F/RRC

ttachment 1.

Date 18-04-88

ETHICAL REVIEW COMMITTEE, ICDDR,B.

rincipal Investigator DR. A. BARI

Trainee Investigator (if any)

pplication No. 88-072

Supporting Agency (if Non-ICDDR,B)

itle of Study Comparison between wheat-Salt solution and Rice-Salt solution for Home Management of Diarrhoea in rural Bangladesh.

Project status:
(✓) New Study
( ) Continuation with change
( ) No change (do not fill out rest of form)

ircle the appropriate answer to each of the following (If Not Applicable write NA).

. Source of Population:
(a) Ill subjects Yes No
(b) Non-ill subjects (Yes) No
(c) Minors or persons under guardianship (Yes) No

. Does the study involve:
(a) Physical risks to the subjects Yes (No)
(b) Social Risks Yes (No)
(c) Psychological risks to subjects Yes (No)
(d) Discomfort to subjects Yes (No)
(e) Invasion of privacy Yes (No)
(f) Disclosure of information damaging to subject or others Yes (No)

. Does the study involve:
(a) Use of records, (hospital, medical, death, birth or other) Yes (No)
(b) Use of fetal tissue or abortus Yes (No)
(c) Use of organs or body fluids Yes (No)

. Are subjects clearly informed about:
(a) Nature and purposes of study (Yes) No
(b) Procedures to be followed including alternatives used Yes No NA
(c) Physical risks Yes No NA
(d) Sensitive questions Yes No NA
(e) Benefits to be derived (Yes) No NA
(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)

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

A Bari

Principal Investigator

Trainee

88-012
19/4

SECTION I

TITLE	:	Comparison between wheat-salt solution and rice-salt solution for home management of diarrhoea in rural Bangladesh
PRINCIPAL INVESTIGATOR	:	Dr. A Bari
CO-PRINCIPAL INVESTIGATOR	:	Dr. AKM Siddique
CO-INVESTIGATORS	:	Dr. ASMM Rahman Dr. ASG Faruque Dr. AH Baqui
STARTING DATE	:	April 1, 1988
COMPLETION DATE	:	September 30, 1989
TOTAL PROJECT COST	:	US$ 70,682
SCIENTIFIC DIVISION	:	This protocol has been approved by the Community Medicine Division

SIGNATURE OF THE SCIENTIFIC PROGRAM HEAD: Iqbal Kabir

DATE: March 16, 1988

16/3/88
Chairperson
CMD Committee

ABSTRACT:

The objectives of the two-cell community study is to assess and compare the usage, safety and effectiveness of wheat-salt solution (WSS) and rice-salt solution (RSS) for home management of diarrhoea in a rural Bangladesh. The study would be implemented in two comparable villages of Chandpur project for one year. Prior to intervention mothers of under-five children will be trained to prepare and usage of WSS and RSS in the respective cell.

Mothers trained will be followed-up at three monthly intervals to assess the retention of training knowledge and practical use of cereal based ORS. Weekly diarrhoea surveillance and once identified, daily follow-up of cases will be done to study and compare the utilization and effectiveness of both ORS in terms of onset of ORS usage, volume consumption, and recovery rate with time period. In terms of safety the electrolyte concentration will be determined by analysing a 10% random sample of both ORS prepared by mothers. The result of the study will help to determine the value of more general implication of ORT and will suggest the formulation of future health policy in diarrhoeal diseases control and management.

REVIEW :

Ethical Review Committee : ----------

Research Review Committee : ----------

Director : ----------

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objectives:

a. To know the availability of wheat and rice at household level of rural Bangladesh

b. To compare the usage of WSS and RSS with optimum provision of training.

c. To compare the effectiveness of WSS and RSS for home management of diarrhoea .

d. To compare the chemical safety of WSS and RSS prepared by rural mothers at home environment.

2. Background:

Global ORT

Oral rehydration therapy (ORT) for diarrhoea has been recognized worldwide as the currently available intervention to reduce diarrhoeal mortality (1). Packets of standard WHO/UNICEF recommended formula of glucose based oral rehydration salts (Glucose-ORS) are being supplied jointly by WHO and UNICEF to promote ORT in the developing countries through diarrhoeal diseases control (CDD) program of WHO. However, a suitable rehydration therapy depends also on the practical factors relating to the cost and availability of ingredients. Moreover, while

searching for a suitable ORT, the crucial question appears to be achievement of large coverage in the population at risk.It is understood that prepackaged ORT, though effective and desirable is not easily available and accessible among the needy and unreached. Due to logistic constraints, the supply of these packets fall far below the total need. Global production of ORS has increased over the years and during 1986 this production is estimated to have been around 270 million litres only (2). From the same source the global ORS access rate was only 51% during 1985.

Simplification of ORT

To make ORT more widely available, less expensive and readily accessible several alternatives have been tried. These include the use of simple salt and sugar/molasses solution (SSS/Laban-gur mixture) by using pinch and scoop method, use of special plastic spoons etc. Several studies have reported the simplicity and practicability of sugar based solution in correcting dehydration and thereby preventing diarrhoeal deaths (3-13). But as these has no demonstrable effect in reducing diarrhoeal stool volume and duration (14-15), the rural mothers couldn't be fully convinced of the usefulness of continued use of sugar based ORT. Moreover, these solutions sometimes cause osmotic diarrhoea and induce vomiting.

Cereal based ORT

In recent years, cereal based oral rehydration solutions have been shown to be an effective alternatives of glucose-ORS. Rice based ORS has been tested mostly at ICDDR,B in Bangladesh and to some extent in India and other parts of the world (16-20). In most of these clinical studies rice based ORS was found to reduce stool volume or duration of diarrhoea than

that of standard ORS. To explore the feasibility of other cereals, Molla et al performed several clinical studies based on wheat, maize, millet, sorghum and observed comparable effectiveness to rice-ORS (Tab. 1, unpublished data). Encouraging results from hospital studies led to a feasibility study of rice-salt solution in the community and observed that rural mothers of Bangladesh can prepare it (21). Following the feasibility study, another community study observed a significant reduction of diarrhoeal duration among the users of rice-ORS than glucose-ORS (22). A drawback of rice based ORT is the low availability of ready-made rice powder in rural Bangladesh at the critical time of need. Moreover, the time and energy required to be spent to make either rice powder or rice paste for preparing the solution may play as a barrier to the effective utilization of the therapy. Wheat flour on the other hand is available as ready-made powder in all corners of Bangladesh. It is the second staple cereal food in Bangladesh. It is relatively inexpensive with more protein and calorie dense than rice. Wheat cultivation is more economic, has been expanding as a realistic and more practical alternative cereal grain in the country. From barely 124,000 hectares in 1974-75, the area for wheat cultivation has been increased to 580,000 hectares in 1982-83. Concomitantly wheat production rose from 100,000 tons in 1974-75 to 1,000,000 tons in 1982. This reflects increasing popularity of wheat as an important cereal food supplement in Bangladesh. Clinical studies with wheat-syrup at ICDDR,B and wheat flour based ORS in Ethiopia have demonstrated better acceptance and effectiveness than that of glucose-ORS. Both the studies postulated that wheat-ORS may provide an alternative source for cereal based ORS in diarrhoea (24,25). A

community study with maize based ORS solution is currently underway in Keneya (26).

There is a great need for further research to identify locally available cereal foods in developing countries, which could be used as practical, acceptable and effective for rehydration and in reducing the severity of diarrhoea, and providing more energy. Table 2. shows the relative merits and demerits of glucose, rice and wheat in ORS solution. Therefore, we propose the comparative study of WSS and RSS in field condition for diarrhoea management at household level. This study may have major implications for the recommendations of future ORT in developing countries in general and Bangladesh in particular.

3. Rationale:

a. Wheat flour can replace the relatively more costly rice / sucrose / glucose for use in ORT and found to be equally effective to provide carrier molecules for co-transport of sodium through gut mucosa in treating diarrhoea (27,28).

b. Wheat is the second staple food and available in almost every house of Bangladesh and in other developing countries.

c. The cost of wheat is significantly less than that of rice or sucrose.

d. Being a cereal food, digested by intraluminal enzymes, liberates glucose molecules slowly and produces no osmotic penalty.

e. Provides energy and carrier molecules (glucose and amino acids). (29) as that of rice.

f. Therefore, the study will allow to promote another ORS where optimum amount of wheat flour is being used in drinkable form. If feasible, will have profound implication in early management of diarrhoeal episodes (30, 31) and early rehabilitation of recuperating malnourished victims. In future people could use wheat based ORT / wheat-salt solution than rice based ORT more readily.

B. SPECIFIC AIMS:

The study will test the following hypothesis

1. Wheat flour is more readily available than rice flour in rural house-holds of Bangladesh

2. The usage of WSS is more than RSS in terms of early usage and increased volume of solution consumption. Early therapy (started within 24 hours of diarrhoeal onset) and late therapy (beyond 24 hours of diarrhoeal onset) users differntial of WSS and RSS might result in early recovery rate of WSS users group than RSS users.

3. WSS is as safe as that of RSS

C. METHODS:

PLACE:

Location: The study area is situated within the Chandpur project of

ICDDR,B under Chandpur District. Which is 70 kilometers from Dhaka in south-eastern direction and 18 kilometers south from Matlab field station of ICDDR,B. The area is located on the bank of river Dakatia (main tribute of river Meghna) and Chandpur-Comilla high way passes through the study area. In September 1978, ICDDR,B started a pilot project for community training and outreach activities on diarrhoea management. The project included 36 villages having an approximate of 50,000 population. The "feasibility of rice-salt solution" and "field copmparison between WHO-ORS and rice-ORS" (22) studies were carried out between 1982 to 1987. For the proposed study we included two new villages in January 1988 and has not been studied like other villages of the project area.

Selection: Two villages having comparable population, socio-econpmic and diarrhoea prevalence are selected for the study (Table 4). Each village represents one cell. Mothers training on WSS would be provided to cell-1 while in the cell-2, mothers will be trained on RSS as part of study. The villages are approachable throughout the year. This advantage will provide uninterrupted collections of informations necessary for evaluating the impact of training on WSS and RSS.

POPULATION:
Prior to intervention existing census data will be updated and it is expected that population will be about 4600 in each cell. The under-five children represent 17% of the total population and mothers of under-five are 11% of total population (Tab. 4 from preliminary survey of the proposed study area).

Sample size: (32).
With the hypothetical difference of usage there might be difference in

effectiveness with time period (Page 8. Specefic Aims).

Power of 80% (Z2 = .84) of getting a significant result at the level 0.05 (Z1 = 1.96)

Expected proportion of diarrhoeal episode recovered in 3 days for Study group (WSS) P1 = 0.5

Expected proportion of diarrhoeal episode recovered in 3 days for Control group (RSS) P2 = 0.4

Let $D = (P1 - P2) = .0.1$; $\bar{P} = (P1 + P2)/2 = 0.45$; $Q = (1 - \bar{P}) = 0.55$

$N = ((Z1 + Z2)^2 \times 2 \times \bar{P} \times Q) / D^2 = 388$

388 diarrhoeal episodes (simple/watery) expected to use WSS/RSS and 50% recover in 3 days time period with 10% difference (Fig. 1). From previous study (Tab. 3) it is expected that at least 50% of diarrhoeal episodes (simple/watery) will use ORS; and each type of diarrhoea constitute approximately one third of total childhood diarrhoea. So the total childhood diarrhoeal episodes will be (388x2x3=2328). In the same study we observed that under-five children suffered from 3 episodes per year and this age group represents about 17% of the total population of the proposed study area. Therefore, the study population in each proposed cell (2328/3) x (100/17) = 4564 or 4600.

PERIOD:

Total 18 months for the following procedures:

1st month -

a. Census updating and tagging of the households with census records in each cell will be carried out.

b. A pre-tested questionnaire survey on mothers about the use and availability of wheat and rice at household level each cell

2nd month -

a. Training of mothers with practical demonstration to prepare and use of WSS in cell-1. They also get instruction regarding, continued feeding during diarrhoea, continued breast feeding of the breast fed children and personal cleanliness. The training will be provided by experienced female health assistants at the home environment in informal sitting to a group of 1-4 mothers at a time and will last for about 1 and half hours. New mothers added to the population during the study period will receive the same instructions. Similar training and instructions will be provided to the mothers cell-2 with RSS.

The preparation of WSS/RSS is to mix one fistfull* of wheat/rice powder with a little over half litre (550 ml) of drinking-water, the mixture is heated with continuous stirring till boiling (3-4 minutes), after cooling the solution a three-fingers pinch of common salt is added. After preparation the solution will remain in drinkable form for 12 hours. Mothers will be instructed to discard the unused solution after 12 hours or whenever distasted by the patients due to perceived bacterial fermentation.

3rd-14th month

a. Diarrhoea surveillance

Because diarrhoea is difficult to define objectively and more

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* Alternately mothers can use one fistfull of wheat/rice grain after being crushed with kitchen stone or pounding pot.

difficult to confirm in a field condition particularly in children. We have chosen respondent's definition of diarrhoea in all cases. Diarrhoea detection will be carried out twice a week by experienced health assistants through weekly visits to each households. The will be asked about the active cases or cases occured since the last visit. Detected cases will be followed to recovery or for 14 consecutive working days and then weekly till the resolution of the episode with the recording of onset, date of visit nature of diarrhoea, dehydration status, care giver's identification, treatment regimens received, amount of ORS consumed and outcome in a precoded surveillance form (Tab.5). Consecutive two episodes will be demarcated by at least two days of non-diarrhoeal period. If required cases will be referred to the Matlab hospital for further management.

c. Follow-up of mother's training

Mothers trained will be followed-up at three monthly, to assess the extent of retention of knowledge and practical usage of ORS. The findings of follow-up will be recorded in specific forms (Tab.6). Reinforcement of training to the mothers who do not retain the appropriate and adequate knowledge as well as the untrained newly added mothers will be carried out.

d. Analysis of WSS and RSS for electrolyte concentration.

Ten percent (10%) random sampling of WSS and RSS prepared by mothers will be done for chemical analysis to assess the electrolyte concentration of home made ORS solutions. Out of the collected samples another ten percent (10%) sample will be analysed

for post hydrolysis glucose concentration. Each sample will be preserved and shifted to biochemistry branch, Dhaka, ICDDR,B in cold chain system.

15th-18th month

Data collection, processing and analysis will be done with the help from data management branch and computer services of ICDDR,B.

Analysis of data:

a. Follow-up of mothers training will be studied and compared among the cell-1, and cell-2 to determine the ORS access rate.

b. Effectiveness of home-made ORT will be assessed by comparing the simple, watery and dysenteric diarrhoeal episodes in 0-4, and >5 age groups of cell-1, and cell-1 on the following parameters:

i. Diarrhoea attack rate (Table.7)
ii. ORS use rate (Table.8)
iii. Use of alternative therapeutic regimens
iv. Volume of ORS use per episode.
v. Recovery rate
vi. Other outcome like death and hospitalization

PERSONNEL:

Apart from the principal and co-investigators the following personnel will be required:

a. Field Research Officer - one
b. Senior Health Assistants - two
c. Health Assistants - six
d. Clerk (grade II) - one
e. Auto driver - one

f. Security guard - three

D. SIGNIFICANCE

The assessment made through the study will provide information to promote an ORT which would be more available, effective, cheap and safe for home management of diarrhoea.

E. FACILITIES REQUIRED

a. Existing Chandpur project office will provide office space.
b. Jeep of the chandpur project will facilitate transportation of the staff members in the study area.
c. Matlab hospital of ICDDR,B will provide necessary treatment to the referred diarrhoea cases.
d. Biochemistry branch of ICDDR,B Dhaka will be used for ORS sample analysis.
e. Data management branch will help for data processing.
f. Computer branch will be used for data entry and analysis.

F. COLLABORATIVE ARRANGEMENTS: Not applicable

TABLE 1. COMPARISION OF EFFICACY OF WHEAT-ORS, RICE-ORS AND GLUCOSE-ORS AFTER 24 HOURS TREATMENT (MEAN ± SD)

VARIABLES	WHEAT-ORS	RICE-ORS	GLUCOSE-ORS
ORS INTAKE (ml/kg.d)	240.6 ± 105.0	162.0 ± 56.0	343.0 ± 151.3
STOOL OUTPUT (ml/kg.d)	89.0 ± 32.0	88.0 ± 54.0	225.0 ± 135.8
% OF STOOL OUTPUT REDUCED	61	61	100
URINE OUTPUT (ml/kg.d)	132.0 ± 117.0	95.0 ± 66.0	101.0 ± 51.0
VOMITUS OUTPUT (ml/kg.d)	5.0 ± 19.3	9.6 ± 18.0	4.0 ± 11.0
CHANGE IN WEIGHT (% OF ADMISSION WEIGHT)	7.4 ± 4.4	8.4 ± 4.9	8.0 ± 3.7
HAEMATOCRIT			
ON ADMISSION	51.6 ± 7.0	54.3 ± 3.8	51.4 ± 6.0
AT 24 HOURS	40.3 ± 8.0	41.0 ± 5.0	41.2 ± 6.0
SERUM SPECIFIC GRAVITY			
ON ADMISSION	1.033	1.036	1.039
AT 24 HOURS	1.025	1.025	1.026

TABLE 2. COMPARATIVE STATEMENT OF GLUCOSE, RICE AND WHEAT AS A BASE IN THE RESPECTIVE ORS PREPARATION

	GLUCOSE	RICE	WHEAT
AVAILABILITY	++	++++	++++
COST/kg IN TAKA	40-50	10-13	6-8
READY MADE POWEDER	++++	+	+++
COOKING	NO	YES	YES
PALATABILITY	+++	++++	++++
EFFICACY IN TERMS OF DECREASING STOOL OUTPUT & DURATION OF DIARRHOEA	++	++++	++++
ENERGY PROVISION	20g/l 80 Kcal	50g/l 200 Kcal	50g/l 200 Kcal

TABLE 3. THE USE PATTERN OF ORS AND DRUGS FOR NON-DYSENTERIC (N-DYS) AND DYSENTERIC (DYSEN) DIARRHOEAL EPISODES (PERCENT)

TREATMENT REGIMENS	N	R-ORS CELL		G-ORS CELL		COMPARISON CELL	
		N-DYS 2578	DYSEN 1291	N-DYS 2552	DYSEN 1186	N-DYS 3430	DYSEN 1451
*ORS ALONE		a 1728 (67)	m 149 (11.5)	b 1477 (58)	n 151 (13)	195 (6)	18 (1)
ORS & DRUG		c 551 (21)	o 641 (50)	d 675 (26.4)	p 439 (37)	349 (10)	114 (8)
DRUG		e 132 (5)	q 431 (33)	f 215 (8.4)	r 545 (46)	1905 (56)	1152 (79)

(Numbers in the parenthesis indicate percentage)

Chi-square test:

a vs. b: P <0.0001 m vs. n: P NS

c vs. d: P <0.0001 o vs. p: P <0.0001

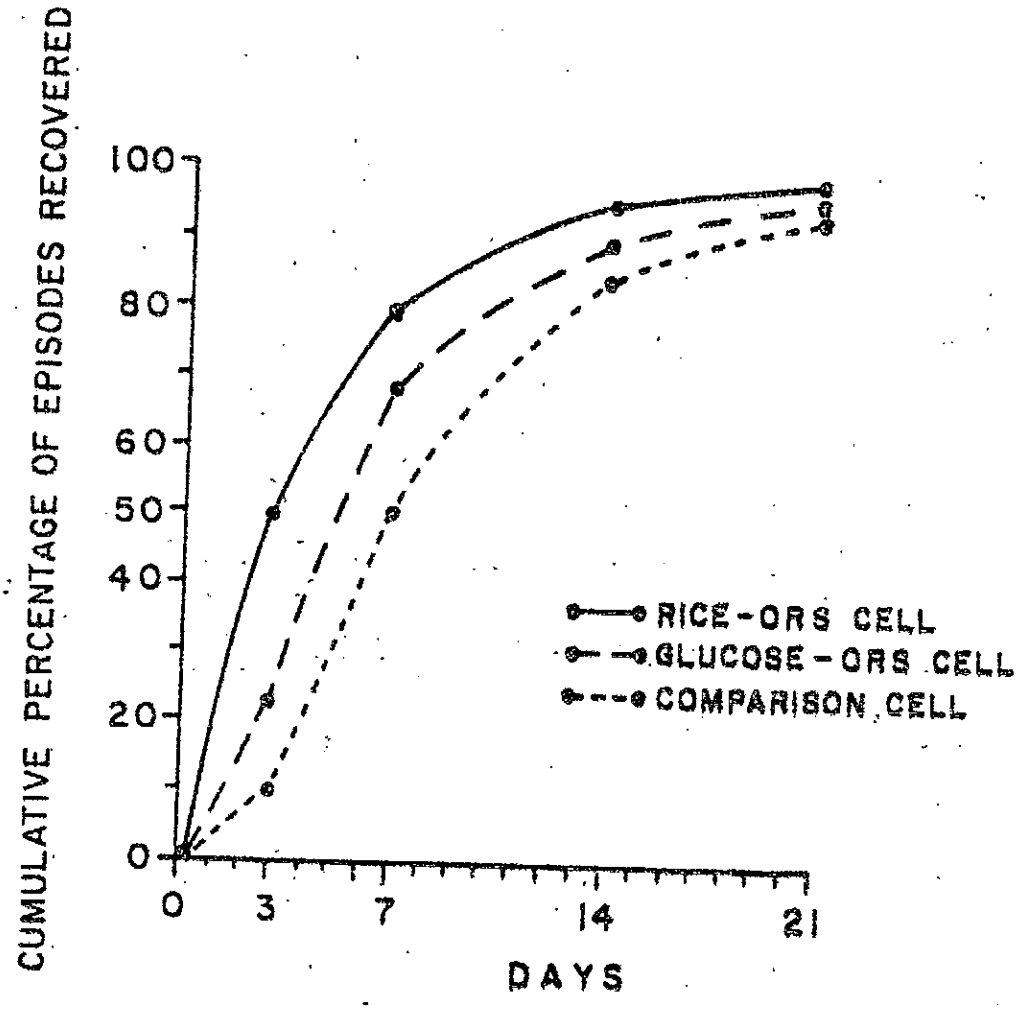
e vs. f: P <0.0001 q vs. r: P <0.0001

* For comparison cell sugar-ORS or sugar salt solution was used from non-study source.

NB: Episodes remaining untreated in each cell are not shown in the table. (Ref. 22 Unpublished data)

FIG. I. CUMULATIVE FREQUENCY OF RECOVERY FROM DIARRHOEA

(EXCLUDING EPISODES HOSPITALISED, ENDED IN DEATH AND OUTCOME UNKNOWN)



NB: Ref. 22 unpublished data.

TABLE 4. CHARACTERISTICS OF STUDY CELLS AND STUDY DESIGN

	CELL-1	CELL-2
VILLAGE	ASHIKATHI	HOSSENPUR
SOCIO-ECONOMIC STATUS	COMPARABLE	COMPARABLE
DIARRHOEA PREVALENCE IN 0-4 AGE GROUP	COMPARABLE	COMPARABLE
POPULATION (APPROX)	4600	4518
SURVEY OF MOTHERS OF 0-4 AGE CHILDREN	502	496
MOTHERS TRAINING ON	WSS	RSS
WEEKLY DIARRHOEA SURVEILLANCE AND FOLLOW-UP	YES	YES
3 MONTHLY FOLLOW-UP OF TRAINED MOTHERS	YES	YES
10% ORS SAMPLE COLLECTION FOR CHEMICAL SAFETY	YES	YES

TABLE 5. DIARRHOEA SURVEILLANCE AND FOLLOW-UP FORM
COMPARISON BETWEEN WSS AND RSS, CHANDPUR PROJECT, ICDDR,B

CELL/__/ BARI/__/__/ FAMILY/__/__/ NAME/__/__/ DOB/__/__/__/ SEX/__/

1-2	3-8	9	10	11-12	13-18	19	20	21-24	25	26	27-30	31	32	33	COL
V#	DD MM YY	DI AR RH OE TY PE	DE HY DR AT IO N	TR EA TM EN T #	DD MM YY	TB1	TW1	VOL	TB2	TW2	VOL	TB3	TW3	END RES ULT	RE MA RK S
1				1											
2				2											
TO 13				13											
14				14											

COL. 1-2: # of visits

COL. 3-8: Date of visits

COL. 9: 1 = Simple diarrhoea
2 = Watery diarrhoea
3 = Dysenteric diarrhoea
4 = No diarrhoea
9 = Absent/No response

COL. 10: 1 = Dehydration present
2 = Dehydration absent
9 = Absent/No response

COL. 11-12: # of treatments

COL. 13-18: date of treatment

COL. 19, 25, 31: Treated by (TB)
1 = Self
2 = Mother
3 = Other family member
4 = Neighbour/Other person
5 = Trained practitioner
6 = Untrained practitioner
7 = Hospitalised
8 = Untreated
9 = Unknown

COL. 20, 26, 32: Treated with (TW)
1 = WSS
2 = RSS
3 = WHO-ORS/Salt-sugar mixture
4 = Drug
5 = Other
6 = Hospital treatment
7 = Untreated/Unknown

COL. 20-24, 27-30: volume of ORS used in ml.

COL. 33: 1 = Cured at home
2 = cured at hospital
3 = Continued
4 = Expired in hospital
5 = Expired in home
6 = Still in hospital
7 = End result unknown

TABLE 6. MOTHERS TRAINING AND FOLLOW-UP FORM
COMPARISON BETWEEN WSS AND RSS, CHANDPUR PROJECT, ICDDR,B

CELL /__/ BARI /__/__/ FAMILY /__/__/ MOTHER /__/ AGE /__/__/__/

1	2-7	8	9	10	11	12	13	14	15	COL.
V	DD MM YY	TRAINING	RETENTION OF TRAINING	NUMBER OF EPISODES TREATED						REMARKS
I				SIMPLE		WATERY		DYSENTERIC		
S				0-4	5+	0-5	5+	0-5	5+	
I										
T										
S										
0										
1										
2										
3										
4										

COL. 1: 0 = Base line training visit
1 = 1st follow-up visit
2 = 2nd follow-up visit
3 = 3rd follow-up visit
4= 4th follow-up visit

COL. 2-7: Day, month and year of visits, exactly

COL. 8: 1 = Participate in training
2 = Do not participate
9 = Absent
0 = No information

COL. 9: 1 = Fully retain training
2 = Do not participate
3 = Partly retain
4 = New mother
5 = Forgotten
9 = Absent
0 = No information

COL. 10: # of simple diarrhoeal episodes in 0-4 age group

COL. 11: # of simple diarrhoeal episodes in >5 age group

COL. 12: # of watery diarrhoeal episodes in 0-4 age group

COL. 13: # of watwry diarrhoeal episodes in >5 age group

COL. 14: # of dysenteric diarrhoeal episodes in 0-4 age group

COL. 15: # of dysenteric diarr. episode in >5 age group

NB: COL 10-15 : Exact # of episodes of previous three months in visits 1-4 only and should be checked with diarrhoea surveillance records.

TABLE 7. DIARRHOEA SURVEILLANCE ON PERSON YEAR AND ATTACK RATE

AGE	PERSON YEAR OF OBSERVATION				DIARRHOEAL EPISODES			
	CELL-1		CELL-2		NUMBER		ATTACK RATE / 1000	
	N	%	N	%	C-1	C-2	C-1	C-2
0-4								
>5								
ALL AGE								

TABLE 8. USE OF ORT AND ORT FAILURE

AGE	USE OF ORT				ORT FAILURE			
	CELL-1		CELL-2		CELL-1		CELL-2	
	N	%	N	%	N	%	N	%
0-4								
>5								
ALL AGE								

SURVEY ON MOTHERS ABOUT THE AVAILABILITY OF WHEAT AND RICE AT HOUSEHOLD LEVEL

Village_____ Bari_____Family _____Mother_____

1. Have you heard about ORS packets avaialble at market for diarrhoea treatemnt? Yes No

2. If yes, do you know the preparation ? Yes No

3. If yes, how do you prepare the solution ? Specify _____
_____

4. Do you know the preparation of home-made ORS with household ingredients ? Yes No

5. If yes, how do you prepare the home-made solution ? Specify_____
_____

6. In case of diarrhoea what is the optimal time to start the rehydration theraphy ? _____
_____

7. How long the therapy should be continued ?_____
_____

8. Do you have any stock of rice grain Yes No
wheat grain Yes No

9. Do you have any stock of rice powder Yes No
wheat powder Yes No

10. Why do you stock rice powder ? _____
wheat powder _____

11. How do you get rice powder ? _____
wheat powder _____

12. Tell me the utility of rice powder _____
wheat powder _____

13. Do you want to know, how to preapare ORS from rice? Yes No
wheat Yes No

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ABSTRACT SUMMARY (FOR ETHICAL REVIEW)

The objectives of the study is to know the availability of wheat and rice flour, to compare the ORS usage, effectiveness and safety of WSS and RSS for home management of diarrhoea with provision of mothers training on respective ORT in a diarrhoea endemic area of rural Bangladesh.

1. The study will be implemented in two villages (2 cells) of Chandpur project for 18 months. The subject population would be the mothers of under-five children. Since children have the highest attack rate diarrhoeal episodes and because the mothers are mostly involved in the care of sick children. So mothers would be trained to use and prepare cereal based ORS solution at home. It is expected that mothers would give consent to participate in this training and follow-up of training.

2. The study methods include training of mothers, interview of mothers about the availability and utility of rice and wheat flour to prepare food stuffs and ORS. The surveillance and follow-up system is required to detect diarrhoeal episodes and to observe the extent of utilization of training and use of home-made ORT. These procedures involve no potential risk.

3. Not applicable.

4. The confidentiality of data collected will be maintained & information will not be passed to any one. Anonymity of the mothers and household will be assured through the use of code numbers for households, mothers, and individuals of the study

area.

5. Since there is no potential risk involved and no invasion of privacy is contemplated, a signed consent will be obtain (enclosed). However, the mothers would be explained the purpose of the proposed interview training, surveillance and follow-up . Only those who will be willing to participate in the activities will be included in the study.

6. The interview, training, surveillance and follow-up will take place in an informal sitting in the households of subject population. Approximately 30 minutes time will be needed for interview, 60-90 minutes for training and 5-10 minutes for surveillance/follow-up. It is expected from our previous field experience that the mothers would spare these times for their own interest.

7. The result of the study will help to introduce a cheap, readily available, effective and safe staple food based ORT for household preparation and management of diarrhoea.

8. The study will not require any hospital record, organ, tissue, body fluid or abortus.

B. BUDGET SUMMARY

EXPENSE CATEGORY	COST OF 1988	COST OF 1989	PROJECT COST
1. LOCAL SALARIES	29232	26690	55922
2. TRAVEL LOCAL	504	756	1260
3. SUPPLIES & MATERIALS	3000	2000	5000
4. OTHER COST	1600	1400	3000
5. INTERDEPARTMENTAL	3500	2000	5500
TOTAL DIRECT OPERATING COST US$	37836	32846	70682

O.K.
16-3-88 Budget office

Section III - Budget

A DETAILED BUDGET FOR 1½ YEARS (APRIL 1, 1988 TO SEPT. 30, 1989)

1. LOCAL SALARIES Name	Position	9 months salary of 1988	6 months salary of 1989	Project Requirement US Dollar
1. A.H. Bhuiyan	FRO	3,141	2,303	5,444
2. Ruhul Amin	Sr. Health Asst.	2,691	1,973	4,664
3. Jaynal Abedin	-do-	2,331	1,709	4,040
4. Umme Kulsum	Health Asst.	2,007	1,471	3,478
5. Fatema Khatun	-do-	2,007	1,471	3,478
6. Mahatab Begum	-do-	2,007	1,471	3,478
7. Rehana Begum	-do-	1,944	1,414	3,358
8. Chand Sultana	-do-	1,944	1,414	3,358
9. Anwara Khatun	-do-	-	1,471	1,471
10. Tazul Islam	Auto-Driver	1,602	1,163	2,765
11. Monsur Ahmed	Clerk	1,620	1,188	2,808
12. Dhan Miah	Security Guard	1,305	957	2,262
13. Abdul Wahed	-do-	1,170	858	2,028
14. Bazlur Rahman	-do-	1,287	943	2,230
15. Dr. A. Bari	Sr. Medical Officer	*4,176	*6,884	11,060
	sub-total:	29,232	26,690	55,922

* 4,176 salary for 6 months & *6,884 salary for 9 months.

	Cost of 1988	Cost of 1989	Project requirement
2. TRAVEL LOCAL	504	756	1,260
3. SUPPLIES & MATERIALS			
Drugs	300	200	500
Stationery & office supplies	600	400	1,000
Material for uniforms	150	150	300
Fuel, oil, lubricants	800	400	1,200
House-keeping supplies	50	25	75
Janitorial supplies	50	25	75
Tools & spares	150	100	250
Non-stock supplies	900	700	1,600
Sub-total:	3,000	2,000	5,000
4. OTHER COST			
Repairs & maintenance	500	300	800
Rent, communication & Utilities	900	900	1,800
Printing & publications	100	100	200
Service charges	100	100	200
Sub-total:	1,600	1,400	3,000
5. INTERDEPARTMENTAL			
Computer	2,000	1,000	3,000
Transport Dhaka	100	100	200
Transport Matlab	100	100	200
Xerox	100	100	200
Bio-chemistry	1,000	500	1,500
staff clinic charge & transport subsidy	200	300	400
Sub-toal:	3,500	2,000	5,500

CONSENT FORM

(Will be read and explained clearly in Bengali before consent is obtained)

The International Centre for Diarrhoeal Disease Research,Bangladesh is planning to under-take a study in your community to find out the effectiveness and safety of wheat based oral rehydration/ ice based oral rehydration solution to treat children suffering from diarrhoea. For this purpose we will ask you about the availability of rice/wheat grain and rice/wheat powder at household level, we will train you to prepare and use of wheat based oral rehydration solution/rice based oral rehydration solution from household ingredient and follow up you by asking about the usage of such solution to treat your children and other family members. We will visit your house twice a week to know about the diarrhoeal diseases for one year.

The result of the study will help to select a better oral rehydration therapy which could be made from household ingredient at low cost and will be beneficial for the children. We will preserve the confidentiality of your information. There is no risk involved.

Your are at liberty to discontinue from this study at any time. We will try to satisfy your any question. If you agree to participate, please sign.

_____ _____

Signature of Principal Investigator

Signature or left thump impression of the mother

Dated _____

সম্মতি পত্র

শিশুদের পেটের অসুখের চিকিৎসার জন্য চাল / গম দিয়ে মুখে খাবার স্যালাইন - এর কার্যকারিতা ও নিরাপত্তা দেখার উদ্দেশ্যে আন্তর্জাতিক উদরাময় গবেষনা কেন্দ্র আপনার এলাকায় একটা গবেষনা শুরু করতে যাচ্ছে। এজন্য আমরা আপনার ঘরে চাল, গম, চালের গুড়া ও আটা আছে কিনা নিশ্চিত করবো। একই সাথে আপনাকে চাল / গম দিয়ে ঘরে তৈরী মুখে খাবার স্যালাইন বানানো ও ব্যবহার করার নিয়ম শিখিয়ে দেবো। শেখানোর পর তা আপনার সন্তান ও পরিবারের অন্যদের পেটের অসুখ হলে ব্যবহার করছেন কিনা তা আমরা জানতে চাইব এবং এক বছর পর্যন্ত আপনার বাড়ীতে সপ্তাহে দু'দিন পেটের অসুখের খোঁজ খবর নেবো।

এর ফলে আমরা অপেক্ষাকৃত ভালো একটা মুখে খাবার স্যালাইন বের করতে পারবো, যা কম খরচে ঘরের মিনিষ দ্বারা বানানো যাবে ও শিশুদের পেটের অসুখের চিকিৎসার জন্য উপকারী হবে। এতে বিপদের কোন কারন নেই এবং আপনার দেয়া সকল তথ্যের গোপনীয়তা রক্ষণ করা হবে।

আপনি যেকোন সময় এই গবেষনায় অংশগ্রহন থেকে বিরত থাকতে পারেন। আপনার কোন কিছু জানার থাকলে আমরা উত্তর দিতে সর্বদাই থাকবো।

এই শর্তে আপনি যদি রাজী থাকেন, তাহলে দয়া করে সই-/টিপসই দিন।

প্রধান গবেষকের সই
ও তারিখ

পাত্রের / অভিভাবকের সই