GC PASSED 78-025

PREVIEW BOARD ON THE USE OF HUMAN VOLUNTEERS
CRL

Principal Investigator Dr. Md. Yunus Trainee investigator(if any) _____

Application No 78-025 Supporting Agency(if Non-CRL) _____

Title of study Oral Therapy Field Trial

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 possibly 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(NA) 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
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 Board for review.

Agree to obtain approval of the Review Board on Use of Human Volunteers for any changes involving the rights and welfare of subjects before making such change.

Principal Investigator _____ Trainee _____

Please return 2 copies of entire protocol to Chairman, Review Board on Use of Human Subjects.

78-025

SECTION I - RESEARCH PROTOCOL

1) Title: Oral Therapy Field Trial

2) Principle Investigator: Md. Yunus and J. Chakraborty

3) Starting Date: November 1, 1978

4) Completion Date: April 30, 1980

5) Total Direct Cost:

6) Abstract Summary:

Syndrome of watery diarrhea with attack rates of 2 or more episodes annually in children often leading to dehydration and death, is by far the major single killer in the developing world including Bangladesh. The intravenous fluid and electrolyte therapy has brought down mortality rates from diarrheal diseases in hospitalized patients to well under 1%. The discovery that oral glucose electrolyte solutions consumed in adequate amounts early in the disease can replace much of the need for intravenous therapy has vastly simplified the technology of treating dehydration in hospital settings. More recently sucrose which is more readily available and less costly than glucose has been shown to be almost equally effective as glucose in treating watery diarrheas. This study proposes a two-cell field trial or oral rehydration therapy with glucose-electrolyte salts in one and lobon-gur (salt-sugar) in the second. Altogether 80,000 population of the Matlab Health Services Area would be served over a period of 18 months. The objective is to determine the acceptability, effectiveness and safety of the two solutions in terms of reducing the need for hospitalization and intravenous therapy and thus reducing mortality. The study has been designed to be bascially implemented by the Female Village Worker with community participation, particularly by mothers. Two thousand mothers will be trained by the F.V.W. to work as depot manager for distribution glucose-electrolyte salt packets and lobon-gur. These depot mothers will also instruct other mothers and patients regarding preparation and administration of oral rehydration therapy with appropriate advice for diets during and after recovery from diarrhea.

If both solutions are found effective, particularly the lobon-gur, this will further simplify the technology of treating diarrhea at home. Ultimate results of oral therapy will come from widespread use of lobon-gur for treating majority of watery diarrhea at home by mothers afrer simple training.

7) Reviews:

a) Research Involving Human Subjects: _____

b) Research Committee: _____

c) Director: _____

d) BMRC: _____

e) Controller/Administrator: _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION:

1. Objective:

The objective of this study is to test and compare under field conditions the acceptability, effectiveness and safety of glucose electrolyte solution in packets and unpackaged lobon-gur.

2. Background:

The mortality and complications form syndrome of watery diarrhea are almost exclusively due to the result of dehydration. The intravenous therapy has brought mortality rates from diarrheal diseases in hospitalized patients to well under 1%.

The discovery of oral glucose electrolyte solution (GES) and its consumption in adequate amounts early in the disease has vastly simplified the technology of preventing and treating rehydration. Oral glucose electrolyte solution is now established as simple, effective and relatively inexpensive fluid replacement therapy for severe diarrheal diseases, the leading cause of morbidity and mortality in developing countries particularly in children. GES has been shown to be effective in all watery diarrheas both in adults and children ( ). By using oral therapy in hospital setting, it has been found that the need for intravenous fluid can be reduced by 70% (Nalin et. al.). In mild to moderate dehydration it is possible to treat patients exclusively with oral therapy. For severely dehydration patients, initial rehydration by intravenous fluid will still be required.

Subsequently various investigators (Asoke et. al., D.L. Palmer et. al) have conducted several clinical trails by using surcrose instead of glucose and it has been found that sucrose is almost equally effective in all types of diarrhea. The sucrose has the advantage of being more readily available than glucose and is less costly.

The theoretical advantages of oral rehydration appears to be early implementation by mothers in the home, rather than in hospital setting, where most published research on oral therapy have been conducted thus far. Furthermore, few previous studies have examined oral rehydration within the context of a village-based maternal-child health program, as is now being advocated by various international agencies and national governments. Within each geoculturally specific setting, moreover, there exists controversy regarding the optimal form of oral rehydration - ranging from pre-packaged glucose-electrolyte packets (often imported) versus home-based preparation, such as lobon-gur made by the mothers themselves. Each mode of technology will have comparative advantages and varying levels of accessability, acceptability, effectiveness, and safety.

In 1975-76, the CRL conducted a small scale oral therapy study in 4 Matlab villages comparing a GES versus Kaolin placebo (Curlin et. al.). The results, while inconclusive, suggested significant safety problems associated with hypernatremia* because of imprecise volume measurements

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*The GES contained a sodium concentration of 120 meq/l.

on the part of mothers. The sample was sufficiently small and the number of cholera cases was too few (with the cholera epidemic occurring in 2 of the 4 villages) to preclude valid comparisons.

3. Rationale:

Oral rehydration is a cheap, simple and effective technology of preventing and treating dehydration due to diarrheal diseases. Effective usage of this technology by mothers at home level will simplify the treatment of watery diarrhea. The porposed study would contribute to more effective delivery of this technology.

B. SPECIFIC AIMS:

1. To determine the accessability of oral rehydration (by the two formula) to diarrhea patients;

2. To determine the acceptability of the two formula by the community, mothers and patients;

3. To determine the effectiveness of the two formula in diarrhea morbidity, mortality and improved nutritional status;

4. To assess potential safety problems associated with the two formula;

5. To derive information about cost, manpower, and other delivery system aspects of implementing an oral rehydration program.

C. METHODS OF PROCEDURE:

Program:

The study will be conducted in the Matlab Health Services Area. This area contains a population of 80,000 divided into 4 blocks; each block consists of 20,000 people served by a sub-center. For the purpose of this study, the Health Services area will be divided into two cells: Block A and C will be Cell I and Block B and D will be Cell II (see attached map). By dividing the area in this way, the average distance of both Cell I and Cell II from Matlab Treatment Centre will approximately be equal. The population in each of these cells is about 40,000. For comparative purposes, a third population of about 40,000 receiving only hospital-based diarrheal services may be utilized for evaluation.

The only difference between Cell I and II is GES versus labon-gur. Program implementation will be otherwise identical in the two cells. Female village workers (FVW) will train 2,000 mothers to work as manager of depot stations. These mothers will be responsible for distribution of Oral Rehydration Packets (G.E.S.) in Cell I and labon-gur in Cell II to mothers of children and adults with diarrhea within her bari. Depot mothers will train the villagers in proper administration of oral fluid. The FVW will initially standardize a one liter vessel in each depot station; when one is not available one will be supplied. The standardized vessel will then be used by the depot mothers to standardize vessels in the other homes of the bari. Basically the depot mothers will deliver the oral

rehydration fluid on request from villagers in her area. The villagers will be told that oral rehydration (Oral Saline) is available for treatment of diarrhea at depot stations and that they should go to the depot mother for the medicine.

When there is a case of diarrhea, the villagers will contact the depot mother with a vessel. The depot mothers will standardize the vessel for 1 liter volume and instruct the mothers on how to mix the packet or labon-gur and how to administer the solution. The depot mothers who will distribute labon-gur will be provided with standard spoons for measuring the correct quantity of labon-gur. After the first visit, it may no longer be necessary to standardize the vessel and with subsequent visit there may be less training required on how to mix and administer the solution. It will be upto the patient or patient's family or guardian to decide whether or not they wish to use this fluid. Attempts will be made to encourage the mother and guardian of the patients to start drinking oral rehydration fluid at the onset of the diarrhea.

The GES will be packaged in Matlab by the CRL. GES packets and labon-gur will be supplied to sub-center, FVW's and to depot managers. The compositions of the two formula are as follows:

Ingredients	GES	Labon-gur
Glucose	20 gms	
Gur		40 gms
NaCl	3.5 gms	5.0 gms
$NaHCO_3$	2.5 gms	
KCl	1.5 gms	
Concentration/liter		
Glucose	111 meq/l	
Sucrose		111 meq/l
Na^+	90 meq/l	80 meq/l
K^+	20 meq/l	6 meq/l
Cl^-	80 meq/l	80 meq/l
HCO_3	30 meq/l	

Basic instructions on preparation and administration of the oral rehydration fluid by the depot mothers will be as follows:

1. Mix the ingredients of the packets or labon-gur in 1 liter of drinking water.

2. Smash the packets or labon-gur to break up lumps and then add to the water in the container.

3. Stir until all powder is dissolved.

4. Immediately after mixing and also after each loose-motion, the mother or the guardian should give the fluid to the patients as much as one can drink. Free water will be encouraged for all patients particularly children.

5. Continue to give oral fluid even if vomiting occurs.

6. Should give oral fluid for all types of diarrhea and dysentery.

7. Oral fluid may be stopped temporarily if the stomach gets too distended. Restart oral saline after distention decreases.

8. Do not give oral fluid to unconscious patients.

Depot mothers will be instructed to keep simple records in exercise books containing information, like name and age of the patient, onset time (morning, noon, afternoon, evening, night) and date, and number of packets, or labon-gur mixture given. Depot mothers, while distributing oral fluid, will also give instructions about diet. For breastfeeding children, the mother should continue breastfeeding. For bottle feeding children, the formula should be diluted at half strength. Frequent and small amounts of digestible and rich foods like cereals, bananas and well cooked vegetables should be advised especially for malnourished children. Feeding should not be stopped during episodes of diarrhea. After recovery, extra calories consisting of extra protein and well balanced diets, should be recommended. The depot mothers will inform their respective FVW's of all new diarrheal cases and their outcome during the FVW's regular biweekly household visits. Depot mothers will also refer severe diarrhea cases to FVW's for possible referral to the Matlab Hospital.

Thorough basic training will be given to the FVW's about diarrhea and dehydration, their effects, principle of management of dehydration and other complications and dietary advice. FVW's in turn will train the depot mothers. When severe diarrheal cases are referred to FVW's by the depot mothers, the FVW's will assess the patient clinically for dehydration, fever, respiratory symptoms, and st[illegible] of consciousness. Severe patients will be further referred to the Matlab Hospital. FVW's will record referrals in an exercise book and will fill up a referral form when referral is made.

One ambulance boat will be placed at a central location in each of the two Cell areas so that patients from each of the cells will have equal access to ambulance stations for coming to Matlab Treatment Centre directly. After six months or so referral point may be shifted to sub-centers. During that time attempts would be made to train CRL workers to operate these sub-centers on routine management of diarrheal patients including intravenous fluid administration and taking care of complications.

When patients come to Matlab Treatment Center from either cell area by referral through FVW's or by themselves, their condition will be assessed, particularly the status of dehydration and need for intravenous fluid therapy. A standard form will be used to describe the status of dehydration and other clinical parameters. A sample of admission blood will be taken to determine the serum specific gravity. Rectal swab will be collected for diagnosis of etiologic agents. Attempts will be made to have the assessment made before knowing whether the patient is from a village that is receiving the GES packet or labon-gur. At the hospital, patients will be treated with intravenous or oral fluid as appropriate and discharged to the village as soon as possible.

Training

It is anticipated that 4-6 weeks will be required to train the CRL staff and to begin program operations. First, the principal investigators and two assistant supervisors will train CRL trainers, consisting of 4 LFPV's and 5 SFA's in the Health Services Area sub-centers. Then the trainers will train the FVW's; there are 20 FVW's per sub-center. FVW's will identify one mother per bari and provide training directly to each bari depot manager. Depot managers will be selected on the basis of their interest and motivation. Depot manager candidates with education would be given preference; no compensation is planned for depot managers.

Research and Evaluation

Research and evaluation will aim to address issues related to accessability, acceptability, effectiveness and safety. The following sources of data are planned:

1. Demographic Surveillance.
2. Depot manager's records.
3. FVW's records and referral forms.
4. Hospital records and special hospitalization form.
5. KAP surveys - baseline and post-program.
6. Nutritional surveys - baseline and post-program.
7. Indepth follow-up of randomly selected patients with field diarrhea.
8. Program statistics on cost, manpower, etc. from administrative records.

Demographic Surveillance System: The DSS data will be used to measure the size and characteristics of the study population. Death reports will be analyzed for mortality, particularly diarrhea mortality.

Depot Manager's Records: These records will provide basic information on the age-sex pattern of diarrhea morbidity, use of oral rehydration, and the amount of fluid required per episode. The records, when compared with random spot checking (see Indepth Follow-up Data) will indicate how accessible and acceptable oral therapy is for the study populations.

FVW's Records and Referral Form: FVW records will be aggregated monthly to indicate the number of diarrhea episodes and the amount of oral therapy used by the study population. Referral forms will be matched with hospital records to identify severe diarrhea cases.

Hospital Form: For each patient from the Health Service Area, a special form will be completed in the hospital providing information on state of hydration, and requirements for IV and oral rehydration, initial and discharge weight, etiologic agent by rectal swab, serum specific gravity, serum electrolytes, duration of hospitalization, history of the illness and history of oral rehydration practice in the village, other medications or practioners. See Appendix for hospital form.

KAP: KAP surveys (Baseline and 9 months and 18 months after program initiation) will be undertaken in the two study cells and in the comparison area to assess knowledge, attitude, and practices related to diarrhea and associated topics (feeding behaviour and treatment). The KAP would be administered for about 600 randomly selected mothers in each Cell. Effort

will be made to use the same sample for the serial KAP's and for the KAP's and nutritional surveys. See Appendix for KAP form.

Nutritional Surveys: Children under 5 years in about 600 randomly selected households (same as KAP sample) in the two study cells and in the comparison area would have anthropometric measurements of weight and height before program initiation and at 6 months after full initiation and at the end of the study. Weight would be taken to the nearest 50 gms by Salter spring scales and height to the nearest 0.5 cm by length boards (for children under 24 months) and by height sticks (for children over 24 months).

Indepth Follow-up Survey: Four male FA's will conduct independent visits to bari depot managers (selected by a random procedure). The FA's would inquire first about all diarrhea cases in the bari and then compare the cases with those recorded in the Depot Manager's records. This will provide an indicator of accessability and acceptability. A sample of diarrheal cases identified by this mechanism will be followed serially on days 1, 3, and 7 of illness. Indepth questionnaires and specimens (oral fluids, rectal swab, serum electrolytes, etc.) will be administered on these visits. See Appendix for form.

Program Statistics: Program statistics on cost, manpower, etc. will be collected from routine administrative records of the CRL. These would be used to compute cost-effectiveness, manpower requirements, etc.

Staffing

The delivery of oral rehydration would be implemented by the regular field and hospital staff of the Matlab Health Services Program. No additional staff are planned for implementation.

Research and evaluation will require additional staff, as follows: (1) The Indepth Follow-up Surveys will require 4 FA's full-time for the duration of the study; (2) Two full-time coding assistant will be required in the central office full-time for the duration of the study; (3) The KAP survey will require 120 person-days per round (15 forms per worker per day for 1800 forms); (4) The nutritional survey will also require 120 person-days per round.

Altogether, the incremental staff requirements are 6 full-time FA's and 720 person-days of FA workers on three ocassions. Plans would be needed to assure the availability of the FA's for the KAP and nutrition surveys.

Data Analysis

Accessability will be determined by the ratio of diarrhea cases detected through random visits by FA's in comparison to records maintained by Depot Managers. Indepth follow-up surveys (on 1, 3, and 7 days) would probe for factors affecting accessability. Furthermore, any death reports of diarrheal deaths from the Health Services Area will be investigated to determine whether service accessability played a rile in such failures.

Acceptability will be measured by KAP surveys baseline and post-program. Furthermore, the indepth surveys (on days 1, 3, and 7) will probe about factors related to acceptability and patterns of use.

Effectiveness: Aggregate measures of effectiveness will be determined by mortality patterns and causes from the demographic surveillance hospitalization rates for diarrhea between the 2 cell and the comparison area. These may be further differentiated according to etiologic agent, degree of dehydration on admission, and other clinical and laboratory indicators. Nutritional impact will be assessed by comparing the weight-for-age, weight-for-height, and height-for-age indices among children in the different cells and before and after program implementation. Changes of KAP would be detected by serial KAP surveys.

Safety: Complications from use of oral therapy as referred to FVW's by depot managers or as referred to the hospital by FVW's would be tabulated. Indepth surveys, moreover, would include evaluation of possible complications and side-effects such as hypernatremia (oral fluids and serum), acidosis (clinical exam and serum), and delayed hospitalization (referral form).

D. SIGNIFICANCE:

Significance of Oral Therapy Field Trial will be manifold. From the results of the study it should be possible to determine the accessability, acceptability, effectiveness, and safety of labon-gur versus glucose electrolyte solution in the treatment of all kinds of watery diarrhea at home. If both the solutions are found effective and well accepted, particularly the labon-gur, this will simplify the technology of diarrhea treatment at home. As a result of which need for hospitalization and intravenous therapy for diarrhea will be much reduced and ultimately mortality from diarrhea will also be reduced. Fluid electrolyte malnutrition due to diarrhea which has detrimental effect on children can be reduced or possibly reversed with early rehydration therapy at home with home oral rehydration fluid by labon-gur.

Of the mother's attitude and practice of dietary restriction during an episode of diarrhea can be changed by simple dietary advice during delivery of oral therapy this may have a direct beneficial nutritional effect in children. Moreover, early rehydration may improve appetite.

Ultimate success or oral therapy will come from widespread use of labon-gur to treat the majority diarrhea patients at home by member of the family particularly the mother after simple training throughout Bangladesh and other countries where a high incidence of diarrheal illness co-exists with insufficient medical facilities.

E. COLLABORATION:

The following investigators will be Case Consultants for evaluation:

1. Dr. W.B. Greenough
2. Dr. L.C. Chen
3. Dr. R. Black
4. Dr. M. Merson
5. Dr. S. Bhatia
6. Dr. C. Haley (EIS Officer from CDC).

ABSTRACT

ORAL THERAPY FIELD TRIAL

(1) This study proposed a two cell field trial of oral rehydration therapy with glucose-electrolyte salts in one and labon-gur (salt-sugar)in the other in 80,000 population of the Matlab Health Services area, over a period of 18 months . The purpose of this study is to determine the accessaibility, acceptability, effectiveness and safety of the two solutions in terms of reducing the need for hospitalization and intravenous therapy and thus reducing mortality. The study has been designed to be beasically implemented by the Female Village Worker with community particiaption particularly by mothers.

(2) Risks of this study are very samll. Dehydration and electrolyte imbalance are possible complications to some of the diarrhea patients.

(3) Patients with any complications will be immediately referred to Matlab Hospital by Female Village Worker for proper care. Female Village Workers will be properly trained up to recognize such complications. Moreover, two ambulance speed boats will be posted for 24 hours for speedy transportation of any complicated patient.

(4) Patients will be identified by number. All records will be kept in a locked office. At the end of the study, identifying information will be removed from study data sheets.

(5) Signed informed consent will not be obtained from patient(s) as there is no serious potential risk to the subject or privacy will not be involved. Besides these, this study will provide direct health care Services for diarrheal diseases. Instead of signed informed consent, verbal consent will be obtained by explaining the study.

(6) The study will involve interview of a sample of mothers for KAP survey. The interview will be conducted at home of the concerned mother which may take ½ hour approximately.

(7) If both the solutions are found effective under field condition, particularly the labon-gur, this will further simplify the technology of treating diarrhoea at home. Ultimate result of oral therapy will come from widespread use of labon-gur for treating majority of watery diarrhoea at home by mothers after simple training.

(8) The study will require the use of records (Hospital, demographic,) and body fluid (blood, rectal swab).

SECTION III - BUDGET

A. DETAILED BUDGET

1. PERSONNEL SERVICES:

Name	Position	% of Effort	Annual Salary	Project Requirements TAKA	DOLLARS
Dr. M.d Yunus	Investigator	40	56,420	22,568	
Mr. J. Chakraborty	Investigator	40	38,980	15,592	
Dr. K.A Mahmud		10	60,800	6,080	
Mr. Golam Kibria		10	41,490	4,194	
Dr. A.S.G. Faruq	Co-Investigator	25	29,240	7,310	
Mr. A. Sattar Miah	Asstt. Supervisor	50	27,200*	13,600	
Mr. Moqbul Hossain	Asstt. Supervisor	50	29,560	14,780	
Mr. Mukhlesur Rahman	Sr. Field Asstt.	25	21,230	5,308	
Mr. Mahfuzul Islam	Sr. Field Asstt.	25	20,540	5,135	
Mr. C.R. Das	Sr. Field Asstt.	25	20,540	5,135	
Mr. Shahidullah	Sr. Field Asstt.	25	20,540	5,135	
Mr. Md. Kashem Ali	Sr. Field Asstt.	25	25,780	6,445	
Ms. Jahanara	LFPV	25	13,460	3,365	
Ms. Jahan Akter	LFPV	25	13,460	3,365	
Ms. Shahida Begum	LFPV	25	13,460	3,365	
Ms. Hena Begum	LFPV	25	13,460	3,365	
To be named	F.A. - 4	100	72,000	72,000	
To be named	720 person days of F.A.	100	54,000	54,000	
To be named	F.V.W - 80	30	506,400	151,920	
To be named	Coding Asstt. (F.A) - 2	100	36,000	36,000	
To be named	Key Punch Operator	50	11,330	5,665	
To be named	Statistical Asstt-1	50	26,020	13,010	
To be named	Computer Programmer	25	26,020	6,505	
A.R.M. Abdul Alim	Sr. Res. Asstt.	10	36,020	3,602	
To be named	Lab.Tech. (Micro,)	25	15,030	3,758	
To be named	Lab.Tech.(Cln.Path)	25	12,000	3,000	
To be named	Lab.Tech.(Dacca Chemistry)	10	19,940	1,994	
			Sub Total:	476,196.	

2. SUPPLIES AND MATERIALS:

Items	Unit Cost	Amount Required	
GES Packets	1.50		150,000
Labon-gur solution	.30		30,000
Measuring spoon	3.00		6,000
Storing Vessels	5.00		15,000
One seer measuring container	2.50		5,000
Carry blair media	.25	2000	500
R.S. Culture for V.cholera	11.50	2000	23,000
R.S. Culture for Shig. + Sal.	10.00	2000	20,000

Items	Unit Cost	Amount Required	Project Requirements TAKA	DOLLARS
R.S. Culture for R. Virus (ELISA Assay)		2000	5,000	
E. coli - chinese hamster ovary assay	3.oo	2000	6,000	
Infant mouse assay	3.00	2000	6,000	
Plasma Sp. Gravity	.25		500	
Blood Electrolytes	3.25	2000	6,500	
Chemical Analysis for Oral Solution	.50	2000	1,000	
Blood Lancet	$ 2.60	10,000		100.00
Micro Capillary Tubes	$ 4.50/100	10,000		450.00
Cotton Wool	Tk. 22/lb.	10 lbs.	220	
Spirit	Tk. 4.25/lb	10 lbs.	42.50	
Sealing Clay	$ 5.40/pkt.	20 Nos.		17.31
Ice Chest	$ 10.00	4 Nos.		40.00
Ice Flask	Tk.500/ea.	8 Nos.	4,000	
Towel	Tk. 10/ea.	4 Doz.	480	
Soap, Toilet	Tk. 3.50	16 Doz.	672	
Candy	Tk. 10/lb	62 lbs	620	
Balloon	Tk. 6/gross	35 gross	204	
Thermometer (Clinical)	Tk. 14/ea.	8 Dozs.	168	
Torchlight	¢ 1.73 ea.	16 Nos.		27.68
Torch Cell	Tk. 3.50 ea.	32 Dozs.	1,344	
Stationery			3,000	
Phls. Syp. Ampicillin	$ 1.10	4000		4400.00
Vls. Inj. Pronapen	Tk. 1.75	10,000 Vls.	17,500	
Crystapen Syrup	Tk. 6.oo	2000 Phls.	12,000	
Distilled Water	Tk. 0.25	10,000 Amp.	2,500	
Syringe 5 ml	$ 11.85/box	10,000 Nos.		2370.00
Stethoscope	$ 20.00	4 Nos.		80.00
Screw Cap Vial (one dr.)	$ 7.00/box	2000 Nos.		98.00
Carrying Bag	Tk. 22/piece	40 Nos.	880	
Gunney Bag	Tk. 5oo/piece	1000 Nos.	5,000	
		Sub Total:	323,130.50	7582.99

3. EQUIPMENT

Item	Unit Cost	Amount Required		
Salter Scale	$ 400.00	8 each		3200.00
Length Board	Tk. 200.00	8 each	1,600	
Calculator (pocket)	¢ 25.00	2 each		50.00
		Sub Total:	1,600	3250.00

		Project Requirements TAKA	DOLLARS
4. PATIENT HOSPITALIZATION:			
No. of Patient days (3000)		390,000	
	Sub Total	390,000	
5. OUTPATIENT CARE:			
Nil			
6. CRL TRANSPORT:			
Transportation by speedboat Two ambulance boats 2 hrs/day. 1440 run hour		144,000	
One speedboat for field trip 8 hrs/day. 1920 run hour		192,000	
Car for field trip 2 hrs/day. 720 run hour		725,200	
Country boat/porter wages for S.F.A., F.V.W., L.F.P.V., F.A. 7200 @ Tk. 11.60		83,520	
	Sub Total	1,144,720	
7. TRAVEL AND TRANSPORTATION OF PERSONS:			
LOCAL TRAVEL			
Matlab-Dacca-Matlab round trip 300 Tk./trip 24 trips		7,200	
Per Diem - for 24 trips Average Stay - 2 days		5,760	
INTERNATIONAL TRAVEL			
(To attend meeting abroad) Two trips to U.S.A. and return or equivalent.			6,000
	Sub Total:	12,960	6,000

		Project Requirements TAKA	DOLLARS
8. TRANSPORTATION OF THINGS:			
		10,000	
	Sub Total:	10,000	
9. RENT, COMMUNICATIONS & UTILITIES:			
Maintenance of 4 Sub-centers		5,000	
Postage		500	
	Sub Total:	5,500	
10. PRINTING AND REPRODUCTION:			
Printing of Forms			
Mimeography		10,000	
Xerox		2,000	
Publication Cost		10,000	
	Sub Total:	22,000	
11. OTHER CONTRACTUAL SERVICES:			
Computer time		25,000	
	Sub Total:	25,000	
12. CONSTRUCTION, RENOVATION, ALTERATIONS:			
Nil			

B. BUDGET SUMMARY

	Category	1st Year Taka	1st Year Dollar	2nd Year Taka	2nd Year Dollar
1.	Personnel	476,196	-	238,098	-
2.	Supplies	215,420	5,055	107,710	2,528
3.	Equipment	1,600	3,250	-	-
4.	Hospitalization	260,000	-	130,000	-
5.	Outpatients	-	-	-	-
6.	CRL Transport	763,147	-	381,573	-
7.	Travel Persons	8,640	-	4,320	6,000
8.	Transportation Things	6,667	-	3,333	-
9.	Rent/Communication	3,667	-	1,833	-
10.	Printing/Reproduction	11,000	-	11,000	-
11.	Contractual Service	10,000	-	15,000	-
12.	Construction	-	-	-	-
	Total:	1,756,337	8,305	892,867	8,528

Total $ 193,446.60

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Form-2

ORAL THERAPY FIELD TRIAL
Indepth Followup Form

Study No. _____
Date:
F.A. Name:

Village:

H.H.No.:

Individual Number _____

Age:

Sex:

DAY ONE

A. History of Diarrhoea:

Onset: Date _____Time _____Day_____Night _____

Start Oral Therapy: Date _____Time _____

Stool: Type	Loose or Watery	Bloody
Symptom:Fever	Yes	No
Abd. Pain	Yes	No
Vomitting	Yes	No
Do you have any other illness If yes-specify	Yes	No
Is diarrhea continuing If no, when did it stop	Yes	No

B. Clinical:

Dehydration	Normal
	Mild
	Moderate
	Severe
Pulse	Normal
	Weak
	Feeble
	Pulseless
Respiration	Normal
	Rapid
	Severe distress

State of Consciousness
Normal
Unconscious
Convalsion

C. Oral Theraphy Use : No. litters prepared _____

No. of litters used thus far
Source of O.T.
Depot Manager
F.V.W.
Other
Are you taking drinking water Yes No
If yes, what quantity (approx)

Problem of difficulties in preparation

_____

_____

Problem or difficulties in use or acceptance

_____

_____

Side-effect as perceived by mother

Thirst Yes No

Abd. Dis. Yes No.

Others: _____

D. Diet

Only Breast Feeding
Continued
Reduced
Stopped
Breast Feeding with Supliment
Continued
Reduced
Stopped
(Non Breast Feeding & Other) FOOD
Reduced
Stopped
Same
Increased

List new foods given for diarrhea

_____

_____

_____

E. Specimen

1. Rectal Swab Yes No _____ Result ____

2. Oral Fluid Yes No Result

Na ____

K _____

Cl ____

HCO_3____

3. Blood Yes No Result Sugar ___

Sg _____

Na _____

K _____

Cl _____

HCO_3____

4. Containuer Volume _____

DAY THREE

A. History of Diarrhoea:

Stool: Type	Loose or watery Bloody	Soft or Formed
Symptom: Fever	Yes	No
Abd. Pain	Yes	No
Vomitting	Yes	No
Do you have any illness	Yes	No

If yes specify

Is diarrhea continuing Yes No

If no, when did it stop?

B. Clinical

Dehydration
None
Mild
Moderate
Severe

Pulse
Normal
Weak
Feeble
Pulseless

Respiration
Normal
Rapid
Severe/Distress

State of consciousness
Normal
Unconscious
Convalsion

C. Oral theraphy use:

No. of litters prepared _____

No. of litters use thus far _____

Are you taking drinking water(along with O.T.) Yes No

If yes what quantity

Side effect as perceived by mother

Thirst Yes No

Abdominal Dis. Yes No

Other _____

D. Diet:

Only Breast Feeding
Continued
Reduced
Stopped

Breast feeding with supliment
Continued
Reduced
STopped
(Non Breast feeding & other) Food
Reduced
Stopped
Same
Increased

DAY SEVEN

A. History of diarrhoea:

Stool: Type	Loose or watery Bloody	Soft or formed
Symptom: Fever	Yes	No
Abd. Pain	Yes	No
Vomitting	Yes	No
Do you have other illness If yes - specify	Yes	No
Is diarrhoea continuing	Yes	No
If no, when did it stop		

B. Clinical:

Dehydration
None
Mild
Moderate
Severe

C. Oral Theraphy Use:

No. of litters prepared _____

No. of litters use thus far _____

Are you taking drinking water (along with O.T.) Yes No
If yes, what quantity

Side effect as perceived by the mother:

Thirst Yes No
Abd. Dis. Yes No
Other _____

D. Diet:

Only Breast Feeding
- Continued
- Reduced
- Stopped

(Non Breast feeding and other) Food
- Reduced
- Stopped
- Same
- Increased

E. Specimen: Blood Yes No

- Sg _____
- Na _____
- K _____
- Cl _____
- HCO_3 _____

F. Any medication past seven days: Yes No

If yes, specify _____

G. Outcome:

Recovery Yes No

If yes, when _____

Referred Yes No

Death Yes No

Form - 3

ORAL THERAPHY FIELD TRIAL

Hospital Record Sheet

HOSP. NO. _____ Study No._____

1. Name _____Census No._____

2. Age _____

3. Sex _____

4. Date and time of onset _____ _____ _____
Day Month Time

5. Date time of admission _____ _____ _____
Day Month Time

6. Weight: Admission _____

Discharge _____

Height/
Length (children upto 5)

7. History:

Stool: Type Loose or watery
Bloody

Vomitting Yes No

Abdominal Pain Yes No

8. Clinical Exam.

Fever Yes No

Temp._____

Dehydration
None
Mild
Moderate
Severe

Pulse Count _____

Respiration Count ____

Clinical acidosis Yes No

Abdominal Dis. Yes No

Tetany Yes No

State of consciousness

Normal
Convalsion
Unconscious
Both

9. Other physical findings: _____

_____

_____

10. I.V. Theraphy: Yes No

If yes, how much _____

11. Oral Theraphy:
O.T. at home _____ litters
O.T. at hospital _____ litters

12. Total stool output in hospital _____

13. Total vomit output in hospital

14. Reason for hospitalization _____

15. Lab. investigation:

	Taken	Lab. Result
R.S.		
S.G.		
Serum Na		
Serum K		
Serum Cl		
Serum HCO_3		
Glucose		
F.B.T.C.		

16. Duration of diarrhea in hospital

17. Total number of hours in hospital _____

18. Other complications or problems : _____

_____

Signature _____

Date _____

Form-4

ORAL THERAPHY FIELD TRIAL

Hospital Referal Form

Date: _____

Study No. _____

Village: _____

1. Name of the referer: _____

2. Census No. Vill _____ H.H.No. _____ Ind.No. _____

3. Reason for referal:
   - Dehydration
   - Other complication(specify) _____
   - Pursue by guardian
   - Other (specify) _____

4. Patient's condition:
   - Normal
   - Mild dehydration
   - Moderate dehydration
   - Severe dehydration
   - Other(specify) _____

5. Date and time of onset:

   _____ Day _____ Month _____ Time

6. Date and time of referal:

   _____ Day _____ Month _____ Time

7. Did the patient take Oral fluid at home: Yes _____ No _____

   If yes, how much _____
   If no, why _____

8. Patient sent to hospital by:
   - Ambulance boat
   - Countryboat
   - Rickshaw
   - Other(specify) _____

K A P SURVEY OF DIARRHEA
September, 1978

Study No._____ _____ (1 2 3)

Name of Field Worker _____

Date _____ _____ (4 5 6 7)

Village: _____ Family: _____ Ind.No. _____ _____ (9 10 11 12 13 14 15 16)

Name of mother: _____ Husband's name _____ Bari _____

1. How do you know child has diarrhea?

   By number of stools: One Two Three Four Five OrMore DK _____ (16)

   By appearance of stool: Watery Greenish Bloody With mucus DK _____ (17)

   By volume of stool: Small Moderate Big DK _____ (18)

2. What do you think of causes of diarrhea?

   Food Water Dirty habit Germs of disease

   Evil spirit other(specify) _____ DK. (19)

3. Do you consider diarrhea is harmful? Yes ____

   Why _____ _____ (20 21)

   No _____.

   Why _____

4. When there is diarrhea,fluid and salts are lost from the body, which causes dehydration. Do you think this loss of fluid, salts could be replaced by giving mixture of lobon gur/by mixture of sugar+other salts/by plain water/by I.V. saline/none/DK. _____ (22)

5. What do you do when your child gets diarrhea?

   Start self treatment/drug from village quak/drug from homeopath/ drug from kabiraj/drug from qualified doctor/drug from CRL worker/ send to CRL hospital/nothing/DK. ____ 23 24

6. Do you think diarrhea can be treated by: Tablet/capsules/syrup/ spiritual treatment/other (specify) _____DK. ____ 25 26

7. In your opinion what is the best treatment of diarrhea _____ ____

   _____ ____

   _____ 27

8. During diarrhea, is it good for a patient to drink fluids? ____

   Yes _____ No _____

   If yes, what quantity: Less volume than usual/same volume as usual/ more volume than usual/DK. ____ 28

9. When do you start treatment:

   For one stool/two stools/three stools/more than three stools/for weakness when it has last for one day/two days/three days/more than three days/when other symptoms with diarrhea/DK. ____ 29 30

10. What is the normal diet of a child?

    Breast milk/breast milk and water/breast milk and other solid diet/ breast milk and other liquid food/no breast milk, liquid food and specially prepared food/mostly solid food with less frequent breast feeding than previously/no BM-using special solid food with or without animal milk/DK. ____ 31

11. Do you offer any special food/medicine during the diarrhea of your child? Yes _____ No ____ ____

    If yes, what are these _____ 32

12. List all foods other than breast milk and ask the following questions for each food stuff.

    When your child has diarrhea? What do you do with that food. Eliminate/Decrease/Keep same/Increase/Other?

List of food	Response	
_____	elim decr same incr other DK	_____
		33 34 35
_____	elim decr same incr other DK	_____
		36 37 38
_____	elim decr same incr other DK	_____
		39 40 41
_____	elim decr same incr other DK	_____
		42 43 44
_____	elim decr same incr other DK	_____
		45 46 47

13. When your child has diarrhea, what do you do about your breast feeding?
Stop BM/reduce BM/increase BM/make no change/DK. _____ 48

14. Who initiate the change in pattern of breast feeding - Mother - Child - DK. _____ 49

15. For case other than children: What do you do about their food during diarrhea? Continue normal food/stop normal food/give soft food/give liquid food/give more water/ no water/DK. _____ 50

16. Do you like to learn how diarrhea patient can be treated at home by oral saline? Yes ____ No _____ _____ 51

Give reason _____

17. Do you like someone else in your Bari should learn the treatment of diarrhea by Oral Saline? Yes ___ No ___ ____ 52

Give reason _____

18. Why do some patient die from diarrhea?

_____

_____ ____

_____ ____
53

19. How do you like treatment of diarrhea by Oral Saline made ____
of (a) Lobon Gur: Like/dislike/DK. Reason _____

____
54

(b) Glucose, lobon, Khaur Soda and other salt:Like/dislike/DK ____
Reason _____

____
55

CALCULATION OF SAMPLE SIZE FOR NUTRITION ASSESSMENT

Ho There is no difference in the nutritional status (W/A or W/H) of children treated with glucose electrolyte solution vs. those treated with labon-gur.

p' = 0.80

α = 0.50

δ (difference to be found) = .07 (7% difference in % W/A).

$$\frac{7.9 \times (.7 \times .3 + .77 \times .23)}{(.70 - .77)^2} = 624 \text{ in each group}$$

Formula $n = (Z_\alpha + 2_\beta)^2 (p_1q_1 + P_2q_2)\ (P_2 - P_1)^2$

P' = 0.80

α = 0.10 = 490 in each group

δ = .07

P' = .80

α = 0.10 = 986 in each group

δ = .05

Form - 1

ORAL THERAPY FIELD TRAIL
For non-users

Diarrhea Surveillance by F.A.
No. cases in past week _____

No. of patient treated by Depot Mother from her record _____

Difference _____

Age	Sex M	Sex F	Male	Female	Male	Female
<1						
1-4						
5-14						
15 over						
Total cases	_____		_____		_____	

No. of cases not treated by Depot Manager by O.T. _____

Age	Male	Female
<1		
1-4		
5-14		
15+		
Total	_____	

Reason for not using Oral Therapy _____

_____

Name of F.A. _____

Date : _____