ETHICAL REVIEW COMMITTEE, ICODR, B.

Pr:	incip	al Investigator Dys. Ay	esho f	101k	Train	nee In	evestigator (if any)	86
Apj	olica	tion No. 82.009	, प्र-	Holla			Agency (if Non-ICDDR,B)	
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Ciı	cle t	the appropriate answer to	o esci	h of t	he fo	11awi	ng (If Not Applicable wri	
1.	Sour	rce of Population:	. /	,	5.	TACAT	ing (if Not Applicable wri	te <u>NA</u>).
	(a)	Ill subjects	Yes	No	٧.	4777	signed consent form be r	
	(b)	NI * # #	Yes	No		(a)	From subjects	Yes No
	(c)	Minors or persons	.03	140-		(b)		/
	•	under guardianship	Yes	No	4	W-11	(if subjects are minors)	Yes No
2.	Does	the study involve:	.05	140	6.	MT17	precautions be taken to	protect
	(a)	Physical risks to the		,	.,	anon	ymity of subjects	Yes No
	, ,	subjects	Yes	No .	7.		k documents being submitte	ed herewith to
	(b)	Social Risks	Yes	No		COMM	 -	
	(c)	Psychological risks	163	NO		******	Umbrella proposal - Initi	ially su bmit ar
	•	to subjects	Yes	No			overview (all other requi	irements will
	(d)	Discomfort to subjects	Yes	_			be submitted with individ	iual studies).
	(e)	Invasion of privacy	Yes				Protocol (Required)	
	(f)	Disclosure of informa-	1.62	Nø			Abstract Summary (Require	> d)
	•	tion damaging to sub-		•			Statement given or read t	to subjects on
		ject or others	Yes	No			nature of study, risks, t	ypes of quest-
	Does	the study involve:	163	NO			ions to be asked, and rig	ht to refuse
	(a)	Use of records, (hosp-					to participate or withdra	w (Required)
	• •	ital, medical, death,		,			Informed consent form for	: subjects
		birth or other)	Yes	No			Informed consent form for	parent or
	(b)	Use of fetal tissue or	165	NO			guardian	
		abortus	Yes	Na			Procedure for maintaining	confidential-
	(c)	Use of organs or body	1 62	No			ity	
		fluids	Yes	17			Questionnaire or intervie	w schedule *
	Are:	subjects clearly informe	ies Joha	No		* 1f	the final instrument is n	ot .completed
	(a)	Nature and purposes of	u abo	ut:		pr:	ior to review, the followi	ng information
	` ,	study		31		sho	ould be included in the ab	stract summary
	(b)	Procedures to be	YWS	No .		1.	A description of the are	
	(-)	followed including					covered in the questionn	aire or
		alternatives used	کـد	N-			interview which could be	considered
	(c)	Physical risks	Yes	No			either sensitive or whic	h would
	(d)	Sensitive questions	Yes	Ne		٠.	constitute an invasion o	f privacy.
	(e)	Benefits to be derived	Yes	No		2.		specific
	(f)	Right to refuse to	Yes	No			questions to be asked in	the sensitive
	• •	participate or to with-					areas.	
		draw from study	VL	No		3.	An indication as to when	the question-
	(g)	Confidential handling	Ybs	No			naire will be presented	to the Cttee.
		of data	Yles	No			for review.	
		Compensation &/or treat	10.2	, NO		. *		
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		or privacy is involved	oro in.	سو				
		any particular procedure	4.51. M. Yafa	e Na				
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a	gree	to obtain approval of the	ne Et	hica1	Penri	ou Co	mittee For any stance	

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

Principal Investigato

Trainee

SECTION I - RESEARCH PROTOCOL

I. TITLE:

Nutrient Intake and Utilisation During

Diarrhoea in Children.

2. PRINCIPAL INVESTIGATORS:

Dr. Ayesha Molla and Dr. A.M. Molla

3. CO-INVESTIGATOR:

Dr. S.A. Sarker

4. STARTING DATE:

1st August, 1982

5. COMPLETION DATE:

July 1983

6. TOTAL DIRECT COST:

\$ 10,970.25

7. SCIENTIFIC PROGRAM HEAD:

Dr. M.M. Rahaman

The protocol has been approved by the Nutrition Working Group.

Signature of Scientific Program Head:

are: 21/6/1982

9. ABSTRACT SUMMARY:

From the previous study (Protocol No. 78-026) carried out on children with diarrhoea due to cholera, rotavirus, ETEC and shigella infection it was revealed that intake of nutrients like nitrogen, fat, carbohydrate and calories was reduced to about 30% compared to the recovery stage of diarrhoea. At about 2 weeks after actue diarrhoea the intake improved significantly. Absorption of nitrogen was mostly affected and absorption of carbohydrate was least affected during the acute diarrhoea of all aetiology studied so far.

The aim of the present research is to study the effect of diarrhoea, due to Giardiasis in the form of cyst and trophozoits, on intake and absorption of nutrients during the acute phase and after recovery. From this study new knowledge about the quantitative aspects of nutrient intake and utilisation would be expected to provide useful information for understanding the nutrient requirements under various gastrointestinal infections.

10. REVIEW:

(a)	Ethical Review Committee:
(b)	Research Review Committee:
(c)	Director:
(d)	BMRC:
(e)	Controller/Administrator:

SECTION II - RESEARCH PLAN

A. INTRODUCTION:

1. Objectives:

The overall objective of the study is to estimate the net effect of diarrhoea on the intake and utilisation of nutrients in children with diarrhoea due to Giardiasis. Food intake and absorption of nitrogen, carbohydrate, fat and calories was previously studied in ICDDR, B during acute and after recovery from diarrhoea due to cholera, rotavirus, E. coli and shigella infection. Results suggest that in acute diarrhoea food intake was approximately reduced to 30% compared to the intake at recovery period, and about 85% and 40% of the ingested carbohydrate and nitrogen respectively was utilised. Thus it can be hypothesized that similar effect may also be seen in diarrhoea due to Giardiasis. Information available from this study would provide new knowledge on nutrient requirements for the affected children and also will have important implications in dietary management and nutritional rehabilitation of these patients with Giardiasis, so common in countires like Bangladesh.

2. Background:

Diarrhoeal disease plays a significant role in the incidence of malnutrition. Recent surveillance research studies suggest that about 750 million children below 5 years of age in Asia, Africa and Latin America suffer from acute diarrhoea every year and between 3 and 6 million in this age group die from acute diarrhoea each year (1).

In general, it has been postulated that repeated attacks of diarrhoea may contribute in producing malnutrition and growth retardation by several mechanisms, these are: (i) reduced intake of food due to anorexia or withholding of food as a measure to control diarrhoea (ii) malabsorption or loss of nutrients in the feces and (iii) catabolism due to infection causing diarrhoea.

Studies in Guatemala showed that repeated attacks of diarrhoea in children upto 7 years of age lead to a significant grwoth retardation both in height as well as in weight which is not so characterisitic in illnessess other than diarrhoea. Martorell et al (2) estimated that about 42-70 Kcal/kg/sick day is needed to replace the lost growth in a child with diarrhoea. In other words, in a 10 kg. child, 420-700 additional Kcal will be needed for each sick day. Thus several questions are posed for possible investigation. These are as follows:

- (1) Does diarrhoea affect food intake of children?
- (2) And if intake is decreased, how long would it take for the appetite to come back to normal.
- (3) Should we offer food to a child having diarrhoea?
- (4) And if the food is consumed how much of it will be absorbed and retained by the body.

Some important informations were obtained from the historical work carried out by Chung and co-workers in 1948 (3). His studies showed that absorption of nitrogen and fat were linearly proportional to the amount of increased intake of calories. He also showed that weight

gain was higher and duration of diarrhoea was lesser in the fed group compared to the starved group of infants.

From our previous study conducted in ICDDR, B (4,5) it was revealed that the intake of calories were reduced to approximately 30% in the acute diarrhoea due to cholera, rotavirus, enterotoxigenic E. coli (ETEC) and shigella infection. Improvement of the intake was remarkable in the group of cholera compared to the rotavirus group.

Absorption of protein (nitrogen) was mostly hampered (about 40% of the intake) in the acute period of diarrhoea whereas absorption of carbohydrate was least affected (about 84%) in the acute stage of diarrhoea of all aetiology. Absorption improved rapidly at two weeks after recovery in all the aetiology except in rotavirus where it took about eight weeks to have the same level of absorption.

The important conclusion drawn from the above study was that, when food is offered, substantial amount is consumed and a significant percent of that is absorbed by the patient in diarrhoea of the four aetiologies studied so far. However, no such study was done to estimate the intake and absorption of nutrients in diarrhoea with Giardiasis, which is also prevalent in this part of the world and possibly plays a more important role on diarrhoea - malnutrition cycle.

The purpose of this present study is threefold: (i) pattern of food intake and absorption of nutrients like fat, nitrogen, carbohydrate and calories will be estimated, after the infants were encouraged to

eat; (ii) role of appetite will be studied in the process of quantitative intake throughout the acute and recovery phase of diarrhoea; (iii) finally, the results obtained from this study will hopefully enable physicians to better formulate the dietary regimen during and after diarrhoea. The long term goal of this study will be to prevent malnutrition leading to recurrent attacks of diarrhoea which is so common in the developing world.

3. Rationale:

The rationale for this study can hardly be over emphasised. The information known from the previous study cannot be extrapolated to the proposed target group of patients mentioned here. Therefore, the present research will help us in getting further informations regarding the absorption of food during and after attacks of diarrhoea due to giardiasis.

B. SPECIFIC AIMS:

The specific aims of the proposed study are:

- (1) To estimate quantitatively the amount of intake of food and nutrients (fat, nitrogen, carbohydrate and calories) during acute and recovery period of diarrhoea due to Giardiasis.
- (2) To estimate the parcentage of absorption of nutrients during acute and recovery stage of diarrhoea.

C. METHODS AND PROCEDURE:

Patient Selection - 30 patients, suffering from acute diarrhoea will be studied. The patients will be selected from ICDDR, B patient population presented in the treatment centre.

<u>Criteria for Selection</u> - The criteria for slection and exclusion are as follows:

- (1) Age 3-5 years, sex Male
- (2) History of acute diarrhoea + 48 hours (No blood and mucus).
- (3) Stool M/E = RBC or pus cells .10-20/HPF. at least I specimen of stool out of 2 specimens examined should be +ve for Giardia, cyst or vegetative form.
- (4) Other parasites not more than one + by routine M/E.
- (5) RS for D/F -ve for V. cholerae.
- (6) Patients with all degrees of dehydration will be included into the study.
- (7) Patients with the following criteria will be excluded:
 - * Fever >101°F
 - * Any signs of systemic infection.
 - * Severe malnutrition or signs of Vit A deficiency.
 - * History of chemotherapy outside.
 - * Any patient needing immediate antibiotic therapy.

Study procedure:

Selected patients with diarrhoea will be first rehydrated with intravenous therapy and the overall management of diarrhoea will be carried out by the physician in charge according to standard ICDDR, B treatment regimen. After receiving therapy for 4-6 hours the patients usually recover from dehydration and demand for food. At that time (zero hour) patient will be fed a charcoal marker, followed by a local familiar diet ad libitum. Accurate weight of the food will be taken upto 0.1 gm. using a Toledo scale and any left over will be weighed again and deducted from the initial weight of the food. The difference will be actual amount of food consumed. Breast fed babies will be allowed to take breast-milk ad libitum and water will also be allowed ad libitum. Infants will be weighed before and after the intake of breast-milk to have the estimation of the quantity of breast milk consumed.

The Study Diet

The study diets will be prepared by a qualified dietician. The nutrient composition of the study diet and the dietary schedule is given in Table 1. Dietary items in the present study is slightly modified from the previous study diet (protocol No. 78-026). In this diet khichuri given during supper is omitted. Halwa is given at breakfast as before. Rice and chicken curry is given at lunch and dinner. Comparability of this study with the earlier one will not be hampered as the nutrient composition of the diets in both the

studies are essentially the same. This change is presently done mainly because khichuri was not gnerally well accepted by the study children. According to NCHS the amount of total calories required for 3-5 years children is 1600 kcal/child/day.

Estimations on Admission

On admission the patients' anthropometric measurements (body wt. height arm circumference) will be taken. body weight will also be taken every morning without having any clothing, throughout the whole study period. Stool and urine analysis, blood for total count, Hct, plasma specific gravity will be carried out routinely. E. coli will be tested for ST and LT by Y, addrenal cell assay and infant mouse assay respectively (7). Only confirmed giardiasis cases will be followed up during the recovery period.

Collection and analysis of the Deits and Specimen

Stool and urine will be collected from the first appearance of the charcoal marker and continued till the appearance of the second charcoal marker fed at 72 hour of the study period. Seventy-two hours stool sample will be homogenised in a blender and stored in duplicate until assayed in the laboratory for fat, nitrogen, carbohydrate and calorie content. Urine will be analysed for nitrogen content only.

The nutrient composition of the five preparation of diets will be analysed and the mean results will be used for calculation of intake and absorption. Fat estimation will be done according to the procedure of Van de Kamer (8). Nitrogen estimation will be done according to Microkjeldahl procedure (9). Total calorie estimation will be done by bomb calorimeter using benzoic acid as the standard.

Screening Tests for Malabsorption

Xylose test will be done by feeding 5 gm. D-xylose dissolved in 100 ml. of water on the second day of study. One ml. of blood sample will be taken for estimation of blood xylose, done according to ROE and Rice method (10). Though D-xylose test may not necessarily reflect the absorption of nutrients, this is the only test available for assessemnt of generalised malabsorption.

Repeat Study During the Recovery Stage

After admission, first seven days will be treated as the acute period. The patients will be given treatment for giardiasis on the 5th day of admission and the treatment will be continued for 5 days. afterwards the patients will be discharged and requested to come back after one week. Then repeat intake, absorption and xylose test will be done as scheduled for acute period. During this time the patients will stay in the hospital for a maximum of 5 days.

Treatment Regimen

(a) Giardiasis:

After the 72 hours balance study is completed, The following treatment will be started:

Mepacrine/Quinacrin 50 mg. three times daily for 5 days.

This particular medicine is chosen as our purpose is to treat only giardia and not other small bowel bacteria which might be present during diarrhoea. Metronidazole usually used medicine for treatment of giardia is known to kill the small bowel bacteria and thus not recommended here, in that case the effect of treatment of giardiasis cannot be separated from that of depression of the bacterial count.

Statistical Analysis

Absorption and <u>Intake</u> of food and the nutrients between acute and recovery stages of diarrhoea will be compared using paired t test. Correlation between the xylose absorption test and absorption of nutrients will be done at both the acute and recovery stages of diarrhoea.

D. SIGNIFICANCE:

Available information suggests that intake of food is reduced due to loss of appetite in cholera, rotavirus, ETEC and shigella infection. Substantial amount of the consumed food is absorbed even during acute diarrhoea, similar findings will further broaden the knowledge with regard to intake and absorption of nutrients in other aetiologies of diarrhoea. Informations gained from the proposed study will be highly significant specially for the prevention of malnutrition associated with diarrhoea due to giardiasis.

E. Facilities Required:

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

SECTION III - BUDGET

A. DETAILED BUDGET

1.	Personnel Services				
	Name	% Effort No. of Days	Annual Salary	Project <u>Taka</u>	Requirement Dollars
	Dr. Ayesha Molla	20% year	Tk. 119000	29,750	
	Dr. A.M. Molla	25% 3 month	\$ 40000	_	2500.00
	Research Biochemistry Assistant	50% 1 year	Tk. 32000	16,000	-
	Research Dietician	10% l year	Tk. 30000	2,000	••
	Research Physician	20% year	Tk. 61000	12,200	<u></u>
	4 study nurses (4 x 25%)	100% 1 year	Tk. 24000	24,000	_
	Res. Officer (clinical)	25% l year	Tk. 30000	7,500	!
		Sub to	al Tk.	2,450	2500.00
2.	Supplies and Materials				
	Stationery goods		T	2,000	
	Xeroxing and Mimeographing			2,000	
	Medical Illustration			5,000	
	Urine collecting bags		•		\$ 300.00
		Sub Tot	al Tk.	9,000	\$ 300.00
3.	Equipment				
	Capital equipments are avail	able in the labo	ratory		<u></u>
	Some spares for bomb calorim				\$ 1,000.00

Equipment

•		<u>Taka</u>		<u>Dollars</u>
Stool Culture and Toxin Testing	Tk. 15x30	450.00		_
Toxin Testing	Tk. 1450x30	435.00		_
Fat, N ₂ , Carbohydrate, Calories		90,970.00	!	_
(110 tests from Food and Feces)				

Sub total Tk.91,855.00

5. Transportaion

Transporting patients at the end of the study 150 miles

Tk. 17/mile - 2,550.00

6. Patients Hospitalisation

 $30 \times 15 = 450 \text{ days}$

 450×200

90,000.00

.Tk. 200 (cost per day)

Total Tk. 2,85,855.00 = \$ 14,292.75

Total \$ 3,800.00

Grand Total

\$ 18,092.75

Incremental cost 1\$ 10,970.25

BUDGET SUMMARY

1.	Personnel	Tk.	92450.00	s	2500.00
2.	Supplies and Materials	Tk.	9000.00	\$	300.00
3.	Equipment			\$	1000.00
4.	Laboratory Test	Tk.	91855.00		www.
5.	Transportation	Tk.	2550.00		-
6.	Patient Hospitalization	Tk.	90000.00		-
	•	መኔ ን	0.05.055.00		3000 00

Tk. 2,85,855.00 \$ 3800.00

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Table I

DIET FOR FOOD ABSORPTION STUDY (3-5 yrs age)

Body Wt - 15.91 kg (NCHS growth curve)

Energy Reqt - 1600 Kcal/per head/day

Protein Reqt - 16.86 gm/day - WHO/FAO (Protein in terms of egg & milk)

Time	<u>I</u>	tems of Food	Quantity	Nutrient Composition			
Morning at		Pico positivo		Prot (g)	Fat (g)	Energy (Kcal)	
7 a.m.	Halwa	Rice powder Milk Sugar Oil	25g 200m1 35g 5g	1.60 4.80 -	5.60 - 5.00	86 114 140 45	
Mid day at		Whole milk Sugar	250m1 15g	6.00	7.00	142 60	
Lunch at 12 noon	Curry	Cooked rice Chicken Onion Oil	250g 30g 10g 8g	5.30 7.77 - -	8.00	300 33 5 72	
at 3 p.m.		Whole milk Sugar	250m1 15g	6.00	7.00	142 60	
Dinner at 6 p.m.	Curry	Cooked rice Chicken Onion Oil	250g 30g 10g 8g	5.30 7.77	- - 8.00	300 33 5 72	
at 9 p.m.		Whole milk Sugar	250m1 15g	6.00	7.00	142 60	
				50.54g 11.2% of total energy	47.6 23.7% of total energy	1811 Kcal	

ABSTRACT SUMMARY FOR ETHICAL REVIEW COMMITTEE

1. 30 children of 3-5 years age, suffering from acute diarrhoea due to Giardiasis will be studied to estimate intake and absorption of nutrients during acute stage and after recovery. Patients without any complication and having moderate to severe degree of dehydration without history of previous treatment will be included in the study.

Previous study carried out in ICDDR, B has shown that nitrogen absorption was mostly affected and absorption of carbohydrate was least disturbed during cholera, rotavirus, shigella and ETEC infection. Similar study is presently proposed in children with diarrhoea due to Giardiasis. Balance study will be conducted in the metabolic ward of ICDDR, B. After rehydration children will be given usual food ad libitum. Study will be done for 72 hours, during both the acute stage and after recovery. Treatment for Giardiasis will be started on the 5th day of admission and continued for 5 days and discharged. Children will be followed up after one week of discharge and the study will be repeated.

The present research will greatly help us in getting new informations regarding intake, absorption and requirement of nutrients in diarrhoea due to Giardiasis.

2. No significant risks are involved in this study.

- 3. The study will be carried out at the ICDDR, B metabolic ward.

 Patients will stay under constant supervision of a nurse,

 experienced clinical research officer and a physician. In

 case of complication, prompt measure will be taken.
- 4. Data will be handled confidentially.
- Informed consent will be obtained from each guardian of the patient after full explanation of the methodology.
- 6. No personal interview except relevant history of illness.
- 7. All patients will be benefitted from the study. During hospital stay they will get full treatment of their illness and will be easier for early nutritional rehabilitation.
- 8. Hospital records, stool, urine, vomitus and a total of 4 ml of blood in 3 occassions (2+1+1) will be required.

CONSENT FORM

International Centre for Diarrhoeal Disease Research is carrying out studies to find out the impact of diarrhoea due to different causes on nutritional status of children. Similar studies were done on cholera, rotavirus, ETEC and shigella. Now we would like to do the same study in diarrhoea due to Giardiasis infection. At first stool of your child will be examined to diagnose Giardia infection. In case the child has the infection, he will be studied for 72 hours during the acute peirod of diarrhoea. He will be fed a specified Bangladeshi diet, scheduled six times daily. His intake will be measured and stool, urine and vomitus if any will be collected. For xylose test only 2 ml. (1+1) of blood sample will be taken during acute period and after recovery to assess the absorption capacity of your child. After the acute period study is over the child will be given treatment for Giardiasis for 5 days and then discharged. Afterwards, we request you to come back after one week and we will repeat then the same study as before. In total the child should stay in the ICDDR,B hospital for about 15 days. other measurements 2 c.c. blood will be drawn on admission for estimation of TWBC, Hot and plasma specific gravity. These blood tests will help his treatment. We would like your child to participate in this study. However, even if you decide not to participate, usual treatemnt for diarrhoea will always be provided in this centre for your child.

Signature of the Investigator

Finger print/Signature of the guardian

भारत्यां अपवासम अपवस्ता त्यन आमाविमान क्छो इजम इस एम अफ्लांक एकम किंद्रुमित्र भावर अत्वस्ता मलाक्ष्य । आसवा आला कलवा, वारी धारे वाडा, आसामार पवः है-कारे মে জাসাবিসা মন তাৰ উপৰ গবেষকা কৰাৰ প্ৰমন্ত্ৰ কৰেছি। ব্যাপাবে গোম্বরা জাপনার বির; গোপনার অস্ত্রুম্ব ছেমেন্ট্রেণ্ডের अत्रत्मानिज कामना कवि । अगस्य वास्तात्व भामणना भवीका कर्व अीमाविष्माव जीवाव भाकाक वासाफ्यक एवं गरामनाम भ्रावन कवा श्रव। তাব্পর ৭২ গুলী মাব্য ডামাবিমা মাকাকালীর মে असम् भावाव एष्डभा व्रत्य जीव भविद्यान पैवः भागणवा, अभाव ७ विभव भविभाव भाभा २८व । (१ अमसुने भावाव अप्रावखिदीक भविका करव एका श्रव स्म कछी भावाव वाधाव भावीत् वहवन्न त्राम्ह । स्रम्भवाव स्मारे ५० मित्व ४७ वाष्ट्रा त्र भा-उन्हे ब्राइम्मानात्म भाक्त व्यव । ध उन्हान वाक्रांक क्रीमान किमान िकिनुसा एएछमा अय । जृष्टिय पैक उपकाय जात्व जिल्लास्य ৭২ গন্ধর সবেমনা র্ভানের গ্রহ করা হবে। ওপ্তির সম্ভাম আম--माव वाष्टाव अधिक फिकिउआ निर्क्तम कवाव अगु २ छ। छि। वक् अगमनाव वाष्टाव देशसन्ति एए भाव उभर आहे (आइ भित्रभा यत्। रिक्षे क्वा देख अवं ठावज्या २ छि छि वक रमञ्भा द्राव। पत्रे , अत्यत्रमात्र ७५% अत्रम क्या अत्रवा मा कवा अस्त्वर्म आधनाव देधावीन। जिल्ला अञ्चन मा कवरमञ्ज आधनाव वा आधनाव वास्ताव अम् श्रात्माअमेम अय किकिऽआहे क्वा श्रव।

কিচ্ছের অবিভারকের স্থান্তর বা টিগমন্থি