Attachment 1.   Date 18 - Feb 88
                                                                      22/2
ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator A. BRIEN   Trainee Investigator (if any) _____
Application No. 88008 / V FAUVEAU   Supporting Agency (if Non-ICDDR,B) _____
Title of Study IS NUTRITIONAL   Project status:
MARASMUS PREVENTABLE   ( ) New Study
BY TARGETED INTERVENTION   ( ) Continuation with change
                                     ( ) No change (do not fill out rest of form)

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Circle the appropriate answer to each of the following (If Not Applicable write NA).
1. Source of Population: 5. Will signed consent form be required:
    (a) Ill subjects   (Yes) No   (a) From subjects   Yes No
    (b) Non-ill subjects   (Yes) No   (b) From parent or guardian
    (c) Minors or persons   (if subjects are minors) Yes No
         under guardianship   (Yes) No   6. Will precautions be taken to protect
2. Does the study involve: anonymity of subjects   Yes No
    (a) Physical risks to the   7. Check documents being submitted herewith to
         subjects   Yes (No)   Committee:
    (b) Social Risks   Yes (No)   ____ Umbrella proposal - Initially submit an
    (c) Psychological risks   overview (all other requirements will
         to subjects   Yes (No)   be submitted with individual studies).
    (d) Discomfort to subjects Yes (No) ____ Protocol (Required)
    (e) Invasion of privacy Yes (No)   ____ Abstract Summary (Required)
    (f) Disclosure of informa-   ____ Statement given or read to subjects on
         tion damaging to sub-   nature of study, risks, types of quest-
         ject or others   Yes (No)   ions to be asked, and right to refuse
3. Does the study involve: to participate or withdraw (Required)
    (a) Use of records, (hosp-   ____ Informed consent form for subjects
         ital, medical, death,   ____ Informed consent form for parent or
         birth or other)   Yes (No)   guardian
    (b) Use of fetal tissue or   ____ Procedure for maintaining confidential-
         abortus   Yes (No)   ity
    (c) Use of organs or body   ____ Questionnaire or interview schedule *
         fluids   Yes (No)   * If the final instrument is not completed
4. Are subjects clearly informed about: prior to review, the following information
    (a) Nature and purposes of   should be included in the abstract summary
         study   (Yes) No   1. A description of the areas to be
    (b) Procedures to be   covered in the questionnaire or
         followed including   interview which could be considered
         alternatives used (Yes) No   either sensitive or which would
    (c) Physical risks   Yes No NA   constitute an invasion of privacy.
    (d) Sensitive questions Yes No NA   2. Examples of the type of specific
    (e) Benefits to be derived Yes No NA   questions to be asked in the sensitive
    (f) Right to refuse to   areas.
         participate or to with-   3. An indication as to when the question-
         draw from study   (Yes) No   naire will be presented to the Cttee.
    (g) Confidential handling   for review.
         of data   (Yes) No
    (h) Compensation &/or treat-
         ment where there are risks
         or privacy is involved in
         any particular procedure Yes No NA   (PTO)

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

_____   _____
Principal Investigator   Trainee

SECTION I - RESEARCH PROTOCOL

1. Title: **IS NUTRITIONAL MARASMUS PREVENTABLE BY TARGETED INTERVENTIONS ?**

2. Principal Investigators: A Briend, V Fauveau

   Coinvestigators: FJ Henry, Md Yunus, J Chakrabhorty

3. Starting date: As soon as the protocol is approved

4. Completion date: 18 months after the starting date

5. Total cost: US $ 10 443

6. Source of Funding:

7. Scientific Division: This protocol has been approved by the Community Medicine Division.

Signature of the Programme Head: _____

Date: _____18/2/88_____

1

7. Abstract:

Clinical marasmus is a major cause of death in rural Bangladesh and its prevention is a priority. However, interventions which can be done on a wide scale on all under 5 children are very few. Hence, it seems necessary to target interventions on smaller groups of high risk children. Although the association between poverty, lack of maternal education, inadequate feeding practices and severe malnutrition is well documented, none of the studies done so far indicate whether these associations are strong enough for targeting interventions. In this protocol, it is proposed to investigate by a case control approach whether severe protein energy malnutrition occurs in limited groups of children from easily identifiable high risk households.

8. Reviews

    a. Ethical Review Committee:_____

    b. Research Review Committee:_____

    c. Director, ICDDR,B:_____

2

SECTION II - RESEARCH PLAN

1. INTRODUCTION

A. Objective

This study plans to investigate to what extent severe protein-energy malnutrition occurs in small numbers of children from easily recognisable high risk households.

B. Background

a) limitations of un-targeted interventions

More than half of children deaths in the age group 6-36 months in Matlab is associated with a low mid-upper arm circumference (MUAC) (MUAC <= 110mm) (1). These children death can be attributed to marasmic since low mid-upper arm circumference is characteristic of marasmus defined as a clinical condition with severe muscle wasting (2). A nutrition rehabilitation unit (NRU) has been set up recently in Matlab to treat the most severe cases but its capacity is limited and it cannot accommodate more than 10 % of severely malnourished children screened every month. Prevention of marasmus is therefore a priority to have any noticeable impact on child mortality (1). Community health workers (CHWs) visiting every family bi-weekly in Matlab are instructed to give messages of health and nutrition education whenever there is a young child in the household. However, because of time constraints, this intervention is superficial and unlikely to be very effective. More intensive support is limited by the size of the population covered by Matlab MCH-FP services.

3

Clinical marasmus is a rare event in Matlab (1). The majority of children grow satisfactorily and are free from major complications. It seems therefore appropriate to concentrate one's efforts on children who are most at risk of becoming severely malnourished (3). This requires however that these children can accurately be recognised in the community. Available evidence suggest that this approach is not straightforward.

b) Review of the literature

Many studies have shown that demographic, socio-economic, dietary and medical factors are significantly related to the child's nutritional status or growth (4-37). Their main findings are summarised in Table 1 to 3. Some general statements can be made from them:

1)Many factors are known to be associated with malnutrition
With a few exceptions, all studies found an association between socio-economic, demographic, medical indicators and nutritional status. It seems reasonable to attempt to use some of them to recognise children at risk of severe malnutrition.

b)Relation between risk factors and prevalence of malnutrition never adequately quantified
One can recommend specific preventive measures in the community only with an understanding of the quantitative effects of different factors on malnutrition. Yet, the quantitative aspects of the risk of severe malnutrition has

4

not been adequately investigated in previous studies. None of these clearly spells out the relative and attributable risks associated with different risk factors, nor their specificity and sensitivity. Some studies did calculate a correlation coefficient between socio-economic and nutritional indices (25, 34, 37). All of them found a weak association and explained less than 5% of the variance of nutritional status by socio-economic indicators suggesting that targeting based on socio-economic indicators may be little effective.

c)Lack of multivariate analysis

Most of the previous studies used bivariate analysis to examine the relationship between these socio-economic indicators and malnutrition. However, many of these risk factors are closely related and it is likely that only few of them would remain significantly related to nutritional status in a multivariate analysis.

d) Type of malnutrition and age not adequately taken into account

Most authors used definitions of malnutrition based on weight-for-age. This indicator tends to classify as malnourished older children, usually stunted and not wasted, with a lower risk of death compared with definitions based on arm circumference (38). Yet, it seems likely that factors associated with malnutrition vary with age (25, 27) and that the factors relate differently to wasting and

5

stunting (32, 35). Risk factors selected in previous studies with definitions based on weight for age may not be relevant for programs aiming at reducing infant or child mortality using arm circumference to detect high risk children.

Need for a new study

To prevent clinical marasmus by targeted interventions several conditions must be fulfilled (3):

a) one or a few selected risk factors must be sensitive ie, must be present with a high frequency among malnourished children.

b) these same factors must be specific ie, they should be rare among healthy children.

c) these factors should have a high attributable risk.

d) these factors should be amenable to interventions

Review of available literature does not give reliable indications on whether clinical marasmus is preventable or not by targeted interventions since none of these questions have been adequately addressed. The proposed protocol aims at answering these questions for rural Bangladesh.

C. Rationale

- Treatment of severely malnourished children is limited by its cost and the capacity of treatment facilities and is unlikely to have a major impact on child mortality.

- Potential interventions to prevent malnutrition are limited by the number of children under surveillance.

- Interventions should be focused on a small number of high risk children.

- Adequacy of indicators to detect children with a high risk of malnutrition has never been assessed.

2. SPECIFIC AIMS

To identify risk factors which could be used to target preventive interventions on a small number of children with a high risk of becoming severely malnourished.

3. METHODS & PROCEDURES

This study will take place in the Matlab MCH-FP area. It will use a case control approach (40) to determine risk factors associated with clinical marasmus. The study will last 18 months: 3 months for testing and improving the questionnaire and training the field workers, 12 months of field work and 3 months for analysis and report writing. During their training, the fields workers will work in the Matlab Nutrition Rehabilitation Unit in order to be able to advise families of malnourished children who cannot be referred. Field part of the study will last 12 months to eliminate any bias in the findings due to seasonality.

Definition of cases and controls

In Matlab MCH-FP area, MUAC is measured regularly in all

7

children between the ages 6-59 months to select children who need referral to the Matlab Nutrition Rehabilitation Unit (NRU). MUAC is measured monthly in children with a MUAC found below 120 mm and 3-monthly for those above that cut-off point. Approximately 200 children (among the 18 000 under screening) are found every month to have a MUAC less than 110mm. They will be eligible to be selected as cases. Children with MUAC > 120mm will be the controls. Children with an arm circumference between 110mm and 120mm (expected to represent approximately 8% of screened children) will not be included in the study to avoid "contamination" of cases and controls groups.

Selection of cases

Matlab MCH-FP area is divided into 4 blocks (A to D). Community Health Workers (CHW) of each group have a monthly meeting where they report to their supervisor the number of children with a MUAC below 110mm they found during the month. To select the cases, during these meetings, each CHW will be asked serially (in a random order) to report to the field team the registration number of children with low MUAC until there are enough cases for a month of field work.

Selection of controls

For each case, 2 controls will be selected (see discussion of sample size). To avoid overmatching, the controls will not be taken in the same village as the cases. To reduce the cost of the study, the two controls will be selected in nearby paras in the same block as the case. They will be matched by age (+ or - 2

months) and sex since the association of these two factors with low arm circumference is already known and can be quantified outside this study.

To select the controls, a bari from the same block will be randomly selected and from the birth registers, the first two children closest to that bari meeting the matching criteria will be chosen.

Sample size

Formal calculation of sample size in this case has little meaning since a large variety of risk factors will be investigated with different prevalences. It is better to estimate the number of cases and controls which can be seen during the field part of the protocol and then to estimate the smallest detectable risk for different hypotheses of risk factor prevalence in the controls (40). The results of this calculation are presented in Table IV assuming that between 100 and 200 cases will be seen with 2 controls per case. Levels of detectable risks suggest that this study will be on the safe side to detect risk factors already found in similar studies.

The number of controls per case to choose depends on the relative cost of finding controls compared to cases (40). In this study, once the field worker went to a randomly selected bari to interview a first control, there will be little additional cost in interviewing a second one in a nearby para.

Field procedure

After selecting cases and controls, a female Health

9

Assistant (HA) will be sent to the corresponding villages. After identifying the child under investigation, she will explain the aims of the study to the family and ask consent from the mother (or guardian) for the interview. Then, she will measure MUAC (to check whether the child is rightly assigned to the case or control group) and start the interview. All answers will be recorded on precoded sheets to facilitate data entry on the computer. At the end of the cases-interviews, she will propose referral to Matlab Nutrition Unit by ICDDR,B transport. If the family refuses referral, the interviewer will give nutritional and health advice for the recovery of the child.

The questionnaire to be used is presented in Annex 1. It was designed to research the risk factors already found in previous studies and a few additional which are thought relevant by the investigators. The questions were adjusted to the Bangladesh rural situation but their relevance will be tested in the field at the beginning of the protocol. Part of the dietary and morbidity history (ie diarrhoea point prevalence, age of introduction of solid food) will be collected from the record book of the Chws to avoid bias in recording. Information about contraceptive use will be collected in the same way to avoid sensitive questions from a unknown field worker. All children and their households will be identified by numbers to preserve confidentiality.

Statistical analysis

Preliminary statistical analysis will be done by standards methods (41). Odds ratios will be calculated for all different

risk factors for boys and girls at different age groups (42). If there are no significant differences in the odds ratios between these categories (after testing heterogeneity), then data will be pooled. Sensitivity, specificity and attributable risk will be calculated for all the risk factors significantly related to marasmus (43,44). Relevance of these factors will then be tested by logistic regression (42).

4. SIGNIFICANCE

If the study shows that a few easily recognisable factors amenable to change are closely related to marasmus with a high attributable risk, (for instance, late introduction of solid food, chronic diarrhoea) this will indicate priorities for prevention. On the other hand, if it is found that marasmus occurs largely at random and that it is not possible to predict its occurrence, then this will mean that prevention of marasmus by focused interventions is not possible. Case finding and treatment, however unsatisfactory, would become the priority. Finally, it is quite possible that the factors which most closely related to the risk of marasmus will be outside the scope of intervention of the health sector (for instance: family income, maternal education). In this case, this protocol will give an estimate of the maximum reduction (if any) of prevalence of malnutrition which can be expected from health interventions.

TABLE I: Factors significantly related to malnutrition in a previous study.

a) Demographic

Maternal age	Li, Jo
Marital problems	Jo
Father living outside home	Ga
Being a girl	Li, Jo, Ba, Sv, Ph
Birth order	Ja, Li, Ni, Ga, Ph
No contraceptive use	Ly
Family size	Le, Li, Sv, Br
Next pregnancy within 1 year	Jo, Za
Caretaker	Zi

b) Socio-economic

Mother's education	Le, Li, Ba, Fa, Br
Father's education/ occupation	Le, Ba, Za, Br, Gu
House size/ type	Le, Li, Ja, Ga, Ba, Br
Family income/ land	Le, Li, Ba, Sv, Zi, Gu, Br
Household possessions	Le, Li, Ga, Ba

c) Medical History

History of prolonged diarrhoea	Le, Ja, Ly, Jo
Repeated illnesses	Jo, Ph
Lack of immunisation	Le
History of hospital admission	Le, Li, Sv
Clinic distance /attendance	Ja, Sv, Zi
Malnutrition in a sibling	Jo

d) Dietary and Nutrition History

Birth weight	Ja, Jo
Length of breast-feeding	Le, Li, Sv
Type of supplementary food	Li
Age of introduction of solid foods	Le, Li
Bottle feeding	Le, Jo
Maternal weight	Za

e) Environmental factors

Washing facilities	Le
Faeces disposal	Le, Ga
Water supply	Le, Ga, Br
Type of kitchen	Le

Le: Lebanon (9) Ly: Libya (21) Ja: Jamaica (31) Jo: Jordan (26) Ga: Gambia (32) Ba: Bangladesh (37) Za: Zambia (22) SV: St Vincent (23) Zi: Zimbabwe (28) Br: Brazil (35) Gu: Guatemala (25) Ph: Philippines (30) (reference number).

TABLE II: Other factors likely to be related to malnutrition.

a) Demographic

    Twin
    Orphan
    Death of a sibling

b) Socio-economic

    Maternal employment
    Religion

c) Medical History

    TB in the family

d) Dietary and Nutrition History

    Breast infection
    Nipple malformation

e) Environmental factors

    Refuse disposal

TABLE IIIa: Odds ratios associated with different risk factors of malnutrition in Libya (Ref. 21 Calculated from tables. Not in the original article).

Indicator	RR	95% CL
Diarrhoea > 1 month	6.7	2.6-17.1
Mother less than 16 years	6.1	1.6-22.8
Family size > 6 members	5.2	2.0-13.4
Birth rank > 4	4.9	2.1-11.5
Mother illiterate	4.2	1.7-10.4
Less than 4 rooms in the house	2.8	1.2-6.6
Being a girl	3.5	1.5-8.0
No contraceptive use	2.7	1.1-6.3

TABLE IIIb: Odds ratios associated with different risk factors of malnutrition in Jordan (Ref. 26 Calculated from tables. Not in the original article).

Indicator	RR	95% CL
Repeated diarrhoea	14.4	4.8-41.9
Next pregnancy within a year	12.3	4.1-36.5
Early bottle feeding	10.9	4.9-24.4
Malnutrition in a sibling	8.8	4.0-19.6
Repeated illnesses	7.4	3.1-17.9
No breast-feeding	6.9	2.3-21.0
Marriage before 17 years	5.3	2.8-9.9
Birth rank > 4	4.9	2.1-11.5
Marital problem	4.6	1.5-14.4
Mother illiterate	3.7	1.9-7.0
Being a girl	3.7	1.9-7.0

TABLE IV. Smallest detectable risk (power : 90%, level of significance: 0.05) given different sample sizes (values for 2 controls per case).

Prevalence of risk factor among controls (%)	Detectable risk	
	For 100 cases	For 200 cases
10	2.03	1.84
20	1.94	1.62
30	1.83	1.54
40	1.79	1.51
50	1.80	1.51

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Annex 1

QUESTIONNAIRE

CHILD'S IDENTIFICATION

Case-Control Set No: _____.   Control No:_____

Date of examination ___/___/_____

RID !_____!   CID !_____!

Date of Birth ___/___/_____   Birth Order: _____

Sex: Male (1) Female (2) Twin (Y-N)

MUAC !_____! Oedema: (Y-N)

Guardian: Mother (1) Grand mother (2) Other (3)

MOTHER

RID !_____!   CID !_____!

Year of birth : _____

Married (1) Divorced (2) Lives outside (3) Widowed (4) Dead (5)

Date of divorce / death / death of husband: ___/___/___

Never went to school (1) Went to school (2)

Grade passed !_____! Years of religious education !_____!

Number of living children: !___!   boys: !___! Girls !___!

Number of other under 5 living children: Boys !__! Girls !__!

1st: Boy (1) Girl (2) DOB ___/___/___

2nd: Boy (1) Girl (2) DOB ___/___/___

3rd. Boy (1) Girl (2) DOB ___/___/___

Number of children who died before 5 years !__!

Pregnant: (Y-N) (*) Under contraceptive: (Y-N) (*)

Sick: (Y-N) - If yes, disease: _____

(*) Take this information from record book / family register

FATHER

Lives in the household (1) Migrated (2) Dead (3)

Never went to school (1) Went to school (2)

Occupation: 1st_____2nd_____

Grade passed !_____! Years of religious education !_____!

FAMILY STATUS

Number of people living in the house (with children): !_____!
(Exclude migrated, married members living outside)

Owns land (Y-N)   If yes: number of decimals: !_____!

Rents out land (Y-N)   If yes: number of decimals: !_____!

Cultivates land (Y-N) If yes: own land: number of decimals !_____!

                              rented land: number of decimals !_____!

Owns cows: (Y-N) Number:_____

Owns a boat (Y-N) If yes: personal use (1) source of income (2)

                  Income per month from the boat !_____!

Pond for fish culture (Y-N)

If yes: personal consumption (1) source of income (2)

Income per year from the pond !_____!

Amount of food reserves in the house _____ (in mauds)

Household appliances: hurricane lamp (Y-N) watch (Y-N) fan (Y-N)

radio (Y-N) electricity (Y-N) wooden bed (Y-N) quilt (Y-N)

fishing net (Y-N) plough (Y-N)

ESTIMATION OF INCOME

Number of earning members in the family: !__!

	Income per day	Working days/week	Income per month
1)			
2)			
3)			
4)			

Remittance: !_____! per month

Debts (Y-N) Amount !_____!

Money in the bank (Y-N)   Amount !_____!

Tax paid last year (Y-N) Amount !_____!

Muslim (1) Hindu (2)

HOUSE

mainly made of: Straw (1) Tin mixed (2) Tin (3)

Size (measure): length !_____! width !_____! (in feet)

WATER AND SANITATION

Tubewell: in the bari (1) in the para (2) No tubewell (3)

Distance (in feet): |_____|

Drinking water: Tubewell (1) River (2) Pond (3) Canal (4)

Cooking water: Tubewell (1) River (2) Pond (3) Canal (4)

Latrines : No (1) Open pit (2) Closed pit (3) Sanitary (4)

Used by Women (1) Adult men (2) Children (3)

Washing hands: (mother)

Before eating: Never (1) Sometimes (2) Always (3)

After defecation: Never (1) Sometimes (2) Always (3)

Done with: Water only (1) Mud + water (2) ash + water (2)
            Soap + water(3)

DIETARY HISTORY

Ever Breastfed (Y-N)   Ever bottle-fed (Y-N)

Still breastfed (Y-N)   Still bottle-fed (Y-N)

Eats suji (Y-N)   Eats adult type food (Y-N)

Month stopped breast feeding (*) |_____|

Month introduction of adult type food (*) |_____|

Maternal MUAC |_____|

Size at birth: very small (1) small (2) Medium (3) Large (4)

Other marasmic children in the family (Y-N)

Problems during breast-feeding: inverted/flat nipple (Y-N)

Breast abscess (Y-N) Feeds during night > 3 months (Y-N)

(*) Take this information from record book

MEDICAL HISTORY

Diarrhoea for more than 2 weeks: (Y-N)

If yes: Type of diarrhoea: Non bloody (1)   bloody (2)

In the last 3 months: Number of episodes: !___! (*)

Watery diarrhoea: !__! Bloody diarrhoea !__! (*)

Number of respiratory infections   !__! (*)

Chronic cough (TB) in the house: Yes (1) No (2)

(*) Check consistency of this information with record book

CONSENT FORM (Verbal)

ICDDR,B is now conducting a survey on factors determining nutritional status of young children. We would like to ask you some questions about yourself, your child, your family and your living conditions. The interview will last about 45 minutes. All the information collected will be kept confidential.

You are free to take part or not to take part to this interview. If you feel some questions are too inquisitive, you just not reply to them.

BUDGET

PERSONNEL REQUIREMENTS

NEW RECRUITS

Job	Level	No	Months	%	Tks/year	Amount (US $)
Field Res. Off.	GS5	1	15	20	81000	675
Health Assist.	GS3	2	15	100	49000	4063

SUPPLIES AND MATERIAL

Diskettes for microcomputer	35
Computer stationery	50
Microcomputer	1300

INTERDEPARTMENTAL SERVICES

Transport Dhaka Matlab Dhaka	500
Water transport Matlab	2000
Xerox	200
Medical illustration	100

TRAVEL INTERNATIONAL

Participation to a regional conference	1500

TOTAL (US $)	10443

ABSTRACT SUMMARY FOR ETHICAL REVIEW COMMITTEE.

This protocol aims at determine whether clinical marasmus occurs mainly in easily recognisable high risk families. It will take place in the Matlab MCH-FP area.

This protocol will rely on interview and observation. Some information routinely collected during service activities will also be used.

An identification number will be used to preserve confidentiallity of the data.

No sensitive questions will be asked to the families.

It is hoped that this protocol will allow a better targeting of MCH activities in Matlab.