

Revised

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Date

25/10/86

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ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Dr. A. S. M. Hossain Trainee Investigator (if any) None

Application No. 86-030(R) Supporting Agency (if Non-ICDDR,B) UNICEF

Title of Study Relative Costs of Home Project status:

Treatment with packaged rice-ORS
and WHO-ORS.

- () 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

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 NA
(c) Physical risks Yes No NA
(d) Sensitive questions Yes No NA
(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 NA

5. Will signed consent form be required:

- (a) From subjects Yes No
(b) From parent or guardian (if subjects are minors) Yes No

6. Will precautions be taken to protect anonymity of subjects Yes No

7. Check documents being submitted herewith to Committee:

- ☒ Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).
☒ Protocol (Required)
☒ Abstract Summary (Required)
☒ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)
☒ Informed consent form for subjects
☒ Informed consent form for parent or guardian
☒ Procedure for maintaining confidentiality
☒ Questionnaire or interview schedule

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

1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific questions to be asked in the sensitive areas.
3. An indication as to when the questionnaire will be presented to the Cttee. for review.

(PTO)

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

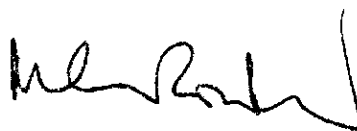
A. S. M. Hossain
Principal Investigator

OCT 29 1986

Trainee

30(R)
25/8/86SECTION I - RESEARCH PROTOCOL

1. TITLE : Relative costs of Home-treatment with packaged rice-ORS and WHO-ORS
2. PRINCIPAL INVESTIGATOR : Dr. A.S.M. Mizanur Rahman.
- CO-INVESTIGATOR : Dr. A. Bari.
- CONSULTANTS : Dr. A.M. Molla
Economist - to be named.
3. STARTING DATE : November, 1986
4. COMPLETION DATE : April, 1987 (9 months from start)
5. TOTAL DIRECT COST : a. US\$40,395/- (b) UNICEF
6. SCIENTIFIC PROGRAMME HEAD : This protocol has been approved by the Community Health Division (CHD).



Signature of the Scientific
Programme Head.

Date: 22 Oct 86

8. REVIEWS:

a) Research Involving Human Subject: ~~Protocol approved by E.R.C.~~

b) Research Review Committee: _____

c) Director: _____

SECTION II - RESEARCH PLAN

Relative costs of Home-treatment with packaged rice-ORS and WHO-ORS

A. INTRODUCTION:

1. Objective: To identify the less costly of Rice-ORS and WHO-ORS, for home treatment of diarrhoea, when made available at household level as packets.

2. Background: Economic considerations have a major influence on almost all the basic aspects of our life including health. Health problems of developing countries are, to a large extent, the problems of poverty; whereas the health problems of the developed countries are largely those of affluence. Yet the policy issues raised in both situations are remarkably similar: how can we get better value for money ? (1)

Because of poverty in developing countries, waste of scarce health resources is intolerable, including the waste of doing well at high cost what could be done equally well at low cost. (2)

Designing efficient medical interventions, preventive or curative, involves three interrelated tasks: to identify

- a) a set of treatable symptoms relating to a particular objective, say reduction of morbidity and mortality;
- b) a set of treatments to deal with the symptoms;
- c) on the basis of a) and b) and a given set of market prices, the most efficient or least costly intervention to meet the objective. (3)

Clinical success of glucose-based oral rehydration solution for treatment of acute diarrhoeal episodes is well known. (4-6) WHO has recognised glucose-ORS with a fixed composition as an effective intervention to reduce diarrhoeal morbidity and mortality (7-11).

Alternatives to the WHO recommended ORS have been tried and sucrose-based ORS was found to be a successful substitute (12-14).

Field studies have shown some direct or indirect nutritional benefit from use of glucose-based ORS or sucrose-based ORS (15-17). However, sufficient calories to meet nutritional needs during diarrhoea can not be provided through glucose/sucrose based ORS without imposing some osmotic penalty.

Recently, researchers showed that a cereal (rice) based ORS is equally effective as glucose-ORS or sucrose-ORS in terms of adequacy of rehydration and may be better in terms of reduction of vomiting, stool output and duration of diarrhoea. In addition it can provide more calories without causing any osmotic penalty. (18-25)

These considerations led ICDDR,B to conduct a feasibility study on rice-ORS, which revealed rice-ORS to be an acceptable form of ORS (26)

Encouraged by the favourable response from the feasibility study ICDDR,B started a 3-cell longitudinal study of field comparison between rice-ORS WHO-ORS and a control area in October 1983. The objectives of that study were:

- a) To compare the efficacy of rice- ORS and WHO-ORS
in terms of adequacy of rehydration and effect on

duration of diarrhoea after initiation of treatment in a field setting.

- b) To compare nutritional impact of both types of ORS in terms of changes in height and weight of 0-4 yr. children.
- c) To compare safety of prepared solutions by mothers while using for treatment of diarrhoea.
- d) To compare the cost of treatment per episode of diarrhoea for each of the two ORS preparations..

The study was carried out in 7 villages of Chandpur district of Bangladesh, with a population of 10,650. All the 3-cells were comparable on socio-economic and epidemiological grounds. Intervention procedures for respective cells are described in Table -1.

Information on diarrhoeal episodes were collected through weekly diarrhoea surveillance and daily follow-up of detected cases up to maximum of 7 visits, with the recording of date of onset, type of

diarrhoea, presence of dehydration, identification of treatment provider, type of ORS used, volume of ORS used, and outcome of the episode. To monitor the nutritional impact, all the children of 0-4 yrs of age were selected (approximately 600 children in each of the 3 cells). All these children had their exact date of birth, base line height and weight recorded. Monthly weight and 3-monthly height were measured for all these children with recording of episodes of non-diarrhoeal illness, breast feeding patterns and presence of oedema etc.

Random samples of prepared ORS of each type were collected for biochemical analysis.

The said study is nearing completion and data are being computerized for final analysis. However, some preliminary manual analysis was done after one year of study on 7-12 months old children of all the cells. Table-2 and Graph I shows the diarrhoeal and non-diarrhoeal morbidity per child per year and duration of respective episodes.

Graph II and Table-3 depicts the weight and height gain of the same children.

These preliminary results suggest that rice-ORS may be more effective in terms of shortening the duration of diarrhoea and increased rate of weight gain in 0-4 yr. children.

Economic appraisal of a health care programme, either preventive or curative, is undertaken to help decision making process, in choosing from alternative courses of action, for allocation of limited or scarce resources, to achieve economic efficiency (27-29).

A review of the nature and type of data collected from the nearly completed comparison study, referred above, revealed that although it will be possible to enumerate and measure some of the benefits that could be expected from each of the alternate ORS regimen, no attempt has been made in the study methodology to enumerate and measure the economic costs for the use of any of the alternate regimens. Therefore, the objective of comparison of cost of treatment with two ORS regimens is not possible utilizing data from the above mentioned study.

Therefore, it is proposed that a prospective study of nine months duration be conducted in the control area population to determine which ORS is least costly when delivered at household level. This study will be thus an extension of the above mentioned field comparison by Dr. Bari et al (Protocol No.83-024)

3. Rationale:

- a) Reduction of mortality and morbidity due to diarrhoea through oral rehydration therapy (ORT) is the undisputed objective of national ORT programmes of diarrhoea endemic countries like Bangladesh.
- b) Both WHO-ORS and rice-ORS are known to be effective in achieving the above objective.
- c) Therefore, it is important to know which one of the two regimen is least costly, for making policy decisions for national ORT programme in a traditionally rice consumer and producer country as Bangladesh.

B. SPECIFIC AIMS:

- a) To find out the extent of consumption of rice-ORS and WHO-ORS for treatment of diarrhoeal episodes in 0-4 year old children and the clinical efficacy of each type of ORS under varying clinical conditions.
- b) To calculate or estimate average cost of treatment of these episodes with rice-ORS and WHO-ORS, based on the above mentioned findings.

C. METHODS AND MATERIALS:

Study Area and Population:

The study will be conducted in 4 villages of the control area of the nearly completed field comparison study for rice-ORS and WHO-ORS. This area will be divided into two blocks, 2 villages each, with an estimated population of 2500 in each block.

However, census updating will be undertaken for these two blocks and all the children of 0-4 yrs. of age will be the target population for the proposed study. Each block will have approximately 400 such children who will be under surveillance for the proposed study period. Whenever, diarrhoeal episodes will occur in any of these children, WHO-ORS will be used for children in one block and rice-ORS will be used for the other. Mothers of these two blocks will be trained to prepare and use respective type of ORS. (See Addendum)

Surveillance:

Diarrhoea surveillance will be made twice weekly with follow-up of detected cases upto a maximum of 7 days if recovery, hospitalization or death does not occur within 7 days of case detection. Diarrhoea surveillance and follow-up team will record the following: date and time of onset of diarrhoea, type of diarrhoea on the day of detection, average daily frequency of stooling upto the day of detection, date and time of starting of ORS, volume of ORS consumed daily till recovery, frequency of vomiting after initiation of ORS regimen, drug used, if any, and the time and date of end of diarrhoea, hospitalization date, if any, and in case of death, the date of death. Reasons for hospitalization and diarrhoea deaths at home will also be noted. Coded forms will be used for such surveillance and follow-up. Surveillance will be continued for six months. With an expected attack rate of 3 episodes per child per year, it is assumed that during six month period about 600 episodes in each cell will be encountered. ORS is expected to be used for 70-80% of these episodes.

Packets of rice-ORS and WHO-ORS will be made available through a Bari-mother system in the respective blocks. The composition of the two types of ORS will be as follows (for making $\frac{1}{2}$ litre solution):

<u>Rice-ORS:</u>	Common salt	1.75 g.	<u>WHO-ORS:</u>	Common salt	1.75 g.
	Sodium bicarb.	1.25 g.		Sodium bicarb	1.25 g.
	Potassium chlor.	0.75 g.		Potassium chlor.	0.75 g.
	Rice powder	40.00 g.		Glucose	10.00 g.

Diarrhoea patients of other age groups will have access to respective ORS packets and will be allowed to use according to their requirement, but will not be followed.

Enumeration and measurement of relevant costs:

Costs are estimated by determining the amount of resource used. Shepard and Cash (30) provides a model for cost-effectiveness analysis of oral rehydration therapy (ORT). In this the cost data are summarised in terms of affordability (cost per 100,000 population) and efficiency (cost per case treated). Health benefits, in this procedure, are measured as number of diarrhoea hospitalizations and deaths averted per 100,000 population per year. Using this model, number of

deaths and hospitalisations are compared: (1) by comparing experiences before and after the introduction of ORT in a single area; and (2) comparing an ORT area with a non-ORT area.

In our present study, we are proposing to compare only the cost per cases treated with two types of ORS. With good accessibility, availability and proper use, hospitalisations and deaths due to diarrhoea are expected to be very few in number from use of any ORS mentioned. Therefore with certain modifications the approach suggested by Shepard and Cash, would be followed in deciding the indicators of costs. We would use the following indicators for enumerating the costs;

A. Cost enumeration: Resource use -

1. Health service resource:

- i) Cost to train mothers on the preparation and use of each ORS;
- ii) Use of consumable supplies: ingredients of each ORS;
- iii) Logistics and supply of ORS packets;
- iv) Hospitalisation: hospital bed use, doctors' and nurses' time, hospital drugs and diets.

Some capital costs, like use of building space, vehicle, minor equipments and administrative costs may not be taken into account, because these will be common for both types of ORS.

2. Household resource:

- i) Cost of fuel for preparation of rice-ORS;
- ii) Cost of diet for patient, if any;
- iii) Cost of other treatment, if required;
- iv) Cost of transportation to hospital, if required;
- v) Cost of attendant during hospitalisation, if any.

Cost of mother's time will not be considered, because in our rural set up valuation of mother's time will be very difficult.

Measurement and valuation of costs:

Changes brought about by each regimen of ORS in resource use would be quantified in terms of units as appropriate for each item enumerated. Economic notion of cost of a unit of resource used is the benefit forgone that could be derived from its best alternative use. In present case, the valuation of each unit of resource used would be made in monetary terms. For this purpose, market based

valuation or imputed market valuation will be used, as may be appropriate for a particular cost estimation. Seasonal variation of costs of supplies and ingredients will also be taken into account in making cost calculation, where necessary.

Data collection and analysis:

Prospective data on clinical efficacy will be collected through diarrhoea surveillance using the surveillance form shown on page -24. An overall assessment of efficacy of respective ORS will be made using the analytical format shown on page-25. Further analysis will be made, by patient stratification according to a) type of diarrhoea, b) frequency of diarrhoea prior to ORS use and c) duration of diarrhoea prior to ORS use. For this purpose formats shown on pages 26-28 will be used.

Cost data for ORS production and distribution will be collected from records which will be kept in office from which ORS packets will be supplied. Data on other costs as enumerated above, will be collected from appropriate records if available and where necessary, through a survey procedure of appropriate design, to be developed later according to actual situation.

Average cost per case treated, without stratification and with stratification will be calculated using these data and compared. Cost per 1000 population served will also be estimated and compared.

D. SIGNIFICANCE:

The results of this relative cost study will provide information to identify the least costly ORS between rice-ORS and WHO-ORS alongwith its relative clinical efficacy and will provide planners of national ORT programme with elements to make a choice between the two ORT regimens.

E. FACILITIES REQUIRED:

- a) Staffs and office of Chandpur Project will be utilized.
- b) Motor vehicle attached to the above project will provide transportation for field activities.
- c) Matlab field hospital will be used to treat diarrhoeal patients needing hospitalisation.
- d) Data management branch in Dhaka will be utilized for data computerisation and analysis.

F. COLLABORATIVE ARRANGEMENTS:

UNICEF will be approached for funding the project.

Table - 1

Intervention procedures in three cells

November, 1983-October, 1985

<u>Interventions</u>	<u>WHO-ORS Cell</u>	<u>Rice-Salt ORS</u>	<u>Control Cell</u>
1. Supply of some type of ORS packets through depot mothers	WHO-ORS Packets	Rice-salt ORS	None
2. Training to mothers to prepare the type of ORS packet supplied	Yes	Yes	Instructions to prepare Sugar-Salt ORS on request during home visits
3. Further instructions and advice at the time of case detection	Yes	Yes	Yes
4. Weekly clinic facilities through health cards	Yes	Yes	Yes
5. Referral to Matlab hospital for complicated diarrhoea cases	Yes	Yes	Yes
6. Referral to Chandpur hospital for complicated non-diarrhoeal cases	Yes	Yes	Yes
7. Availability of transport facilities for referred patients	Yes	Yes	Yes

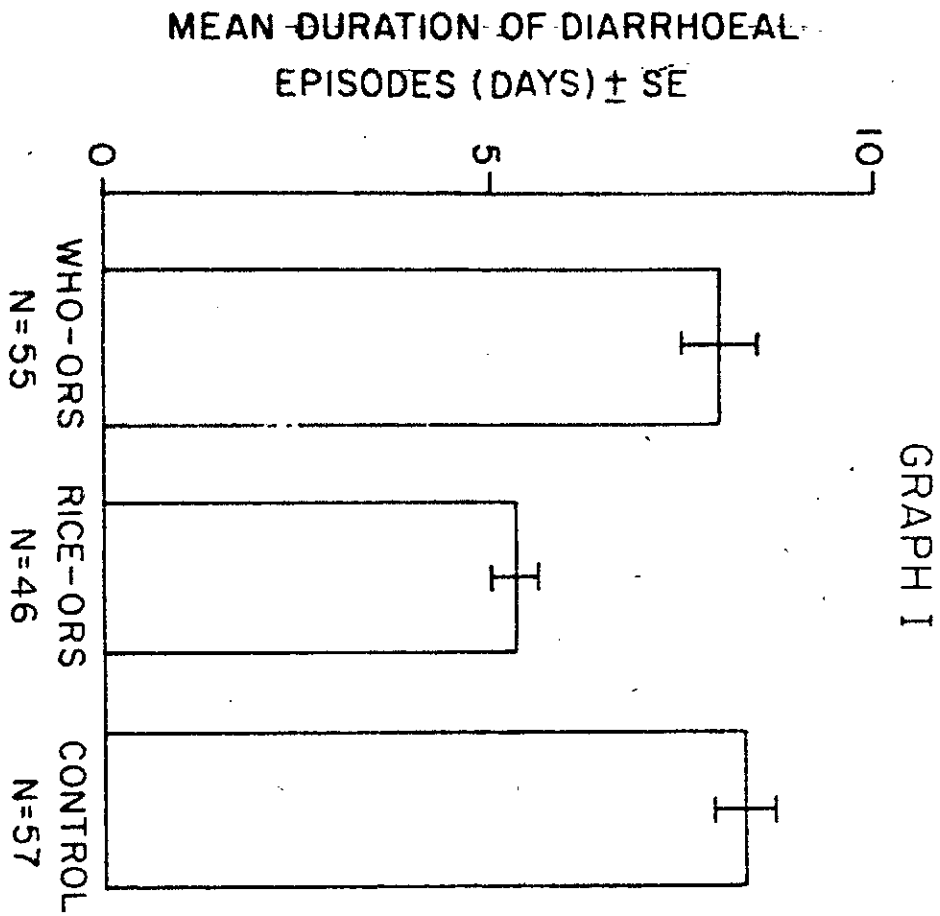


Table - 2

Diarrhoeal and Non-diarrhoeal morbidity of 7-12
month old children in three study cells.

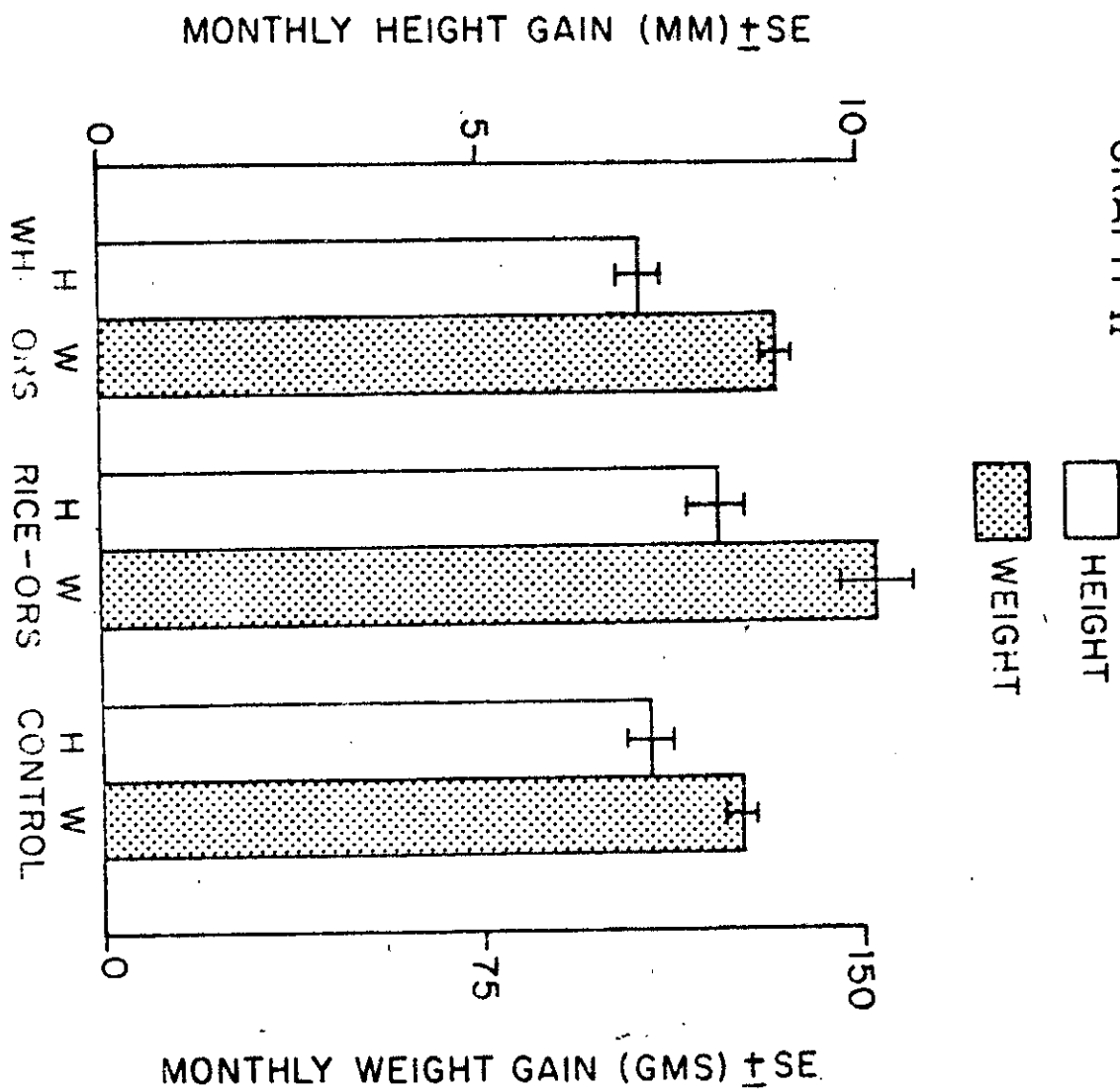
Study Cell	Number of patients	Diarrhoeal Episodes		Non-diarrhoeal episodes	
		Mean No. of episodes	Duration (days) per episode (Mean + SE)	Mean No. of episodes	Duration (days) per episode (Mean + SE)
WHO-ORS	55	3.4	8.0 + 0.5	2.3	41.7 + 1.4
Rice-Salt ORS	46	4.9	5.3 + 0.3	2.9	43.1 + 1.8
Control	57	3.5	8.3 + 0.4	2.5	49.0 + 2.0

Table - 3

Nutritional impact in 7-12 month old children
in the three study cells

Study Cell	Number of patients	Mean base height (mm)	Mean monthly height gain (mm) + SE	Mean base weight (Kg)	Mean monthly weight gain (gm) + SE
WHO-ORS	55	65.6	7.1 + 0.3	6.487	134 + 3.4
Rice-Salt ORS	46	65.2	8.1 + 0.4	6.515	154 + 3.4
Control	57	65.5	7.2 + 0.3	6.456	126 + 2.5

GRAPH II



REFERENCES

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ABSTRACT SUMMARY
(For Ethical Review)

The objective of the proposed study is to identify the least costly ORS between Rice-ORS and WHO-ORS when used at household level.

Enumeration of costs related to the use of each type of ORS, and their clinical efficacy will be determined and compared.

1. The study will be conducted in 4 villages of Chandpur Community Training Project for nine months. The subject population for the study will be children under 5 years of age, who are the most vulnerable group for diarrhoeal attacks and its consequences.
2. The study method will include interviewing the mothers, diarrhoea surveillance, weighing of children with diarrhoea and distribution of respective ORS packets. There is no potential risk involved in the study.
3. Not applicable.
4. Confidentiality of data collected will be maintained and information will not be passed out to any one. Anonymity of the households, mothers and children will be maintained through use of code numbers.
5. Since there is no potential risk involved and no invasion of privacy is under consideration, a signed consent will not be obtained. However, the mothers will be explained of the purpose of the proposed interview and weighing of the children and only those who will be willing to participate will be included in the study.
6. The interview and the weighing of the children will take place in an informal setting in the households of the study population. Approximately, 15 minutes time will be needed for interview and 10 minutes time for weighing of the child with diarrhoea.
7. The results of the study will help to identify and introduce a cheaper and more effective ORS for treatment of diarrhoea at household level.
8. The study will not require use of any hospital records, organs, tissues, body fluids or abortus.

SECTION-III : BUDGET

A. Detailed budget for nine (9) months

1. Personnel Services

<u>Name</u>	<u>Position</u>	<u>% of Service need</u>	<u>Gorss Annual Salary (US\$)</u>	<u>Project requirements (in US\$)</u>
Dr ASM Mizanur Rahman	Principal Investigator	80%x9m	8,640	5184
Dr Abdul Bari	Co-Investigator	100%x9m	5,520	4140
Dr A M Molla	Consultant	10%x1m	54,000	450
Mr A Halim Bhuiyan	Sr. Health Asstt.	100%x9m	2,928	2196
Mr Ruhul Amin	Health Asstt.	100%x9m	2,640	1980
Mr Joynal Abedin	"	100%x9m	2,244	1683
Ms Umme Kulsum	"	100%x9m	1,764	1323
Ms Fatema Khatun	"	100%x9m	1,860	1395
Ms Chand Sultana	"	100%x9m	1,740	1305
Ms Rehana Begum	"	100%x9m	1,680	1260
Ms Mahtab Begum	"	100%x9m	1,824	1368
Ms Anwara Khatoon	"	100%x9m	1,872	1404
Mr Tajul Islam	Driver	100%x9m	1,380	1035
To be named	Admin Clerk	100%x9m	2,100	1575
Daily wager x 3	Porters	100%x9m	2,064	1548
To be named	Consultant Economist	100%x1m	54,000	4500
"	Computer Programmer	10%x3m	6,560	164
"	Statistical Asstt.	10%x3m	3,440	86
"	Key Punch Operator	10%x3m	2,880	72
			Sub-Total	28,168

2. SUPPLIES AND MATERIALS:

<u>Items</u>	<u>Project requirements</u>	
	<u>Taka</u>	<u>US\$</u>
a) Office stationaries	15,000	-
b) Rice-Powder ORS packets	5,000	-
c) WHO-ORS packets	8,000	-
d) Candy for children	2,000	-
e) Medicines	5,000	-
Sub-Total	35,000	1,167

3. EQUIPMENTS:

None needed

4. VEHICLE MAINTENANCE:

Spare parts	2,000
Service charge	1,000
	<u>3,000</u>

5. ICDDR,B TRANSPORT:

Field trips & back		
20 miles/day x 288 days/yr		
= 5760 miles x Tk. 5.00/mile	28,800	
	<u>28,800</u>	960

6. TRAVEL & TRANSPORTATION OF PERSONS:

Local: Dhaka-Matlab-Chandpur		
2 trips/month x 12 months	3,000	-
Chandpur-Matlab-Dhaka		
2 trips/month x 12 months	3,000	-
Per diem for 1 person for		
60 days x Tk. 150/day	9,000	
	<u>15,000</u>	500

7. TRANSPORTATION OF THINGS:

Local transportation of		
supplies and materials from		
to Dhaka-Chandpur	2,000	
	<u>2,000</u>	67

8. RENT, COMMUNICATION & UTILITIES:

a) Rent for office space for		
12 months x Tk.2500/. months	30,000	
b) Utilities Tk. 500/month x 12 m	<u>6,000</u>	
	36,000	1200

9. PRINTING & REPRODUCTION:Project requirements

	<u>Taka</u>	<u>US\$</u>
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a) Diarrhoea Surveillance forms

No. - 10000

b) Health Card, No. 2000

c) ORS supply form No. 3000

15000

10,000

333

10. OTHER CONTRACTUAL SERVICES:

Computer Services

5000

5000

Grand Total ~

40395

B. BUDGET SUMMARY

Category	<u>Project requirement</u>	
	<u>Taka</u>	<u>US Dollars</u>
1. Personnel	-	28168
2. Supplies & Materials	35,000	1,167
3. Equipments	-	-
4. Vehicle Maintenance	-	3,000
5. ICDDR,B Transport	28,800	960
6. Travel & Transportation of persons	15,000	500
7. Transportation of Things	2,000	67
8. Rent, Communication and Utilities	3600	1200
9. Printing & Reproduction	10,000	333
10. Other Contractual Services		5,000
Grand Total	-	40,395

(US\$ 1 = Tk. 30/-)

Clinical Effectiveness of Rice-Salt ORS
Vs WHO-ORS : Overall View

Criteria of Effectiveness	Rice-Salt ORS N =	WHO-ORS N =
Frequency of diarrhoea/day after ORS use Mean $\pm$ SD		
Duration of diarrhoea. after ORS use Mean (days) $\pm$ SD		
ORS consumption (Mean (ml) $\pm$ SD		
Vomiting frequency after ORS use Mean $\pm$ SD		
Rate of wt. gain (gm/month) Mean $\pm$ SD		
Cured (%)		
Hospitalised (%)		
Expired at home (%)		
Diarrhoea continued >7 days (%)		
Outcome unknown (%)		

[illegible]

[illegible]

ADDENDUMInstructions to Mothers

Apart from specific instructions and demonstrations on the preparation of respective ORS, the mothers will be given the following instructions on the use of ORS.

1. Start giving the child prepared oral rehydration solution as soon as you are aware of his/her diarrhoea.
2. For infants (upto 1 yr.of age), give about 50-100 ml (approximately $\frac{1}{4}$ - $\frac{1}{2}$ glass full) of ORS per loose motion, and for older children, give about 100-200 ml (approximately $\frac{1}{2}$ -1 glass full) of ORS per loose motion, depending on the volume of stool in each loose motion.
3. Continue giving oral rehydration solution till stool consistency and frequency becomes normal for the child.
4. Do not stop giving oral rehydration solution if there is mild vomiting. For severe vomiting, ask advice from the health worker in your area.
5. If patient's condition deteriorates inspite of drinking sufficient ORS or the patient refuses or is unable to drink the ORS, ask advice from your health worker or if neccessary, take the patient to a nearby hospital.
6. Continue giving the child his usual food and if breast-fed, continue breast-feeding during diarrhoea.
7. Give patient plain water to drink as required.
8. Discard unused solutions of rice-ORS and WHO-ORS after 8 hours and 12 hours of preparation, respectively.
9. Do not use any drugs for the treatment of diarrhoea without consulting a qualified medical practitioner.