Attachment 1.

Date 18/10/88
21/11/88

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Claire Tauveau Mizan Siddiqi
Trainee Investigator (if any) _____
Application No. 88028 (Rev)
Supporting Agency (if Non-ICDDR,B) _____
Title of Study # Targeted intervention Preventing Protein-energy malnutri- in slum children
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
   (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 N A
   (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 N A
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 a 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.

C Tauveau — Mizan Siddiqi
Principal Investigator — Trainee

88-028 (Rev)
21/11/88

SECTION I : RESEARCH PROTOCOL

(1) Title: A targeted intervention for preventing protein-energy malnutrition in slum children.

(2) Principal Investigators: Claire Fauveau and Mizan Siddiqi

Co-Investigators: André Briend
Diana R. Silimperi

Consultant: Shakuntala Thilsted

(3) Starting Date: November, 1988

(4) Completion Date: May, 1990
12 months field part
6 months for analysis and report writing.

(5) Total direct cost: $15,070

Source of funding: Urban Volunteer Program

(6) Scientific Program Head:

This protocol has been approved by the CHD Working Group.

17/10/88

Signature of the Scientific Program Head

Date:

7. ABSTRACT SUMMARY

This study aims at comparing the impact of food supplementation and weaning education on the growth of a small group of children. This study will take place in a Dhaka slum. One hundred and fifty children selected for this study will be in the age range 6 to 9 months All these children will come from the catchment area of a nearby Nutrition Rehabilitation Centre where the most severely malnourished children will be referred. Study children will be randomly allocated into two groups, one in which weaning education will be accompanied by food supplements,and one with weaning education alone, and their growth will be followed by monthly weighing. It is expected that if there is any difference in growth, it will be detected within a year of field work.

(8) Reviews: Community Health Division

(i) Ethical Review Committee _____
Approved/not approved

(ii) Research Review Committee _____
Approved/not approved

(iii) Director's Signature and Remark, if any

_____

_____

SECTION II: RESEARCH PLAN

INTRODUCTION

A) **Objective:**

To evaluate the impact of a preventive targeted nutrition programme on the nutritional status of at risk children (6-12 months).

B) **Background:**

At the national level, malnutrition is less prevalent in urban than in rural Bangladesh.[1] However, there is growing evidence that in the slums, the situation is worse than in the rural areas.[2] The Urban Volunteer Programme (UVP) for several years tried to address this question by setting up Nutrition Rehabilitation Centres (NRC) to treat severely malnourished children in the community. Although some success has been obtained in terms of short term improvement of nutritional status[3], this approach has clearly major limitations:

(a) The number of children which can be reached by this approach is too low to have any significant public health impact.

(b) The cost of the treatment of a malnourished child in these NRC, is presumably too high to replicate this type of intervention on a large scale.[4]

(c) This approach is mainly curative.

On the long term, the NRC should be associated and ideally replaced by preventive interventions.

Although, there is a debate going on the respective role of lack of food and repeated infections at the origin of malnutrition in Bangladesh, it is clear that insufficient food intake during the weaning period is involved in the process.[5] Introduction of solid foods rarely takes place before the age of 12 to 18 months.[6] Rice flour boiled in large quantities of water is the main food than children receive in addition to breast-milk before that period which is clearly inadequate. A preventive action should address this question in priority, whether it takes the form of a weaning food distribution programme or of intensive nutrition education during the weaning period.

Many studies showed that indiscriminate distribution of food has little, or even maybe no impact at all on the prevalence of child malnutrition.[7] Adequate targeting seems to be a key of the few successful food distribution programmes.[8,9,10]

Previous studies in ICDDR,B showed that children really at risk of death from malnutrition can be easily recognized in the community just by measuring mid-upper arm circumference (MUAC).[11] It seems also that between 6 and 12 months of age, growth of children tend to join a narrow channel that they then follow with little deviations throughout the weaning period, or even later.[12] This suggests that preventive interventions should be directed

towards children of this age range who have a low MUAC and are the most likely to become malnourished later on. Children with a low MUAC represent a small percentage of all under 5-children and even in a large slum with a large total population, should represent a number small enough to be easily amenable to intervention. Some controversy exists regarding the need to give weaning food to prevent malnutrition or to limit oneself to educational inputs.[6, 7] This protocol will explore in the community whether food distribution with nutrition education is more effective than nutrition education alone for preventing malnutrition in this high risk group of children.

C) **Rationale:**

(a) Children who are underweight at the age of 6-12 months are at a high risk of remaining underweight and becoming malnourished later on in life.

(b) Interventions to prevent malnutrition seem to be cost-effective only when addressing a small number of high risk children.

(c) These children represent only a small proportion of under-5 population and are a suitable target for interventions.

(d) If proven effective, such a program could be implemented at large scale at reasonable cost.

This protocol will determine whether weaning food distribution with nutrition education is more effective to prevent malnutrition than nutrition education alone in this small high risk group.

D) Methods:

Study area

This study will take place in the Shahidnagar slum (Lalbagh thana), in the surroundings of a NRC operated by the UVP since 1987. The catchment area of this NRC has been estimated by mapping and household census in 1987. The total population is about 30,000 . This is a low income area with 75% of household heads having a daily income of 50 Takas or less.[12]

Study design

Selected children will be randomly allocated into two groups: a group will receive food supplement and weaning education and the other one weaning education alone. For simplicity, the first one will be referred as intervention and the second one as control group. Randomization will be done at the "bari" level to ensure that children from nearby households are allocated in two different groups.

Nature of the interventions

Ten Community Nutrition Workers (CNW) with 8 years of education will provide to the intervention group a weekly

distribution of a low-cost cereal pulse mixture to be cooked with oil. This prepacked powder will daily provide 350 calories if given 3 times. The intervention group will get practical demonstration at home and emphasis will be given on hygiene and conservation of the food. Other under 5 children from the family will receive an extra packet. Different preparations will be tried for acceptability. Minimal amount of sugar will be added to increase acceptability, if needed. At the beginning frequent home visits will be made.

The mothers of both groups of children will receive monthly half an hour weaning education emphasising the need for frequent feeding and the importance of fat to cover energy needs in this age group. The session will be conducted at home. The importance of breast-feeding will also be stressed. Children and mothers from both the treatment and control groups will be offered the same primary health care services provided by the CNW, including ORS packets, in case of diarrhea, referral for immunizations and family planning and referral to local health facilities in case of severe infection. Children from both groups will be taken by the CNW to the nearest immunization center for measles vaccine at 9 months of age. Children will be weighed monthly and bi-weekly health record will be kept in both groups. The only difference to be evaluated between the two groups will be the impact of the supplementary weaning food.

Selection of study children

An initial screening will be performed by Field Research Officers (FROs) along with the CNW before the onset of the intervention to measure MUAC of all children between 6 to 9 months. They will refer to the NRC all children aged 6 to 9 months who have a MUAC less than 110 mm. These severely malnourished children will receive adequate treatment in the NRC and, if needed, will be referred to another treatment facility (SCF Child Nutrition Unit.) They will not be included in the preventive intervention. In addition to that, the screening team will note the identity, address and MUAC of all children aged 6 to 9 months. This information will be given to the supervisor of the project who will randomly assign the study children to either intervention or control group. They will be selected in order of A.C. starting from 110 mm onwards until the sample size is reached.

Sample size

The study aims at detecting a difference in weight between the two groups of 400g after 6 months of intervention. Analysis will be carried at 6 months and will aim at detecting differences in weight gain of 400g or more and if a significant difference is found in the 2 groups, food distribution will be started in both groups. Previous ICDDR,B studies (Chandpur Project, Mirzapur Handpump Project, unpublished) suggest that in this age group, weight gain over 3 months has a standard deviation of about 600g.

With this information, usual formulas were used to calculate sample size[13] and it was found that for a power of 80% at the 5% level of significance, a total of 70 children in each group is needed for this study.

Monitoring the impact

Children from both areas will have their weight taken monthly for a period of 6 months after the enrollment into the study. The impact of food supplementation will be evaluated by comparison of mean weight gain in each group after 3 and 6 months using a t test after checking that weight gain distribution is normal.

Significance

If distribution of food on a limited number of high risk children can substantially improve their growth, this may be proposed to reduce the prevalence of severe malnutrition at the community level.

ABSTRACT SUMMARY FOR ETHICAL REVIEW COMMITTEE

The purpose of this study is to determine whether food supplement associated with weaning education distributed to a small number of 6 to 9 months children with a high risk of malnutrition can substantially improve their growth. This study will take place in Lalbagh slum of Dhaka. This study will be carried out in six months. Impact will be evaluated on growth velocity.

1. The study population will be children aged between six to nine months.

2. The study does not involve any potential risk to participants.

3. Not applicable

4. The names of the subjects, their area or any identifying charecteristics will not be published or available to the public. Data will be maintained using code numbers.

5. a) A written consent will be obtained from the child's parent/legal guardian. The study involves no risk to the subjects.The purpose of the research will be honestly and carefully explained to the parents /legal guardian. Intrusive or unwelcome interviews will be avoided. Apart from taking arm circumference and weight, no physiological tests, procedures or measurments will be carried out. If however, the researcher or their assistant come accross sick individuals in the course of the study who ask for their help, they will do their best to help and to refer and to transport them to the appropriate health center.

b) Not applicable.

c) Not applicable.

6. Interviews and education sessions will be conducted at time and places that best suit the mother in home.

7. Intervention children will receive weaning food and both intervention and control group will receive measles vaccination,weaning food education of mothers and referral to appropriate health facilities.The parents/legal gurdian will be informed about the results of the study.Health and nutrition information will be made available to the entire community.

8. The study does not require the use of records, organs, tissues or any other such matter.

CONSENT FORM

The Urban Volunteer Programme of ICDDR,B is trying to improve the nutritional status of young children in this area. We propose to come and visit you regularly to advise you on the best way to feed your child (and we will provide you some food to prepare the recipes that we think are good for the growth of your child*). To follow the growth of your child, we will measure his weight every month. We will inform you of its progress.

You are free to withdraw from this study whenever you want.

*to be read in intervention areas only

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Name of the respondant Signature or thumb impression

Witness (CNW) Signature

_____

_____

_____

সম্মতি পত্র

আই.সি.ডি.ডি.আর,বি -এর আরবান হেলথ্‌ট্রিয়ার প্রোগ্রাম আপনার এলাকার ছোট বাচ্চাদের পুষ্টির অবস্থার উন্নতি করার চেষ্টা করছে। আমরা প্রস্তাব করছি যে, আমরা আপনাকে নিয়মিত দেখতে আসব এবং আপনার বাচ্চাকে কি করে হালোভাবে পুষ্টিকর খাবার খাওয়ানো যায় সেই সম্পর্কে উপদেশ দেব (এবং আমরা আপনার বাচ্চার জন্য এমন খাবার দেব যা আপনার বাচ্চার স্বাস্থ্যের উন্নতিতে সহায়তা করবে বলে আমরা মনে করি। *)। আপনার বাচ্চার স্বাস্থ্যের উন্নতি হচ্ছে কি না দেখার জন্য প্রতি মাসে আমরা বাচ্চার ওজন নেব এবং তার স্বাস্থ্যের উন্নতি সম্পর্কে আপনাকে জানাব।

এই গবেষণা কাজ থেকে আপনার যখন ইচ্ছা তখনই চলে যাবার স্বাধীনতা রয়েছে।

*যাদের খাবার দেয়া হবে শুধুমাত্র সেক্ষেত্রে পড়তে হবে।

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উত্তরদাতার নাম স্বাক্ষর অথবা টিপসহি

(সি.এন.ডব্লিউ-এর স্বাক্ষর)

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2. Henry F. Preliminary results of a study comparing rural and slum prevalence of malnutrition. Personal communication.

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12. Khan MU, Growth & Development Studies: Rural Meheran, Comilla - Bang Med J7, 74-90, 1979.

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14. Center for Urban Studies. Dhaka University. 1988

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SECTION III DETAILED BUDGET

) PERSONNEL (3100)

	No.	Level	Rate/month (Tks)	Yearly (Tks)	Dollars
PI	1	NOC	24,000	288,000	9,600
PI	1	NOA	-	-	-
FRO	4	GS-5	-	-	-
CNW-Supervisor	2	-	1,200	14,400	480
CNW	10	-	4,000	48,000	1,600
) TRAVEL (Local) (3500)			1,350	16,200	540
) SUPPLIES AND MATERIALS (3700)					
(a) Food			3,750	45,000	1,500
(b) Stationary			1,250	15,000	500
) PRINTING & REPRODUCTION (4300)					
(a) Xerox and Medical illustration			625	7,500	250
) OTHER COSTS					
(a) Grain breaking			500	6,000	200
(b) Helpers for packaging and carrying food			500	6,000	200
(c) Training Stipend (CNW) & Materials			500	6,000	200
			37,675	452,100	15,070

Budget under the UVP Core Budget Code #300211.

B. BUDGET SUMMARY

	A/C Code	Expense Category	Amount in dollars
1.	3100	Personnel Salaries	11,880
2.	3500	Travel	540
3.	3700	Supplies	2,400
4.	4300	Printing and Xeroxing	250
		Total direct cost	15,070
		+	
		Indirect cost (31%)	4,671
		Total:	$ 19,741

2 Weeks Health Recall

1) Did the child have abnormal stool since my last visit? Yes ¦_____¦

No ¦_____¦

2) Which type - watery/liquid ¦_____¦

- mucoid diarrhea ¦_____¦

- dysentery ¦_____¦

3) How many days since my last visit? _____

4) Any other condition

Yes ¦_____¦

No ¦_____¦

Describe:

দুই সপ্তাহের স্বাস্থ্য সম্পর্কিত বৃত্তান্ত

১।	আমার মেয়েবার আসার পর, বাচ্চার কি অস্বাভাবিক ধরণের পায়খানা হয়েছে ?	।____।
২।	কি ধরণের পায়খানা হয়েছে ?	
	পানির মত পাতলা	।____।
	আমাশা	।____।
	রক্ত আমাশা	।____।
৩।	কতদিন	।____।
৪।	অন্য কোন অসুবিধা	।____।
	বর্ণনা	।____।

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URBAN VOLUNTEER PROGRAM
ICDDR,B

5 to 9 months identification survey

Team # |_____| Bustee bari # |_____| (if any) Detailed address area name _____

Map Road # |_____| Survey bari # |_____| |_____| |_____|

Child # per bari	Name of Child	Sex	Age(m)	AC (mm)
|_____|	_____	|___| |___| |___||___||___|

Mother's Name

_____

BF |___| Stay >3 months |___|

Sex	M 1 F 2
BF	Y 1 No 2
P will Stay in same house more than 3 months	Y 1 No 2

Landlord's Name

_____

Household head name

_____

LWFP:ID Survey:DOI 11/88

Annex 1.

ble 1. Quantity , energy, protein content and cost of the daily food supplement

Name of food	Amount (g)	Energy (Kcal)	Protein (g)	Cost (Tk.)
Rice flour	30	104.7	2.5	0.36
Wheat flour	30	102.3	3.6	0.30
Dal flour	15	51.4	3.7	0.33
Oil	15	132.6		0.36
Water	300			
Total cooked volume	240	391 Kcal	9.8	1.35

Process of cooking

Mix 5 teaspoon of the mixture in 100 ml of cold water. Add 1 teaspoon of oil then cook it for three minutes. Let it cool down Add some salt before serving.

Annex - 2

MESSAGES

- Continue breast feeding for at least 2 years.
- Add semi-solid food at 6 months of age
- Feed the child enough food (at least 3 times/day).
- Add oil to the porridge. It is well digested by the child.
- Continue to feed the child when sick.
- Wash your hands before preparing and serving food.
- Keep food well covered.

cl/clara