

Date - 19/4/84

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Dr. A. M. Hossain Trainee Investigator (if any) 215  
 Application No. 84-018 Supporting Agency (if Non-ICDDR,B) CNU  
 Title of Study Effect of acute protein energy malnutrition (PEM) on the absorption of macromol-  
ecules in Bangladesh children Project status: Iskaton  
 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).

- Source of Population:
  - (a) Ill subjects Yes No
  - (b) Non-ill subjects Yes No
  - (c) Minors or persons under guardianship Yes No
- Does the study involve:
  - (a) Physical risks to the subjects Yes No
  - (b) Social Risks Yes No
  - (c) Psychological risks to subjects Yes No
  - (d) Discomfort to subjects Yes No
  - (e) Invasion of privacy Yes No
  - (f) Disclosure of information damaging to subject or others Yes No
- 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
- 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
- Will signed consent form be required:
  - (a) From subjects Yes No
  - (b) From parent or guardian (if subjects are minors) Yes No
- Check documents being submitted herewith to Committee:
  - Umbrella proposal - Initially submit overview (all other requirements will be submitted with individual studies)
  - Protocol (Required)
  - Abstract Summary (Required)
  - Statement given or read to subjects of nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)
  - Informed consent form for subjects
  - Informed consent form for parent or guardian
  - Procedure for maintaining confidentiality
  - Questionnaire or interview schedule

\* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:

- 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.
- Examples of the type of specific questions to be asked in the sensitive areas.
- An indication as to when the questionnaire will be presented to the Committee for review.

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

Ayub Molla Principal Investigator 215 Trainee

REF

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SECTION I - RESEARCH PROTOCOL

1. TITLE: Effect of Severe Protein Energy Malnutrition (PEM) On The Absorption of Macronutrients In Bangladeshi Children.
  
2. PRINCIPAL INVESTIGATORS: Dr. Ayesha Molla  
Dr. A. M. Molla
  
3. CO-INVESTIGATORS: Dr. Sultana Khanam, Ms. Makhduma Khatun, A Research Physician and Mr. N. Majid.
  
4. CONSULTANT Dr. M. Mujibur Rahaman
  
5. STARTING DATE May 1984
  
6. COMPLETION DATE May 1985
  
7. TOTAL DIRECT COST US \$38,860 (incremental cost \$24368)
  
8. SCIENTIFIC PROGRAM HEAD: Dr. M. Mujibur Rahaman

This protocol has been approved by the Nutrition Working Program.

Signature of Scientific Program Head:

Date:

*M. Mujibur Rahaman*

*12/4/1984*

## 9. ABSTRACT SUMMARY

Forty male children aged between 1½ to 3 yr with severe protein energy malnutrition without any signs of systemic infection or after successful treatment of systemic infection will be selected both from Children's Nutrition Unit (CNU), Dhaka and ICDDR,B treatment centre and will be studied in the metabolic study ward of ICDDR,B hospital or at the recovery ward of Children Nutrition Unit. Children under study will be divided into two equal groups, Marasmic (classified as wt. for height  $\leq$  60% of NCHS standard and without oedema) and kwashiorkor/marasmic-kwashiorkor (60 to 80% wt. for height and with oedema). Two main diets containing low (30% kcal derived from fat) and high (50% kcal from fat) concentration of fat will be given to each group of patients. In addition the patients will receive all clinical care and will be treated following a scheme of management for malnourished children as has been established in the Children Nutrition Unit. The quantitative intake of food at the beginning of dietary rehabilitation and at the end of recovery will be estimated. The ability of the patients with severe protein energy malnutrition to absorb different macronutrients fat, nitrogen, carbohydrates and calories will be assessed during two phases of the study.

The acceptability and the effect of low and high fat diet on their early rehabilitation will also be studied.

## SECTION II - RESEARCH PROTOCOL

A. INTRODUCTION1. Objectives:

The ultimate goal of this study is to find out how soon a child with severe protein energy malnutrition can be rehabilitated with an available and familiar high energy Bangladeshi diet of known composition.

2. Background:

Following international nutrition surveys (WHO 1972) it was suggested that about 85 to 90 million children below the age of five suffer from moderate to severe degree of malnutrition. Similar data was also obtained in the recent Bangladesh Nutrition Survey. According to WHO, protein energy malnutrition can be defined as: "a range of pathological conditions arising from a coincident lack, in varying proportions of protein and energy, occurring most frequently in infants and young children and commonly associated with infections." Two extreme conditions for severe protein energy malnutrition are kwashiorkor and marasmus. Several factors, like poverty, poor hygienic conditions, infectious diseases specially diarrhoea, various socio-economic factors and maternal ignorance in child rearing practices are responsible for precipitation of severe PEM. Many studies have shown a very close association between malnutrition and mortality (1,2). Recently, in one of the studies conducted in Matlab, a field study area of ICDDR,B it was demonstrated that severely malnourished children (wt. for age 56%) had a risk of death 14 times more than that of their well nourished counterparts (66% wt. for age). It was emphasised that immediate priority should be given in providing nutritional rehabilitation, which will help in reduction of the young children (3). The most important causes of secondary PEM are,

1) reduced intake due to decreased appetite or anorexia  
2) diarrhoea and malabsorption leading to unavailability of nutrients to the body and 3) increased rate of catabolism in various infectious diseases. PEM depresses the body's immune function, with reduction of resistance to infection (4). Thus excess supply of nutrients specially protein and calories are essential to cope with the increased need of these nutrients during PEM. Also, serum level of micronutrients like vitamin A, folic acid, calcium, phosphorus, potassium, magnesium and iron were reported to be low (5-11) in PEM. However, the body can make use of outside supply of macro and micronutrients if they are administered in optimum proportions. In 1978, Waterlow et al (12) described two main principles for feeding children with severe protein energy malnutrition. According to him, feeding high energy and high protein diets should be introduced gradually in view of the fact that children with severe PEM might not be able to tolerate and assimilate the nutrients in the body and might go into heart failure due to high cardiac input. Based on the same principle, Rees and Brook (13) carried out a trial in children with diarrhoea aged six weeks to 4 years where three formula feeds e.g. 1) a full strength milk 2) 0.18% sodium chloride and 4% dextrose in water till diarrhoea settled, followed by a full strength milk immediately and 3) 0.18% sodium chloride and 4% dextrose solution till diarrhoea settled following gradual introduction of full strength milk. The results did not show any significant difference in the length of their hospital stay and the usual course of recovery. However, it needs to be emphasized that children with acute diarrhoea are different from the children with severe PEM who needs intensive clinical attention as well as carefully selected dietary therapy. According to the second principle of Waterlow et al (12), in order to reduce the danger of hypothermia, hypoglycaemia and to avoid overloading the gut, food should be given in small amounts e.g.

one hourly feeds for the 1st and 2nd days of hospitalization. According to Alleyne et al (14) therapeutic diets in PEM was provided in Uganda and Jamaican children as shown in Table 1. To reduce hypoglycaemia and hypothermia, formula feeds were given frequently through the whole day to achieve 150-200 kcal/kg/day for marasmic and 110 kcal/kg/day for kwashiorkor till the oedema disappears and diuresis was achieved. After that to achieve maximum rate of weight gain increased amount of milk feeds i.e. 150-200 kcal/kg/day were supplied (14).

In Dhaka, Eskaton, a Children Nutrition Unit (CNU) was established in 1975 by UK, Save the Children Fund, where marasmic, marasmic-kwashiorkor children have been treated successfully with mortality of only 5% of the total admission. In CNU, Dr. Sultana and her co-workers are using a diet regimen which contain local, inexpensive ingredients and is culturally acceptable and provides adequate nutrients to satisfy the requirement of the children aged  $1\frac{1}{2}$  to 5 years. The dietary regimen are presented in the Table 2. The formula for dried skimmed milk DSM (given 2 hourly for 24 hours), rice pudding or suji (given at breakfast at 8 a.m.), rice vegetable and meat mixture (given at 12 noon) or chapati who do not like rice, snack roll (at 3 pm) and dal, rice (given at 6 pm) are given in Table 3. Some children refuse to eat initially due to anorexia, and other complications and then accept food within a few days. All foods are salt free and offered ad libitum. At the beginning of 2nd week of hospitalization milk feed was reduced to 4 times (6 am, 10 am, 4 pm and 10 pm) with 180 mls of DSM each time. Solid cooked meals were offered 3 times at breakfast, lunch and supper. Egg, banana is given at special circumstances, usually when serum protein is lower than 3 gm% and in case of food refusal. In addition to the solid and milk feed, vitamin A, multivitaminic acid, ferrous sulphate, vitamin K, potassium, magnesium (and blood transfusion when indicated) are given routinely. In

case of clinically suspected iodine deficiency lugols iodine is commonly used. With the above dietary regimen feeding 200 kcal/kg/day in CNU, the children usually achieve maximum catch up growth and weighs up to 80 to 85% of weight for height of the Median Harvard standard. The average hospital stay is up to 4 weeks.

To obtain some basic informations with regard to quantitative intake and absorption of nutrients during the early and late phase of rehabilitation it is essential to formulate a proper nutritional therapy for the children with severe PEM. So far in the literature informations on absorption of macronutrients in severe PEM are lacking. In our previous studies (15) in children with acute diarrhoea and mild to moderate degree of malnutrition, evidence has shown that in general there is a negative correlation between absorption of nutrients and nutritional status of children. However, absorption of nutrients varied in different aetiology of diarrhoea and also different nutrients were absorbed with varying degrees of efficiency. The detailed findings of these studies are recently published (16-19). With this background information, a new study is designed to investigate the quantitative intake of nutrient and their absorption for evolving a high energy, culturally acceptable and easily available dietary regimen for rapid rehabilitation of children with severe PEM. We intend to carry out the study with two kinds of diet containing lower and higher quantity of fat during rehabilitation and find out if the length of rehabilitation process can be shortened with high fat diet.

### 3. Rationale:

Severe protein energy malnutrition (PEM) can be regarded as a scourge in the developing countries. Highest mortality was observed in 2 year aged children with severe PEM (3). Specific



information on intake and absorption of nutrients are needed for formulation of an effective dietary regimen for early and rapid nutritional rehabilitation. High energy diet is a key factor for rapid rehabilitation and the concentrated energy can only be provided through fat. Hence, it is essential to find out, to what extent diets with higher fat content are absorbed in children with severe PEM. These informations can be used as a guide for effective dietary therapy of the children with PEM.

B. SPECIFIC AIMS:

1. Estimate the quantitative intake of food and the co-efficients of absorption of nutrients (fat, nitrogen, calories and carbohydrate) in severely malnourished children in the early and later stages of rehabilitation.
2. Find out the extent of fat absorption from two diets containing lower (30%) and higher amount of fat (50%).

C. METHODS AND PROCEDURES:

Patients: Study patients with severe PEM will be selected both from the Children Nutrition Unit (CNU) and ICDDR,B treatment centre. However, to minimize compounding variables, it would be better if the metabolic study is done in Children Nutrition Unit. In case it is not feasible to carry out the study in CNU, the patients after preliminary investigations should be transferred to ICDDR,B. The classification of malnutrition will be done according to the existing practice of Children Nutrition Unit.

Selection Criteria

- i) 40 malnourished male children, aged between 1½ year to 3 years and completely weaned from the breast milk will be selected.
- ii) Nutritional status will be determined by weight for height percentage of NCHS standard and presence or

absence of oedema. Patients will be divided into 2 groups, one with 20 children and having 80-60% of standard wt. for ht. with oedema, will be accepted in the kwashiorkor group and the second 20 with  $\leq 60\%$  of standard wt. for ht. and without oedema will be taken in the marasmus group. Each twenty will further be subdivided into two equal groups each group having 10 children. Ten children from both the kwashiorkor or marasmus groups will receive diet 1 (low fat content) and rest will receive diet 2 (high fat content). Table 4 presents the criteria for selection. Table 5 and 6 present the low and high fat diets.

iii) Children having acute diarrhoea, liver disease, surgical conditions, injury, tuberculosis, septicaemia or any other severe systemic disease will not be included in the study. Children having urinary tract infection, upper respiratory infection or any other systemic infection with mild manifestations will be first treated by appropriate antibiotics and included into the study after the antibiotic course is over and successful clinical recovery.

### Procedure

Step I. Initially after admission, during the first 2 days, a thorough physical examination will be done and routine clinical investigations will be carried out. 3-5 mls of venous blood samples will be taken for blood culture, TC, DC, Hct, haemoglobin and total plasma protein. Stool and urine samples will be taken for microscopic examination and bacteriological culture. X-ray chest will be taken if indicated.

Step II. Children with severe PEM most often have associated diarrhoea, vomiting and dehydration. In presence of dehydration, patients should be treated with intravenous fluid routinely as usual in ICDDR,B. Amount and type of fluid to be given should be decided by the treating physician on clinical judgement

and guided by serum electrolyte results. Within 4 to 6 hours of rehydration therapy the children can be fed by mouth if the patients' condition permits.

Step III. If the patients are unable to eat due to ulcers in the mouth, anorexia or extreme debility, the feed will be homogenized into semi-liquid formula and fed through a nasogastric tube till the child is able to eat by mouth. For the first 3 days of hospitalization, feeding schedule will be kept as shown in Table 7.

Step IV. Nearly all malnourished children suffer from deficiency of vitamins and minerals. According to the usual practice of CNU, all children will be given folic acid, riboflavin, ascorbic acid, folfetab (and high potency vitamin A cap) throughout the whole period of rehabilitation.

Step V. Balance Study. After the first three days of hospitalization or at a time when it will be proved that the patient is free from any systemic disease, the balance study will be started. Before that all patients will be fed ad libitum two hourly as shown in Table 7 to provide 100 to 150 kcal/kg/day. The daily allowance of calories, fat and nitrogen per kg of wt. will be decided according to the standard practice in children nutrition unit. Seventy-two hour balance study will be carried out by using markers as previously published (16-19). Feeding schedules during balance study are given in Table 5&6. Quantitative measurements of all intake and output will be recorded. aliquotes of homogenized food and stool will be analysed for the content of nitrogen, fat, carbohydrate and calories according to standard techniques (20, 21). After the first 72 hour study the patients will continue getting the same diets and the progress interms of daily weight gain will be recorded. The progressive increase in calorie intake will be according to standard practice in Children Nutrition Unit and daily weight

gain will be recorded until the patient goes home i.e. weight for height will be at 85th centile or more. At that time a second 72 hour balance study will be carried out and this study will serve as the control of the previous one. A second blood sample of 2 ml will be taken for monitoring the biochemical improvement of the patient.

Step VI. Screening Tests for Malabsorption. D-xylose test is the only test available to assess generalized malabsorption. This test will be done by feeding 5 gram D-xylose dissolved in 100 ml of water on the day before starting the study. After 1 hour of drinking D-xylose solution, 0.5 ml of blood sample will be drawn for estimation of serum xylose level (22). Repeat xylose will be done on the day before the second balance study.

D. STATISTICAL ANALYSIS

- i) Intake of food and nutrients in marasmus and kwashiorkor group between the early and later stage of rehabilitation process will be compared using paired t test.
- ii) Co-efficients of absorption of nutrients in severe protein energy malnutrition will be estimated and compared with the recovery period of rehabilitation.
- iii) Correlation between weight gain and absorption of different nutrients will be done.
- iv) Ability of the patients to absorb higher amount of dietary fat at different degrees of malnutrition will be estimated and tolerance will be compared between the acute and recovery period of different nutritional status.

E. SIGNIFICANCE

For early rehabilitation of severely malnourished children, intake of increased calories is mandatory. Volume of the food often becomes a problem. Hence caloric dense diet will be a substantial help in this regard. Fat provides most calories among all the nutrients. But the ability of children with 3rd degree malnutrition in handling the higher amount of fat (50% of total energy) is not known. This study will provide valuable information in this respect and these informations will contribute significantly in the formulation of a proper dietary therapy for the early rehabilitation of these children.

F. FACILITIES REQUIRED:

- i) No new office space is required.
- ii) Laboratory facilities for routine microbiology, biochemistry and clinical pathology are adequate.
- iii) Statistical data analysis: Help of Statistical Branch will be utilised. Mini computer HP 85 will be adequate for the purpose of data analysis.
- vi) Hospital Resources: The study will utilise patients selected from the outpatient treatment centre of ICDDR,B and CNU. The balance study will be conducted in the metabolic ward of ICDDR,B or in CNU.

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SECTION III - BUDGET

## A. Detailed Budget

## 1. Personnel Services:

<u>Name</u>	<u>Position &amp; Annual Salary</u>	<u>% Effect</u>	<u>Project Requirement</u>	
			<u>Tk.</u>	<u>US \$</u>
Dr. Ayesha Molla	Assoc. Scientist Tk (494100.00)	25% 1 yr	123525.00	-
Dr. A.M. Molla	Scientist \$ (63741.00)	10% 1 yr	-	6,374.10
One physician ICDDR,B	(Gr.6 Step 1) Tk (76,376.00)	20% 1 yr	15275.20	-
One physician CNU	-	15% 1 yr	-	-
Dr. Sultana CNU	Medical Director	10% 1 yr	-	-
Mrs. N. Majid	Dietician Tk (64,608.00)	20% 1 yr	12921.00	-
Ms. M. Khatun	Res. Officer Tk (77,229.00)	20% 1 yr	15445.80	-
One Study Clerk	Tk.33,786.00	20% 1 yr	6757.20	-
Four cleaners	Tk.116,124.00	25% 1 yr	29031.00	-
Sub Total :			202955.20	6,374.10

2. Supplies and Materials:

Stationery Goods	2000.00	-
Xeroxing and mimeographing	2500.00	
Medical illustrations	1500.00	
PUC bags	-	300.00
Miscellaneous (including vitamins, minerals and medicines)	4000.00	-
	10,000.00	300.00





BUDGET SUMMARY

		<u>TK</u>	<u>\$</u>
1.	Personnel	2.02955.20	6374.10
2.	Supplies & Materials	10,000.00	300.00
3.	Equipment	-	-
4.	Laboratory tests	1,27966.00	-
5.	Transportation	22.500.00	-
6.	Patient Hospitalization	4,48000.00	-
		<hr/>	
	Total	8,11421.20	6404.10
	Grand Total in	\$ 38,860.84	
	Incremental Cost	\$ 24,368.00	

Table 1.

## MILK FORMULAE USED IN UGANDA AND JAMAICA (14)

Uganda (100 kcals, 2.8 gm protein in each 100 ml)		Jamaica (135 kcal, 3.14 gm protein in each 100 ml)	
Dried Skimmed Milk Powder	789 gm	Full Cream Milk	
Cotton Seed Oil	59 gm	plus added carbohydrate (Pelargon)	190 gm
Sucrose	47 gm	Arachid oil	55 gm
Kcl	1.0 gm		
Mg (OH) <sub>2</sub>	0.5 gm		
Made in 1 litre		Made in 1 litre	

Table 2

## DIETARY REGIMEN AT THE CNU, ESKATON

Food item	Marasmus	Marasmus- kwashiorkor	Kwashiorkor
Dried skim milk (DSM) given 2 hourly for 24 hrs using cup or spoon	150 ml/kg/day initially then increased up to 250 - 300 ml/kg/day	100 ml/kg/day	100 ml/kg/day
4 types of cooked solid meal (without salt). <u>Offered from the 1st day of admission at 8 am, 12 noon 3 pm &amp; 6 pm</u>	Offered ad libitum	Offered ad libitum	Offered ad libitum
3 types of cooked meal (breakfast, lunch, & supper) & 4 milk feeds (6am, 10am, 4pm & 10pm) <u>given at the beginning of the 2nd week</u>	Offered ad libitum	Offered ad libitum	Offered ad libitum

Table 3

FULL STRENGTH DSM (CNU)

DSM	-	80 gm
Vegetable Oil	-	30 gm
Glucose	-	67.5 gm
Made upto	-	1 litre

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828 calories/litre

RICE PUDDING

		<u>Kcal</u>	<u>Protein (gm)</u>
Rice 900 gm	-	3105	61.2
Sugar 200 gm	-	800	0
Milk 200 gm	-	714	76.0
After Cooking		68 Kcal %	1.94 gm %

RICE-MEAT-VEGETABLE

		<u>Kcal</u>	<u>Protein (gm)</u>
Rice 1200 gm	-	4152	76.8
Pumpkin 2000 gm	-	520	20.0
Meat 1200 gm	-	1368	271.2
Onion 10 gm	-	6	0.18
Oil 38 gm	-	270	0
After cooking		80 cals %	4.3 gm %

Table 3 (cont.)

<u>RICE-DAL</u>		<u>Kcal</u>	<u>Protein (gm)</u>
Rice 1000 gm	-	3460	64.0
Dal 700 gm	-	2401	175.7
Onion 10 gm	-	6	0.18
Spices 5 gm		0.9	0.05
<hr/>			
After cooking		77 cal %	2.9 gm %

<u>SNACK ROLL</u>		<u>Kcal</u>	<u>Protein (gm)</u>
Atta (wheat flour) 400 gm-		1384	42
Sugar 40 gm	-	160	0
Oil 10 gm	-	90	0
Yeast 2 gm	-	5	0.74

Table 4

SELECTION OF STUDY PATIENTS, WHO WILL BE  
GIVEN TWO EXPERIMENTAL DIETS

Particulars	Low Fat Diet (30%)	High Fat Diet (48%)
Age (yrs)	1½-3	1½-3
<u>Grades of Malnutrition</u>		
wt. for ht. and number of patients		
(a) (80-60% with oedema kwashiorkor/m. kwashiorkor	10	10
(b) < 60% No oedema marasmus	10	10

Table 5.

LOW FAT DIET AND THE FEEDING SCHEDULES  
FOR THE BALANCE STUDY OF SEVERE  
PEM PATIENTS (Age 1½ yr to 3 yr)

Energy required 1300 kcal  
Extra for wt gain - 500 "

Time	Cooked Food	Ingredients (gm)	Nutrient Contents		
			Prot (gm)	Fat (gm)	Kcal
7 am	Halua	Rice Powder 35	11.27	10.35	628
10 am		Dano 35 Sugar 60 Veg. Oil 10 Water 225			
10 am	Mild	Dano 16 Rice Powder 5 Sugar 10 Veg. Oil Water 200	4.5	6.27	158
12 noon	Rice Curry	Rice 50 Chicken 60 Onion 20 Veg. Oil 12	3.20 15.54	- 12.0	173 183
3 pm	Milk	as above	4.51	6.27	158
6 pm	Rice	as above	18.74	12.0	356
9 pm	Milk	as above	4.51	6.27	158
			62.28	62.16	1814
			13.7% of calories	30% of calories	

\* The solid diet of this Table will be prepared packaged in polythene bags, supplied twice weekly to CNU. These will be stored in -20°C and warmed to make it soft before feeding.



Table 6.

\*  
HIGH FAT DIET AND THE FEEDING SCHEDULES FOR THE BALANCE STUDY  
OF SEVERE PEM PATIENTS (Age 1½ yr to 3 yrs)

Energy Required - 1300 kcal  
Extra for wt gain - 500 kcal

Time	Cooked Food	Ingredients (gm)	Nutrient Contents			
			Prot (gm)	Fat (gm)	Kcal	
7 am	Halua	Rice Powder	25	8.05	38.67	576
		Dano	25			
		Sugar	35			
		Veg. Oil	25			
		Water	175			
10 am	Milk	Dano	16	4.38	9.27	162
		Rice Powder	4			
		Sugar	6			
		Veg. Oil	5			
		Water	200			
12 noon	Rice	Rice	35	2.24	8.0	193
		Veg. Oil	8			
	Curry	Chicken	60	15.54	12.0	183
		Onion	20			
	Veg. Oil	12				
3 pm	Milk	as above		4.38	9.27	162
6 pm	Rice & Curry	as above		17.78	20.0	376
9 pm	Milk	as above		4.38	9.27	162
				56.8	99.5	1814
				(13% of total calories)	(50% of total calories)	

\* The solid diet of this Table will be prepared packaged in polythene bags, supplied twice weekly to CNU. These will be stored in -20°C and warmed to make it soft before feeding.

Table 7.

TWO HOURLY FEEDING SCHEDULE FOR THE FIRST  
3 DAYS OF HOSPITALIZATION  
(100 TO 150 KCAL/KG/DAY)  
FOR A 8 KG CHILD

<u>Time</u>	<u>Coocked Food</u>	<u>Quantity (gm)</u>	<u>Kcal</u>
6 am	Halua <sup>*</sup>	50-100	90-180
8 am	Khichuri	50-100	140-280
10 am	Milk	80-100	64-100
12 noon	Khichuri <sup>**</sup>	50-100	50-100
2 pm	Halua	50-100	90-180
4 pm	Khichuri	50-100	50-100
6 pm	Milk	80-100	64-100
8 pm	Halua	50-100	90-180
10 pm	Khichuri	50-100	50-100
12 midnight	Milk	80-100	64-100
2 am	Milk	80-100	64-100
4 am	Milk	80-100	64-100
		750-1200 gm	880-1620

All feeds will be given ad libitum

\* Halua : See the preparation in Table 5.

\*\* Khichuri : Rice 80 gm, lentil 20 gm, chicken 30 gm,  
potato 25 gm, onion 25 gm, oil-20 ml.

Nutrient content prot. - 2.6 gm%, fat 2.9 gm%,  
Energy 100 kcal%.

CONSENT FORM

International Centre for Diarrhoeal Disease Research is carrying out studies to find out the impact of diarrhoea due to different casuses on absorption of nutrients in children. Similar studies were done on cholera, rotavirus, ETEC, Shigella and in diarrhoea due to Giardiasis. Now we intend to carry out a study on severely malnourished children to investigate the quantity of food intake pattern and absorption of nutrients during early and late phase of rehabilitation. If the age of your child is between 1½ and 3 years, severely underweight compared to normal (marasmic) and has oedema (kwashiorkor) will be admitted in the study. During the first three to four days of hospitalization, all sorts of infection will be diagnosed and treated. During this time 3 to 5 cc of blood will be taken for diagnostic purposes. The children will be fed milk formula in every two hour and if necessary, will be fed by using nasogastric tube. After that, a 72 hour balance study will be done. During this time babies will be fed, Milk, Halua, Rice, Chicken Curry etc. six times a day. Quantity of intake and output will be recorded and food, urine and stool will be analyzed in the laboratory. Before going home, another 72 hour balance study will be done in a similar way. To monitor the improvement of your child, 2 c.c. blood will be taken at this time for laboraotry investigation. For assessment of absorption status, xylose test will be done two times during early and late phase of rehabilitation. For this purpose, a total of 1 c.c. blood (0.5 c.c. each time) will be taken. For complete recovery, your child would need to stay in the hospital for 3 to 4 weeks and during this time one guardian should stay with the child in the hospital.

Entirely it depends upon your decision if you would like to participate in this study or not. However, if you decide not to participate, usual treatment for child will be provided. please give your signature if you decide to participate.

\_\_\_\_\_  
Signature of the Investigator

\_\_\_\_\_  
Fingerprint/Signature of  
the Guardian

Date \_\_\_\_\_



