select 'at risk' children is not clearly established (Table I). Before advocating its use on a wide scale,

TABLE 1

1. Weight for age is the best nutritional indicator to select children with a high risk of death.
2. Measurement of variations of nutritional status over time improves the selection of 'at risk' children.
3. The previous hypothesis implies that scales with a high accuracy are desirable for screening programmes.
4. The risk of death is the same for the same degree of malnutrition independently of age.
5. Nutritional monitoring should be continued up to the age of 5 irrespective of the child's nutritional status.

Current assumptions with respect to growth charts in their present form.

several questions should be answered first:

a) Is weight for age or arm circumference the best indicator for screening 'at risk ' children ?

We know from a few cross sectional studies in Punjab, in Bangladesh and in Zaire that for lowest weight for age categories, the risk of death is higher than for well nourished children from the same community (4-6). However, the quality of the assessment of risk of death by weight for age was poor in all these surveys. None of them would have allowed adequate targeting

for an intensive nutritional intervention susceptible to reduce substantially the number of deaths in these communities: sensitivity specificity curves show that selection of children with weight for age measured cross sectionally leads the inclusion of very large numbers of children in the 'at risk' category to obtain a satisfactory level of sensitivity.

Arm circumference measurement was proposed more than ten years ago as a low cost alternative to weight measurement in the assessment of nutritional status (7). Yet, the best assessment of risk of death ever obtained in a community by cross sectional nutritional screening was found in a study in rural Bangladesh using arm circumference without correction for age or height (8). Unfortunately, weight for age was not taken during this survey and a direct comparison of the validity of these two indicators on this sample is not possible. A previous study on nutritional status assessed by anthropometry and the subsequent risk of death in rural Bangladesh also suggested that arm circumference, without correction for age, gave as estimation of the risk of death slightly better than weight for age (5, 9). In this study however, weight were censored for upper categories and a rigorous comparison of the validity of these indicators cannot be derived from the data. In a yet unpublished study from ICDDR,B Dhaka hospital (10) where all classical anthropometric indices were carefully collected, arm circumference was again found to give an estimation of the risk of death slightly superior to weight for age. The hospital environment however may not be relevant to determine the validity of nutritional indicators to be used at the community level.

Arm circumference is much easier to measure in the field than weight for age. Therefore, weight for age can be recommended only if it is shown to be clearly superior to arm circumference. Available evidence suggests that arm circumference could give an evaluation of the risk of death as good or maybe slightly better than weight for age. A rigorous study is needed however to test this hypothesis adequately in a community.

Weight for height has been proposed as an alternative to weight for age when age is not known (11). In two studies however, this indicator ranked far behind arm circumference without correction for age to assess the risk of death (5, 10). Height for age was also found to have no predictive value once arm circumference was already taken into account (8, 10). The validity of height related indices will not be tested in this protocol.

b) How useful are longitudinal measurements ?

We know from a previous study from Bangladesh that in terms of specificity and sensitivity, the estimation of the risk of death given by arm circumference can be dramatically increased by using short follow-up periods (8) which can be obtained by repeating cross sectional measurements. Whether the quality of the prediction obtained in such a way can be increased by incorporating arm circumference variations over time among the criteria used to select 'at risk' children is an open question. We do not know, to what extent repeated cross sectional

measurements of weight for age will improve the estimation of the risk of death. We do not know either if inclusion of variations of weight or weight for age over time in the definition of malnutrition improves the estimation of the risk of death. Yet, the use of growth charts is based on this hypothesis. Since plotting weights on a chart is time consuming and requires some degree of formal training (12), this assumption has to be tested.

c) How accurate should be the assessment of nutritional status?

The relevance of weight variations for the selection of 'at risk' children has major implications for the choice of scales to be used in the field. If these variations are important to know, most portable scales who have an accuracy of about 100 g are not suitable. After one year, monthly weight gain, even in a healthy child, is low (about 200 g) and to derive it from the difference between two measurement, a 100 g accuracy is clearly not enough. In practice, this can be obtained only with heavy mechanical scales or with expensive electronic equipment. Alternatively, if weight variations do not matter but if weight itself only is related to the risk of death, very rough cheap scales could be enough for screening: reading errors account usually for a very small fraction of the variance of weight in a sample of children (10).

This argument has some relevance also for the choice of the indicator for screening. Usually, arm circumference is considered as a 'second choice' indicator of nutritional status

since it is difficult to assess with a precision of more than 1% or 2% even by a skilled anthropometrist. This compares unfavorably with the accuracy of 0.1% or 0.2% which can be achieved with high precision weighing scales. If such an accuracy is irrelevant for selecting 'at risk' children, this argument in favor of weight measurement for screening might be shown to be fallacious.

d) What is the effect of age on the risk of death associated with malnutrition ?

In its present form, the growth chart assumes that children who lose weight or fail to gain weight for two consecutive months are 'at risk'. Age is not taken into account in this definition, although we know this factor is a very important factor: failure to gain weight for two months at the age of 4 months is incomparably more dangerous than for a child of four years. Sticking too strictly to the rules of the growth chart will lead to an underestimation of risk of death in young infants and undue alarm for older children.

This problem can be overcome by designing growth charts representing functions of weight and age (or arm circumference and age) giving the best discrimination between children who will survive and those who will die instead of giving the normal growth curve of healthy children. If it can be shown that these functions are independent of age within large limits as found in a previous study for arm circumference (8), this would give a weight limit below which the child should be considered 'at risk'

independently of his age. This would make the selection of 'at risk' children much easier and more effective.

e) When should we stop screening ?

In its present form, the growth chart implicitly recommends that growth monitoring should continue up to the age of 5 with a special emphasis on children below the age of 3. The rationale for these limits is not clear. In two set of data where this question has been addressed (8, 10), nutritional indicators were found better indicators of the risk of death than age itself in terms of specificity and sensitivity. This means that for instance, a limit based on arm circumference would be more appropriate than the traditional age limit. In practical terms, this can have major implications: original data on the study of the relation between arm circumference and mortality (8) suggest that if instead of the age limit of 36 months, screening is stopped for children with an arm circumference above 130 mm, the same number of death will be predicted, although the number of children to be screened is reduced by 30%. Correction of this small detail in the conception of the growth chart may considerably reduce the cost of screening. Available data however were not collected to chose this limit adequately and a precise answer to this question has to be included in the aims of this protocol.

3. Rationale

-The choice of weight charts in their present form is based on a series of untested hypotheses.

-Arm circumference could be an indicator of nutritional screening as good, if not better than weight for age.

-The relevance of longitudinal monitoring of nutritional status has never been established.

-The degree of precision needed for the assessment of nutritional status has never been adequately determined.

-The interaction between the effect of age on the risk of death associated with malnutrition has never been estimated.

-The age limit beyond which nutritional screening is no more recommended may be inadequate.

-Efficacy and simplicity of nutritional screening might be dramatically increased by designing a method optimising the discrimination of children who die from those who survive in a set of carefully collected anthropometric data.

B. SPECIFIC AIMS

-To measure weight and arm circumference with a maximum of precision in about 1800 under 5 rural Bangladeshi children living in a community where age is known.

-To derive from the data of children who died before the age of 5 and those who survived an optimal method of nutritional screening.

C. METHODS OF PROCEDURE

1. Study population

This study will take place near Chandpur, an Upazila headquarters in Comilla district located 40 miles from Dhaka on the Meghna river. Since 1983, ICDDR,B has carried out a the field comparison of WHO and cereal based ORS (No 83 024). In a study area located 8-12 miles from Chandpur along the Comilla highway with a total population of 12000 inhabitants, growth monitoring of a cohort of 1800 under five children has continued for 2 years. The same team of trained health workers and dedicated supervisors known to the community will be used for this new protocol. All under 5 children from the same study area will be included in this study. Children of the previous study cohort who will still be below the age of five at the beginning of this new protocol will be included. This should give a total sample of 1800 children, the exact number depending on the number of births occurring during the study since all newborn infants will be included. Chandpur is under ICDDR,B demographic surveillance and vital events have been recorded weekly since 1980. This means that the age of every under five child is known with precision which allows the use of weight for age growth charts in ideal conditions.

2. Duration of the study.

The number of deaths occurring among under five children in the study population is the main criteria for determining the duration of the protocol. Previous studies on the relation between anthropometry and mortality indicate that approximately

40 deaths are needed to obtain interpretable results. Data from previous years in the same community suggests that some 50 deaths may be expected every year in the 6-60 months age group. A duration of two years should yield a number of deaths large enough to give an answer to the questions raised by this protocol. A smaller duration of the study does not seem appropriate however since measles vaccination may be introduced in the coming months and substantially reduce the number of deaths to be expected in the study population.

3. Anthropometric measurements

Weight and arm circumference will be taken every month by carefully trained and supervised health workers following the routine established during the previous protocol. Weight will be measured by electronic scales to the nearest 10g at the same time of the day to minimize the effect of diurnal variation.

Arm circumference will be measured with plastic insertion tapes which minimize the reading mistakes (13) to the nearest 2mm.

For this protocol, height will not be measured. Previous studies on the relation between anthropometry and mortality show that none of the nutritional indices based on this variable has any predictive value when arm circumference or weight for age are already taken into account (8, 10).

4. Collection of dietary and morbidity information

Basic information on dietary and morbidity histories will

also be collected during this study. Most likely, some children will die from diseases such as chronic diarrhoea which first result in a pronounced weight loss. If weight charts are analysed without morbidity information, the risk associated to these diseases could be attributed to weight loss. This confounding factor can be easily recognised if basic morbidity and dietary data are included in the analysis. The attached form adapted from the form already used by Health Workers in Chandpur for the Rice Based ORS Protocol shows the information which will be collected every month.

5. Attitude towards severely malnourished or critically ill children

Before the beginning of the study, every health worker will be given basic training in health and nutrition education in order to be able to give sound advice every time they see a child with unsatisfactory growth. They will be asked to inform families about immunisation programmes and will assist in providing a capsule of vitamin A for all children enrolled in the study. Whenever they come across a critically ill child, they will be asked to propose to refer him to the project physician, at Matlab hospital or Chandpur medical government facilities with ICDDR,B transport.

6. Data collection.

Data collected by field workers will be checked by a Senior Health Assistant (level 4) and coded in Chandpur by a

Coding Assistant (level 3). Data entry will be carried out in Dhaka.

7. Statistical analysis.

a) Comparison of weight for age and arm circumference as estimators of the risk of death.

In this first step, data will be analysed as if they were cross sectional: cumulative frequency tables for weight, weight for age, arm circumference and arm circumference for age will be calculated for different 6-months age groups from data of children who were still alive 6 months after the measurement. These data from survivors will be used for comparison with children who died during the 6 months following measurement. Cumulative frequency tables will be calculated for different 6 months age groups for children who died within 1, 2, 3 and 6 months of measurement. Then, sensitivity specificity curves of different nutritional indicators will be derived from these cumulative frequency tables for different age groups and different durations of follow-up (14). If necessary, several age groups will be pooled together to obtain meaningful results for older children with a lower risk of death. This will rank the relevance of every indicator used cross-sectionally to assess the risk of death. This will also be done by a second method using different univariate logistic models (15) for which goodness of fit will be measured by the Hosmer and Lemeshow statistics (16). Survival will be used as a dichotomous dependent variable,

measurements of children who died after different follow-up periods and those of age matched survivors being used as independent variables.

b) Assessment of the relevance of nutritional status variations in the selection of 'at risk' children.

For each child who died and for every age matched survivor indicators of variations of anthropometric measurements such as their difference, their ratio and the slope of their variations from month to month will be calculated. These indicators of nutritional status variation will be included as potential predictors to previously calculated univariate logistic models. Their significance to improve the assessment of the risk of death will be assessed by comparison of the log likelihood statistic (15). It will be tested also whether these indicators are still significant when morbidity and dietary variables are already included in the logistic model.

c) Estimation of the degree of precision needed for assessment of nutritional status.

From the original data, new files will be created by adding computer generated random numbers to anthropometric measurements. This will reproduce the data set which would have been obtained by using scales of different accuracies. These measurements will be used with the models found most effective to predict deaths in the previous analysis and the effect of these 'measurement errors' on their goodness of fit will be measured by the Hosmer Lemeshow statistic (16). With the log likelihood

statistic of these different models (15), it will be determined what level of error measurement significantly alters the estimation of the risk of death.

d) Determination of the effect of age.

Age will be included among the potential estimators of the risk of death. Its interactions with other variables will be investigated with the standard techniques used for logistic models (15). Then, its relevance to improve the assessment of the risk of death will be tested by determining to what extent it improves the models by the log likelihood statistic.

e) Determination of the optimal limit for nutritional screening.

Sensitivity specificity curves of nutritional indices and of age to estimate the risk of death will be compared. The potential benefit which can be obtained from a limit based on a nutritional status indicator instead of chronological age will be estimated. This analysis will be repeated after introducing random errors on real age in order to see the effect that an imprecise knowledge of age may have on such an approach.

D. SIGNIFICANCE

This study will test the relevance of the present approach to select 'at risk' malnourished children. Growth charts raise many logistic problems, especially in places like Bangladesh

where women's movements are restricted, where nutritional screening should be done at home and where many mothers feel that weighing may be dangerous for their child (17). This study may produce a simpler growth chart designed especially to screen malnourished children with a high risk of death which would be more effective than the present one for that purpose. Alternatively, it may show that weight measurements have no advantage compared to arm circumference for nutritional screening which would have major practical implications.

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DIETARY AND MORBIDITY INFORMATION TO BE COLLECTED

Coding sheet.

Oedema:	Oedema present:	1
	Oedema absent:	2
Breast feeding	Breast fed:	1
	No breast fed:	2
Meals in 24 hours		exactly
Diarrhoeal episode	Simple diarrhoea:	1
	Watery diarrhoea:	2
	Blood mucoid diarrhoea	3
	No diarrhoea	9
Duration of diarrhoea		exactly
Number of days ORS used		exactly
Treatment of diarrhoea	IV	1
	Drug	2
	Other	3
	Hospital	4
	IV + drug	5
	IV + other	6
	IV + hospital	7
	Drug + other	8
	Not applicable	9
	Drug + hospital	10
	Other + hospital	11
	Un-treated	12
	Any three type	13

End result of diarrhoea episode	Cured at home	1
	Cured at hospital	2
	Continues	3
	Expired at home	4
	Expired at hospital	5
	Still in hospital	6
	End result unknown	7
	Not applicable	9
Non diarrhoea episode	Measles	1
	Respiratory infection	2
	Fever	3
	Skin disease	4
	Night blindness	5
	Other	6
	Not applicable	9
Treatment	Drug	1
	Indigenous	2
	Spiritual	3
	Combined treatment	4
	Un-treated	5
	Unknown	6
	Not applicable	9
Outcome of episode	Cured	1
	Continues	2
	Expired	3
	Unknown	4
	Not applicable	9

ABSTRACT SUMMARY FOR ETHICAL REVIEW COMMITTEE

1. Description of the study

This study aims at evaluating whether methods now recommended to select 'at risk' malnourished children can be improved or simplified. The growth chart recommended by UNICEF for that purpose raises many practical problems and arm circumference measurements may be as effective at a much lower cost.

This protocol will take place near Chandpur in a community where ICDDR,B has been monitoring growth for several years for the needs of an other protocol on rice based ORS. Arm circumference and weight of children will be measured every month by community health workers (CHW) who already regularly visit every household. At the end of the study, anthropometric measurements of children who died under the age of 5 and of those who survived will be compared. The best indicator of risk of death will be determined by appropriate statistical methods.

Health workers will be asked to inform mothers if they find that their child is malnourished and will be trained to give sound nutritional education to the families. If the condition of a child is severe, the CHW will be asked to refer him to the project physician.

2. No risk, physical or psychological will result from this protocol.

3. NA

4. Children examined during this protocol will be identified by a code number and anonymity will be protected during the analysis.

5-6. NA

7. Individual subjects examined during this protocol will benefit from the presence of the project physician in case of disease. If hospitalisation is needed they will be referred to Chandpur or ICDDR,B hospital with ICDDR,B transport.

8. NA

BUDGET:

(based on the asumption that cost of common services will be shared by other protocols taking place in Chandpur)

1. Personnel

Designation	Level/step	No of persons	% time	Cost per year
Principal Investigator	NA	1	20	Not supported by ICDDR,B
Co-investigator	National B	1	10	640
Senior Health Assistant	4/10	1	100	3130
Health Assistant	3/10	2	100	5200
Porter	1/5	2	100	3280
Security Guard	1/6	1	100	1695
Driver	2/7	1	100	2010
Clerk	2/10	1	20	450
Coding Assistant	3/10	1	25	650
Data entry technician	3/10	1	25	650
		Total for 1 year		17 705
Estimation for 2nd year (+30% increase of local salaries)				23 015

Subtotal: 40 720

2. Supplies and Material

Office stationery including paper, files, etc...	1000
Candies for children	200
Raincoats (7 pieces)	125
Umbrellas (15 pieces)	100

Carrying bag (10 pieces)	150
Diskettes of Microcomputer (10 pieces)	50
3. Equipment	
Electronic scales (4 pieces)	2000
Measuring tapes (25 pieces)	25
4. Emergency Medicine	400
5. Vehicle Maintenance	1500
6. Transport	
Field trips and back, 40km per day 310 days per year (25 000 km)	
7. Travel and transportation of persons	
a. local	
Dhaka-Matlab-Chandpur: 2 trips per month x 24 months Chandpur-Matlab-Dhaka 2 trips per month x 24 months each trip 20 US $	2000
per diem (200 days)	
b. International 1 international travel per year.	5000
8. Transport of things	200
9. Rent, Communications, Utilities, Furniture	
Office Rent for 24 months	750
Local communication:	200
Utilities	200
Office desk, table, chairs	250
10. Computer services	500

11. Printing, Xeroxing, Publications	500
Total	64 370
Overhead (30%)	83 681