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FACE SHEET)

Date December 26, 1990
15/1/91

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Dr.ASG Faruque

rincipal Investigator Dr.D.Mahalanabis

Trainee Investigator (if any) _____

pplication No. 90-021

Supporting Agency (if Non-ICDDR,B) _____

itle of Study Impact of ready-to-use packaged rice ORS....in rural Bangladesh

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

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

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

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

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

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

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.

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

Mahalanabis

Principal Investigator

Trainee

A-032079

90-021
15/1/91

How do you assess nutrition in pract

SECTION I - RESEARCH PROTOCOL

Title : Impact of ready-to-use packaged rice ORS on morbidity and nutrition of infants and young children, and response of mothers when provided as an antidiarrhoeal medicine in rural Bangladesh

Principal Investigators : Dr. A.S.G. Faruque
Dr. Dilip Mahalanabis

Co-investigators : Dr. Dilip Kumar Das
Dr. Samiul Hoque
Mr. Mujibur Rahman

Starting date : January 1, 1991

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Total direct cost : US $ 1,11,020

Scientific Programme Head : Dr. Dilip Mahalanabis

ABSTRACT SUMMARY

We propose to study the role of precooked, prepackaged, ready-to- use rice ORS in reducing morbidity (i.e. duration of episodes, thereby, total diarrhoeal days per year) and improving nutritional outcome compared to glucose ORS in infants and young children with mild diarrhoea while implemented at the community level. The randomised controlled design will be followed so that at the design stage no severe imbalance in composition of groups exists. This will ensure that any observed difference in outcome variables between intervention and control can be confidently attributed to the real effect of the intervention. To differentiate the effect of glucose ORS from rice ORS by itself or from the effect of rice ORS plus antidiarrhoeal promotion message, comparable communities will be randomly allocated to intervention and control. Of the target children in 24 communities, 6 intervention communities will receive rice ORS (50 g/litre) with standard message, another 6 intervention communities will receive rice ORS (50 g/litre) plus antidiarrhoeal message, 6 intervention communities will get rice ORS (80 g/litre) along with antidiarrhoeal message and the remaining 6 communities will receive glucose ORS (control) for all diarrhoeal attacks over the whole period of study. Diarrhoeal children will be followed from initiation of ORT to day 16 of illness initially then the observation of these children will continue for 12 consecutive months. To ensure quality control of data, identical forms,

equipments, definitions, and methods will be used throughout the study period in both intervention and control communities. Messages for ORS preparation and administration will be standardised and field tested. Trained community depot holders will distribute ORS packets. Moreover, female interviewers will be trained on interviewing techniques, and taking anthropometric measurements. The performance of depot holders and interviewers will be monitored by regular observation at the field level. Whenever mothers feel it necessary, sick children will be referred to the appropriate health facilities. Data will be summarised and rice ORS and glucose ORS groups will be compared. Statistical tests such as chi-square test, student's t test and, if necessary, equivalent nonparametric tests will be performed. When appropriate, significance tests may be computed by using transformed data. More advanced techniques such as multiple regression for continuous outcome variables and logistic regression for dichotomous outcome variables will be used when elimination of influence of confounding variables will be needed. The result of the study will help to formulate future health policy in diarrhoeal disease control and management and will have far reaching implications for child survival efforts.

Reviews:

Research review committee : _____
(approved/not approved)

Ethical review committee : _____
(approved/not approved)

Director's signature : _____

A. INTRODUCTION

Objective:

The proposed randomised controlled community based study will promote a precooked ready to use rice ORS formulation as an antidiarrhoeal agent in addition to being a hydrating fluid with the following objectives:

1. to evaluate the role of rice-ORS in reducing the morbidity (i.e. duration of episodes and total diarrhoeal days per year);

2. to evaluate the role of rice-ORS in improving nutrition in infants and young children with mild disease implemented under optimal public health conditions (i.e. at the community level).

Background:

The role of glucose-ORS solution in efficiently replacing faecal losses of water and electrolytes is well documented (1-3). However, it does not reduce frequency and stool volume during diarrhoea or shorten the duration of illness. This raises the practical problem of its acceptance and sustained use since a major concern of mothers during diarrhoea is to reduce frequency and volume of child's stool. This results in a persistent desire to use antidiarrhoeal drugs which are either harmful or ineffective.

In 1982, Molla and his colleagues demonstrated that a rice powder-based ORS (30 g/litre) was as effective as sucrose-based ORS (40 g/litre) in adults and older children with cholera (4). In the same year, Patra and his colleagues reported a randomised controlled trial in children aged under 5 years, in which a rice-based ORS using a higher quantity of rice powder (50 g/litre) could significantly reduce the volume (by 49%) and the duration (by 30%) of diarrhoea (5). In a subsequent randomised trial in adults and older children with predominantly cholera, Molla and his colleagues used a large amount of rice powder (80 g/litre) in a ORS formulation and confirmed that ORS based on large quantities of rice powder is substantially more absorption-efficient than glucose-ORS (reducing diarrhoeal stool volume by 28% and ORS consumption by 27%) (6). Field trials of early home therapy with rice based ORS have demonstrated better monthly weight gain when compared with children given glucose ORS. Better weight gain could presumably be due to an effect of correction of fluid-electrolyte deficits on appetite, resulting in better food intake, or perhaps more rapid healing of intestinal mucosa in addition to partial maintenance of calorie intake (7).

The preparation of rice ORS is time-consuming and requires fuel. Therefore, researchers have attempted to develop an ORS formulation that contains low cost traditional precooked rice powder which could be used in a prepackaged ready-to-use form, like the present glucose-ORS.

Several rice snacks e.g. puffed rice ('moori'), popped rice ('khai'), and flaked rice ('chira') are extensively used in the subcontinent, particularly in Bangladesh. Popped rice ('khai') is made from paddy (i.e. unmilled rice with

husk intact). To prepare popped rice, sand is first well heated in an earthenware pot; then sundried paddy is poured on the hot sand and stirred with wooden sticks. The rice grains rapidly expand into 'khai' and the husk automatically splits away. It is very light, white with brown spots, fluffy with an irregular surface and has a bland taste. It is a traditional snack mainly for the rural population. A rice-based food made of 'khai', yoghurt and sugar is still given to patients with diarrhoea. Popped rice is made by many village women as a traditional cottage industry and the product is marketed in the local village markets. It can be stored for several months in an air tight container. 'Khai' is very dry and contains only a trace of moisture, its protein and total energy contents are 8.0 g/100 g and 4.0 kcal/g respectively. Once crushed into a fine powder by roadside wheat grinders, these traditional village based rice snacks were found to be suitable for use in precooked, prepackaged ready-to-use rice ORS.

The first clinical trial of popped rice- based ORS in children with diarrhoea demonstrated its improved absorption efficiency compared to glucose ORS (5). This popped rice powder ORS packet was mixed with drinkable water and used without any further cooking. The only apparent disadvantage was that, the popped rice powder, being in suspension, tended to settle on standing. In practice this was not found to be a problem; mothers were advised to shake the mixture from time to time while in use. In addition, ORS preparations containing upto 80 g/litre of popped rice powder could be used without making it too thick for infants and young children to drink. It may be noted that when 80 g/litre rice powder is cooked into rice ORS, the mixture becomes too thick (gruel like) for infants and children to drink. Therefore, 'khai' ORS offers the potential advantage of the feasibility of using larger quantity of rice powder in the oral saline solution.

Attempt has also been made to conduct community-based studies to evaluate the role of cereal-based ORS in shortening the duration of diarrhoea, reducing the rate of persistent diarrhoea, and rendering nutritional benefit. A recent field study in rural Bangladesh indicated that in predominantly mild disease, rice ORS when used at home may reduce morbidity from diarrhoea (i.e. duration of episodes and incidence of persistent diarrhoea) and render nutritional benefit (i.e. better weight gain) when compared with the group treated with glucose ORS (7,8). The findings if confirmed, may have important implications for Control of Diarrhoeal Diseases (CDD) programmes. However, serious methodological problems with this study design made the conclusions tentative at best. Comparability of the intervention and control groups was not established prior to intervention. The study failed to collect information on intervening processes. Many intervening processes are related to changes in behaviour and usage, particularly in the intervention group. Without any information on change in behaviour and ORS usage, it is difficult to explain the health impact of the intervention. Moreover, the study observed significant differences in diarrhoeal incidence rates in intervention and control village, which may be a reflection of differing influences of confounding variables. Thus, any observed post intervention differences in health cannot automatically be attributed to the intervention. It is epidemiologically evident that a given intervention producing specific effect is best measured in the context of a randomised controlled trial where intervention and control are randomly allocated to matched communities (9). Without a randomised controlled trial design it is difficult to ensure that all possible sources of bias have been addressed. The study in question,

selected two villages thought to be similar in demographic characteristics and intervention was applied to one while the other village served as control. Such an approach may appear reasonable, but it is theoretically incorrect because intervillage variation in key variables may not have been zero and thus lead to biased conclusion. The sample size in each category was one and hence no statistically valid conclusion can be drawn. Though the high costs of intervention studies encourage the adoption of one intervention community, the scientific validity of the randomised trial results justifies the costs. Although randomised community studies are often difficult, such a design is increasingly accepted for the health interventions (10).

The basic design of intervention trials is similar to that of clinical trial with one major exception: intervention is applied at the community rather than at the individual level. Thus to deal effectively with one-to-one comparison problem, it is more practical to study a sample of households in each of the several communities. According to underlying model in intervention research the positive effect of the intervention on the outcome of interest takes place through some mediating process (11).

Intervention _____ > Change in behaviour _____ > Change in outcome

Thus one can hypothesise that the positive effect of rice ORS on diarrhoeal morbidity and/or growth should take place through some improvement in ORS use pattern and the specific effect of the improved ORS. However, changes in both behaviour and outcome may even occur over time in the absence of any intervention. It is therefore, difficult to conclude whether the observed change is due to the program and not due to an independent secular trend. Use of pre-intervention and post-intervention comparisons of mediating factors and outcomes with adequate controls within the framework of a controlled trial is likely to strengthen the study design considerably and serve as an appropriate tool to measure evidence of the success of the intervention more definitely. In assessing the impact of a newly introduced precooked ready-to-use ORS that was not previously available in the community, any observed increased correct adoption of that ORS can safely be attributed to the intervention.

Rationale:

1. Although rice ORS is convincingly shown to reduce diarrhoea output and its duration, the preparation of the solution needs cooking and in case of fuel shortage at the household level the process becomes further difficult. However, precooked ready to use ORS made of traditional rice snacks obviates that problem.

2. Due to methodological flaws of the previous study public health decisions can not be taken without further confirmation. Therefore, it is imperative to repeat the study with the more convenient precooked ready to use packaged rice ORS within the framework of a randomised controlled community trial.

3. The value of rice ORS in reducing the duration and obtaining other clinical benefits relative to glucose ORS in mild disease has been questioned (12). From the diarrhoeal disease control point of view it is important to know if

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rice ORS can shorten illness and improve weight gain in mild diarrhoea to a significant extent. If precooked ready to use rice ORS is shown to be effective in reducing duration of acute diarrhoea and rate of persistent diarrhoea, then its promotion at the community level will have an additional justification.

4. As a logical extension of clinic based studies, it will be wise to promote an ORS which has known advantages in ameliorating certain symptoms of diarrhoeal diseases. It is important to determine whether an ORS which provides curative relief can reproduce similar results in the community by reducing the additional health care seeking behaviour and increasing its adoption more correctly in the long run.

B. SPECIFIC AIMS

The specific aims of this randomised controlled community trial are:

1. To determine if rice ORS use leads to reduced diarrhoea duration in infants and young children with mild diarrhoea compared to glucose ORS under optimal public health conditions in the community.

2. To evaluate if rice ORS use leads to better nutritional weight gain in infants and young children compared to glucose ORS over a short as well as long period of follow-up.

3. To study the effect of rice ORS when promoted as an antidiarrhoeal medicine on its acceptance, correct use (timely started, correctly prepared, and used in adequate amount for adequate duration), and additional health care seeking behaviour of mothers under the condition of the study.

4. To study the time trend of ORS use when promoted with different messages under optimal public health conditions.

C. EXPERIMENTAL DESIGN

The experimental intervention and control:

Twenty four communities (clusters of 40-50 households with at least one under four child in each household), geographically separated from each other will be selected in the project area. To avoid bias these communities will be assigned randomly to receive either 50 g/litre of prepackaged, precooked, ready to use popped rice powder ORS or 80 g/litre of the same rice ORS or glucose ORS with different message through depot holders in the community. Communities getting rice ORS will serve as intervention group while glucose ORS communities will act as the control. Therefore,

A - 6 communities will get rice ORS 50 g/litre with standard message

B - 6 communities will get rice ORS 50 g/litre with antidiarrhoeal message

C - 6 communities will receive rice ORS 80 g/litre with antidiarrhoeal message

D - 6 communities will receive glucose ORS with standard message.

The comparisons between group A and group B will evaluate the impact of message, comparisons between group B and group D, and group C and group D will show the effect of rice ORS, and comparisons between group C and group B will assess the impact of rice ORS 80 g/litre on weight gain as compared to rice ORS 50 g/litre particularly in long run.

Through discussions with the local community leaders and researchers of a nearly completed study on growth monitoring (supported by National Nutritional Council) we gather some preliminary information as the location and distribution of the villages, existing health problems and we made an assessment of the feasibility of the randomised community cluster approach.

The need for randomised control design:

The randomised controlled design will be used to ensure that any observed difference in outcome variables between the intervention and control groups can be confidently explained due to the real effect of the intervention and not attributed to any difference in the baseline composition in the groups. Therefore, it is crucial at the design stage that no severe imbalance in composition of the groups occurs. It has been suggested that even in extreme situations at least four communities are needed in each group to demonstrate a statistically significant difference (11). Closely similar communities will be randomly assigned to receive either the intervention or to act as controls. Thus any difference in observed outcome between interventions and controls is due to the intervention and not due to chance. Moreover, randomisation will:

1. ensure that initial composition of the intervention and control groups are similar

2. enable to infer a causal relationship of observed difference between intervention and control groups

3. ensure that conclusions drawn out of the study are generalizable to other areas.

For randomised design it has been suggested that whenever possible the design should be blind. However, since this intervention aims at achieving a behavioural change, the use of a control intervention rather than no intervention will be be more meaningful. Thus, even with a single blind design bias could be minimised by selecting more objective measurements, with precise questionnaires and procedures.

Setting

The project area is situated about 15 miles away from ICDDR,B in easternly direction of the capital city, and stands on the bank of the river Shitalakhaya under Bandar Upa-zila (sub-district) in Narayanganj district (Appendix 1).

In order to maximise the likely impact of intervention the selection of the study site was based on the following criteria:

1. the area is known for diarrhoeal disease endemicity with high morbidity thus warranting an intervention to minimise the problem

2. lack of adequate static health facilities, poor outreach coverage, poor ORS use rate, lack of appropriate knowledge of preparation and administration of ORS, and very low access to prepackaged formulations is likely to influence the achievement of desired outcomes when more effective and convenient ORS formulation is introduced in the study population

3. Given the existing health and socio-economic problems, the proposed intervention is feasible by utilising available resources

Response variables:

The major response variables are:

1. Weight gain (or loss) : i.e. weight gain (or loss) in g/kg on day 16 of illness compared with baseline weight in short follow-up period;

2. Duration of diarrhoea : i.e. time in hours from initiation of the study treatment until diarrhoea stops as ascertained by the mothers;

3. Weight gain (or loss) : i.e. weight gain (or loss) in g/month compared with base line weight in long follow-up period; for age independent comparison Z-scores of weight for age and weight for height will be used.

Secondary response variables are:

1. Correct use of ORS i.e.

   a) it is started promptly (i.e. started no later than after first 6 hours of onset of diarrhoea), and

   b) it is correctly prepared (i.e. total amount of each packet is dissolved in half litre of water), and

   c) the child is given ORS, at least 50 ml/kg/ 24 hours converted from units of one quarter of half litre container) during diarrhoea, and

   d) ORS is used for at least two thirds of total duration (measurements will be made in 6 hourly units using a picture calendar).

2. total diarrhoea burden i.e. total diarrhoea days per child per year;

3. time trend in ORS use i.e. an increase or decrease in ORS use rate over the time period;

4. additional health care seeking behaviour i.e. outside assistance that has been sought even after the ORS use including use of other antidiarrhoeal medicines.

Eligibility criteria (to evaluate diarrhoeal duration and short term nutritional outcome) for study subjects are:

1. Patients aged 3-47 months
2. Patients with acute watery diarrhoea (three or more watery or liquid or loose stool without any visible blood in 24 hour period or when mothers feel that their children have diarrhoea) for 6 hours or less prior to reporting to community depot holders for ORS
3. With no physical signs of dehydration
4. Patients of both sexes
5. Patients with or without a history of taking drug or antibiotic prior to rehydration therapy
6. Patients with no serious concurrent illness or with no recognised chronic disease
7. Children not suffering from severe malnutrition
8. Children irrespective of feeding habit
9. Resident in the community

Eligibility criteria (to evaluate long term nutritional outcome) for study subjects are:

1. All children in the community aged 3-47 months.
2. Resident in the communities

Sample size estimate:

Comparison of outcome variables between the groups will be performed on all the study children independent of the correct ORS use. It is assumed that ORS will not be used correctly in all episodes at the community level. Therefore, the expected change is relatively less than that of a clinical trial.

(a) To determine impact on diarrhoeal duration (short term follow-up):

Using unpublished data from a clinical trial in children with mild diarrhoea, the sample size (80 % power, alpha=0.05) to detect a difference of 12 hours (mean duration of diarrhoea=91 hours and SD=35 hours) is:

$$N = \frac{2X35X35}{12X12} \times 8$$

= 137 in each group

While calculating the sample size an adjustment for outmigration (10%) from the area of residence is critical.

Therefore, the sample size is 151 in each group. However, after obtaining data from first 100 patients an initial analysis will be conducted. Such analysis will assist in modifying the sample size, if needed.

(b). To determine impact on weight gain on day 16 of illness (short term):

Again using unpublished data from a clinical trial in children with mild diarrhoea, the sample size (80% power, alpha=0.05) to measure a difference of 7 gm (mean=17 gm and SD=28 gm) in weight gain per kg body.weight over 16 days of illness is:

$$N = \frac{2X28X28}{7X7} \times 8$$

= 256 children in each group

While calculating the sample size an adjustment for outmigration (10%) from the area of residence is important. Therefore, the sample size is 282 in each group. However, after obtaining data from first 200 children an initial analysis will be performed. Such attempt will assist in determining the sample size more accurately.

(c). To determine impact on monthly weight gain (long term follow-up):

Using published data (8,13) from two different community based rice ORS and water and sanitation interventions in rural Bangladesh, the sample size (80% power, alpha=0.05) to measure a change of 30 gm per month (mean=124 gm and SD=125 gm) is:

$$N = \frac{2X125X125}{30X30} \times 8$$

= 278 children in each group

with adjustment for outmigration (10%) = 306 children in each group

Therefore the sample size is 306 in each group.

Enrolment of subjects:

Informed consent : Informed consent will be obtained from parents (preferably mothers) of all children before their participation in the study. Mothers will be fully informed about the study and freely- given consent for the subject to participate will be obtained, preferably in writing. The consent form in simple and understandable words will indicate:

- the general purpose of the study
- the benefits and known risk (if any) to the mother
- length of the follow-up

The consent form will also clearly indicate the mothers right to withdraw her child from the study at any time and the fact that the child will continue to receive the ORS packets for the diarrhoeal episode. Depot holders will obtain the informed consent from mothers.

Baseline examination:

Female interviewers will identify family units and children. They will collect baseline information with particular attention to socio-economic and environmental status (appendix 2). Baseline anthropometric measurements of young children prior to initiation of short term follow-up phase will also be conducted by them. Households will be mapped according to their distribution in the communities.

Randomisation:

Steps will be taken to ensure that equal numbers of communities are assigned to each of the three different intervention groups and one control group. Since the most important variable that may confound the outcome is the mother's literacy, relevant information will be collected. These community clusters will then be sorted and arranged in descending order according to proportion of the mothers with no education. Permuted block randomisation technique will be used to assign an equal number of communities into four groups, three intervention groups and one control group from a set of four closely comparable communities from top. Therefore, 6 intervention communities will receive rice ORS 50g/litre with standard message, 6 intervention communities will receive rice ORS 50 g/litre with antidiarrhoeal message, another 6 communities will receive rice ORS 80 g/litre with antidiarrhoeal message and the remaining 6 communities will receive glucose ORS (control). In fact, a stratified randomisation will be implemented to achieve comparability in base line characteristics; however, for the purpose of analysis the strata will be ignored.

Standard case management and the experimental treatment:

Observation of these children for disease and nutritional status will continue daily and once a month, respectively, for 12 consecutive months (long period of follow-up). For short period of follow-up, diarrhoeal children will be followed from initiation of ORT to day 16 of illness as indicated below. The same type of ORS as assigned to the cluster will be offered and used for all subsequent attacks of diarrhoea.

Standard case management

Both mothers and depot holders will receive educational messages to indicate our definition of diarrhoea: three or more loose or liquid or watery stool without any visible blood in a 24-hour period (watery diarrhoea) or any number of stools with visible blood (dysenteric diarrhoea). Since diarrhoea is difficult to define objectively, particularly in children, we will also follow 'mothers qualitative definition'(i.e. whenever they feel their children have diarrhoea). Depot holders will provide ORS packets whenever they detect diarrhoea children during their daily disease surveillance rounds. Moreover, mothers will be advised to collect ORS packets for their diarrhoea children from the community depot holders. Depot holders will educate and demonstrate the preparation and administration of ORS to the mothers. A standard measure (water mug) will be used to measure the required volume of water (half a litre). Breast-fed children will be encouraged to receive milk while being treated. These children will also be followed at the households by the depot holders. The mothers will be further advised on the continuation of unrestricted breast-feeding, diet, and plain water from time to time in small volumes. Pretested forms will be used for recording relevant information. Depot holders will be instructed to refer the children to the nearest appropriate health facility whenever the mothers feel the need (described later).

Organisation of the study:

Curriculum and form development

The curriculum for training of the depot holders includes lectures, demonstrations, and participatory practice on the treatment of diarrhoea by prepackaged ORS. Two distinctly separate standardised educational messages will be developed to be administered by depot holders. These messages will be field tested for validity, comprehension, and acceptability in 10-20 mothers.

Standard message to be administered for promotion of ORS to mothers is:

(a) Water and salts come out of the body during diarrhoea. This 'saline water' (means appropriate ORS solution) replaces the loss and the child gets better.

(b) You must start giving the oral saline as soon as diarrhoea starts; the more you delay in starting saline the worse will be the condition of your child.

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(c) To prepare oral saline for diarrhoea management, a packet of ORS is dissolved in one mug of water;

(d) Give prepared ORS in frequent sips, a small amount at a time using a tea spoon until the diarrhoea stops.

(e) Do not stop giving ORS just because the child vomits.

(f) If the child passes stool frequently, then give relatively more ORS.

(g) In between administration of ORS, offer some plain water.

(h) Continue breast-feeding during the whole period your child has diarrhoea. Also continue giving the usual food you normally give to your child during diarrhoea;

(i) If the child passes less urine, develops sunken eyes, a depressed soft spot on the head in case of infants, and excess thirst, take your child to the nearest appropriate health facility (location of suitable health facilities will be identified before starting the programme);

(j) Twelve hours after you have prepared the 'saline water', discard whatever is remaining and prepare a fresh one.

Antidiarrhoeal message to be administered for promotion of rice-ORS to mothers is:

(a) Water and salts come out of the body during diarrhoea, this ''saline water' (means appropriate ORS solution) not only replaces the loss but also reduces frequency and volume of stool, and duration of illness. Thus the child gets better sooner as well as stronger;

(b) You must start giving the saline as soon as diarrhoea starts, more you delay in starting saline worse will be the condition of your child;

(c) To prepare oral saline for diarrhoea management, a packet of ORS to be dissolved in one mug of water;

(d) Give prepared ORS in frequent sips of small amount at a time using a tea spoon until diarrhoea stops;

(e) Do not stop giving ORS just because the child vomits;

(f) If the child passes stool frequently then give relatively more ORS;

(g) In between administration of ORS offer some plain water;

(h) Continue breast-feeding during the whole period your child has diarrhoea. Also continue giving the usual food you normally give to your child during diarrhoea;

(i) If the child passes small amount of urine, develops sunken eyes, depressed

soft spot on head in case of infants, and excess thirst take your child to the nearest appropriate health facility (location of suitable health facilities will be identified before starting the programme);

(j) Eight hours after you have prepared the 'saline water' discard whatever is remaining and prepare a fresh one.

It may be noted the differences in the two sets of messages are contained in nos. (a) and (j).

In addition, tools for measurement of outcome variables will also be developed and pretested. A questionnaire will be developed for recording relevant information on ORS intake, frequency of stool and vomiting, and feeding practices. However, prior to its use, the questionnaire will be field tested for validity, comprehension, and acceptability in 10-20 mothers. A picture calendar will be developed to use as an instrument to record the duration of diarrhoea along with ORS use. Each mother will be demonstrated how to use the picture calendar. Each calendar will have hand drawn pictures of: (a) a sick child passing diarrhoea stool and (b) a child with diarrhoea is being given ORS by tea spoon out of the feeding cup. Next to these pictures there will be hand-drawn blank boxes in series. Of them, four boxes will be earmarked for recording events occurring in four six-hourly periods of each day. On the top of each box, pictures of the sun and moon will indicate morning, noon, evening, and night in sequence. Mothers will be expected to give check marks with pencils, one mark for each passage of stool and one mark for ORS indicating that ORS has been given during that 6 hourly period. Such a simple and easily understandable picture calendar will facilitate recording of diarrhoeal duration and provision of rehydration therapy with a precision of plus or minus 6 hours. However, this calendar will be field tested in 10-20 mothers before finalising (appendix 3).

Selection and training of depot holders

Community leaders will be explained the objectives and expected benefit out of the proposed study and their active co-operation will be sought for successful implementation of the intervention. With their active assistance, 24 women, one from each community will be selected as depot holders. Women aged 15-40 years, with some education (years of schooling no less than 8 years), intelligent, willing to serve the community and with the permission of their legal guardians to serve as depot holders will be preferred. They will be trained on diarrhoea management at the household level. They will also be trained on face-to-face teaching and demonstration techniques. Depot holders will attend a 2-day lecture, demonstration and practical sessions in ICDDR,B's Dhaka hospital. The method of educating mothers involves showing the method of preparation of ORS by measuring the required volume of water using a standard measure, a half litre mug. The other aspects of education are demonstration of administration of ORS by the depot holder to the child for a while. Moreover, mothers will be advised on continuation of breast-feeding, diet, and plain water from time to time. Once the depot holder is convinced that the mother can prepare and administer ORS up to her satisfaction, then the mother will be allowed to continue the management of the child.

Training of female interviewers

Six female interviewers will be trained to collect household information, health-related data, and anthropometric measurements by using prescribed forms.

Enrolment of children

The study will progress in phases. Management of diarrhoea cases through distribution of ORS packets, disease and nutritional surveillance will start in all communities at a time in each phase. Depot holders will be provided with respective ORS packets for distribution among sick children with diarrhoea in communities. Two months after the beginning of the distribution system, depot holders will be asked to recruit children into the study by maintaining proper records, particularly information on: age, sex, date and time of onset, and diarrhoeal stool characteristics.

Data collection

Data will be collected in two phases:

1. Short period follow-up phase:
   to determine the impact on morbidity and weight gain over a short period

2. Long period follow-up phase:
   to determine the impact on nutritional status over a long period

Short term phase:

Following the initiation of the short term phase, female interviewers will visit those communities, contact depot holders and based on their logs, will ultimately visit all children (according to time and date of onset) with acute watery diarrhoea in each community. These children will be home visited daily till the recovery. The end of an episode will be recorded when the child is found to be have normal stools according to the mother and that cessation of the episode continues for three consecutive days. This will also be confirmed by three subsequent daily visits. If the child is taken to any health care provider or health facility, the nature and type of health care provider and medicines received will be recorded. Anthropometric measurements will be repeated on day 16 of illness.

To facilitate smooth follow-up visits, a diary will be maintained by each female interviewer. The diary will readily provide information on dates of follow-up visits for each child.

Long term phase:

Once started, ORS distribution in all communities will continue for 12 consecutive months through distribution system of depot holders. Surveillance for diarrhoea, ARI, and other common ailments in all study children will be

conducted daily by depot holders using field tested forms. Mothers will be asked about the active cases or cases occurring since the last visit. Detected cases will be followed till recovery or adverse outcome. Two consecutive diarrhoeal episodes will be demarcated by at least three non-diarrhoeal days. Anthropometric measurements will be repeated every month for twelve consecutive months. Investigators during their routine visits to the communities and one investigator, a paediatrician with good familiarity with the communities and population, will treat if necessary sick children and if needed will refer the children to the nearby Rotary Club operated MCH Clinic, Upa-zila Health Complexes, and Narayanganj District Hospital. An appropriate referral linkage will be established with the concerned health facilities well ahead of starting the project. If required, diarrhoeal children will be referred straight to the ICDDR,B hospital.

Quality control

To ensure quality control of data, standardised field tested messages for promotion of ORS will be developed. Moreover, female interviewers will be trained on interviewing techniques and taking anthropometric measurements. The performance of depot holders and interviewers will be monitored by regular observation at the field level. Regular checks on data will be carried out. In 10% cases data collection will be repeated by the supervisor and 5% cases by the investigators. Errors, if any will be corrected on the spot. Moreover, forms will be reviewed daily for completeness. For the sake of standardisation any intra-observer and inter-observer variations will be monitored on weekly basis for controlling such variations. Monthly meetings will review the progress of the work. Identical forms, equipments, definitions, and methods will be used throughout the study period in both intervention and control communities.

Consideration of withdrawals and treatment failures during analysis:

The reasons for withdrawing a patient from the study are: non-compliance of the subject, either because the patient requires unscheduled intervention for a serious intercurrent illness or complications that prevented the planned treatment from being conducted, or migration from his place of residence. Results from all study children will be included in the analysis. Data from patients withdrawn because of any reason will be included in the analysis up to the time of withdrawal.

Summary of procedures:

1. Baseline information with particular attention to the socio-economic and environmental status will be collected. Households will be mapped.

2. Permuted block randomisation technique will be used to assign an equal number of communities into four groups, three intervention groups and one control group from a set of four closely comparable communities.

3. Community leaders will be explained the objectives and expected benefit out of the proposed study and with their active assistance community depot holders will be selected.

4. Community depot holders will be trained on diarrhoea management at the household level. Two distinctly separate standardised educational messages will be developed. Respective educational message along with demonstration of preparation and administration will be administered to the mothers. Appropriate dietary advise will also be given. Each mother will be provided with a picture calendar and its use will be carefully explained to record the diarrhoea events and rehydration therapy. Patients will also be home visited.

5. Anthropometry of eligible children will be conducted prior to starting of distribution of ORT program.

6. The study will progress in phases.

7. Short term follow-up phase will determine the impact on morbidity and weight gain over a short period. Long period follow-up phase will ascertain the impact on nutritional status over a long period.

8. Standardised procedures will be followed to ensure quality control.

Methods to measure the response variables:

__ body weight : by weighing children undressed on a scale sensitive to 20 grams;

__ ORS volume : by counting number of quarters of half litre mug consumed;

__ duration : by counting number of six hourly periods on the picture calendar;

__ correct use of ORS : an independent assessor unaware of the type of ORS the child received will be furnished with information on the presence of diarrhoea with stool and vomiting along with ORS use for the entire period of illness in prescribed summary form. He will be briefed about the criteria for considering the correct use of ORS. He is expected to give his comments by reviewing the information provided whether the ORS use was correct or not (appendix 5);

anthropometry (length, MUAC) : by supine length board (to the nearest of 0.1 cm) by measuring tape (to the nearest of 0.1 cm).

Study schedule:

An outline schedule indicating the time to be required for the different phases of the project is given below:

Year 1:

January-March 1991	: Recruitment and training of study personnel; Development of study materials; Field test of study materials; Procurement of supplies; Establishment of methods.
April-December991	: Carry out long term and short term follow-up; Quality control; Data checking.

Year 2:

January-August 1992	: Carry out long term follow-up; Quality control; Data checking; Data entry.
September-October 1992	: Data analysis.
November-December 1992	: Report writing.

Data management and analysis:

Information will be recorded on the field tested forms. Communities assigned to interviewers for data collection will be changed periodically. They will not be specifically informed of the hypothesis being tested. Data forms will be checked by female interviewers (if information is collected by depot holders), and senior health assistant (if information is collected by female interviewers and if forms are checked by female interviewers). Then all the forms will be checked by the investigators. Data will be cleaned as they are collected and entered into the computer. Apart from visual checks, logical and [illegible] checks of the data will be conducted. System files will then be created using SPSS PC+ software for analysis.

ICDDR,B

During this study two types of data will be collected:

(a) Pre-rehydration therapy data:

Age (months)
Base line weight (Kg)
Base line weight for height (%)
Duration of diarrhoea before rehydration therapy (hours)
Duration of vomiting before rehydration therapy (hours)

(b) Response data:

ORS intake ml/kg/hr during diarrhoea
Stool frequency during diarrhoea
Vomiting frequency during diarrhoea
Weight change g/kg at day 16 of illness
Weight change g/month and change in weight for height and height for age over time
Duration of diarrhoea from start of rehydration therapy (6 hourly units) and cumulative diarrhoea duration per child per year

Although the unit of intervention is a community cluster, the confounders (initial nutritional status of the child, child's age and sex, breastfeeding status, maternal education, socio-economic-condition of the parents etc) will operate at individual child level. We, therefore, plan to analyse the outcome variables taking the individual child as the unit of analysis. Moreover, it is very likely that in this longitudinal study not all mothers will use ORS correctly and data may not be complete in case of all children due to dropouts or temporary absence because of social visits. Therefore, simple and straight forward analysis for differing lengths of follow-up on an individual child basis is crucial.

Data will be summarised, and rice ORS and glucose ORS groups will be compared. To assess the impact on morbidity and nutrition over a short period, groups will be compared with regard to mean and median of age (in months), frequency of stool and vomiting, and duration of diarrhoea prior to start of rehydration therapy (in hours), and base line weight, height, and mid upper arm circumference. Similarly outcome responses will also be summarised and compared. Data on frequency of stool and vomiting during diarrhoea, ORS intake (ml/kg/hr), weight gain (g/kg), and duration of diarrhoea (hours) will be used.

Statistical analysis will include descriptive as well as analytic methods, arithmetic mean and standard deviation if the distribution is normal, and median and ranges if the distribution is not normal will be computed. If the outcome is expressed as a categorical variable, the significance of differences will be evaluated by the chi-square tests. If the outcome is expressed as a continuous variable, the statistical significance of group mean comparisons will be determined by student's t test. If necessary equivalent nonparametric tests will be computed because asymmetric distribution of measurements may occur.
To estimate the impact on nutrition over a long period, the primary objective of the analysis will be to see changes over time. The monthly measurements will be compared with those at base line to reveal whether the effect of

intervention was progressive. Control communities will also be followed in the same fashion. Moreover, monthly changes between intervention and control communities will be compared. The Chi-square for trends will be performed in order to evaluate the significance of differences.

For continuous outcome variables, multiple regression analysis will be used to adjust for several independent variables. In addition, for dichotomous outcome variables logistic regression will be computed where the variable of interest will be regressed on independent variables to estimate relative risk while adjusted simultaneously for various potentially confounding variables. Mantel-Haenszel procedure for stratified analysis will also be performed to check on the validity of logistic regression models.

Weight for height, weight for age, and height for age expressed as percentage of the National Centre for Health Statistics (NCHS) median as well as Z scores will be used as the indicators of nutritional status of the children. For all tests a p value less than 0.05 will be considered to be significant.

Comparison of the data collected on the major outcome variables for short period of follow-up will also be meaningful among the subgroups of children for whom correct ORS use is reported. Therefore, further analysis will be performed taking this point in view. This will be accomplished using logistic regression techniques using correct use of ORT as one of the outcome variables. Moreover, to ascertain the changes in nutritional status for those who will be present throughout the intervention and to guard against bias from differential dropouts or absence, we will perform separate analysis according to differing lengths of follow-up in addition to the subgroup of children present throughout the full year of analysis.

Personnel requirements:

A. Professional scientific staff	#	% time	# months	
			Yr. 1	Yr. 2
1. Dr. ASG Faruque		20	12	12
2. Dr. Dilip Mahalanabis		7	12	12
3. Dr. Dilip Kumar Das		100	12	12
4. Dr. Samiul Hoque		10	12	12
5. Mr. Mujibur Rahman		5	8	8

B. Technical staff

1. Senior Health Assistant	1	100	12	8
2. Female Interviewer	6	100	12	8
3. Field Attendant	3	100	12	8
4. Community Depot Holders	24	100	12	8

SUMMARY BUDGET

			1991	1992
1. Personnel	:	US $	46,020	40,000
2. Local travel	:	US $	5,500	5,000
3. Supplies	:	US $	4,500	4,000
4. Interdepartmental Services	:	US $	3,200	2,800
5. Total	:	US $	59,220	51,880

ABSTRACT SUMMARY FOR ETHICAL REVIEW COMMITTEE

1. This study aims to determine the role of precooked prepackaged ready to use popped rice ('khai') ORS in reducing morbidity and in improving nutritional outcome compared to glucose ORS in infants and young children with mild diarrhoea when implemented at the community level. Hospital based studies with children having severe disease due to acute diarrhoea showed that rice ORS can significantly reduce diarrhoea stool output and duration of the illness. The value of rice ORS in reducing the duration of diarrhoea and gaining better weight in mild disease has been questioned. Due to methodological flaws of the previous community based study public health decisions can not be taken without further confirmation by a randomised controlled community based design. It is also important to determine acceptance and use of rice ORS when it is promoted as having antidiarrhoeal effects. Infants and children (3-47 months) will be included in this study because they are the children vulnerable to high risk of diarrhoea and malnutrition. These children will be followed for consecutive 12 months.

2. No potential risk to infants and young children is involved.

3. The children will be under constant observation of physicians, health workers, and community depot holders.

4. During data analysis only the identification numbers of children will be used and confidentiality will be maintained.

5. Informed consent in a consent form will be obtained from the authorised legal guardian or parents of the child before being included in the study. Mothers will be fully informed about the study and freely given consent for the subject to participate will be obtained, preferably in writing.

6. Interview of mothers will be conducted at their households by female interviewers and community depot holders to know baseline information with particular attention to socio-economic and environmental variables. Information on morbidity, ORS use, other health care seeking behaviour, and nutritional status will also be collected at regular intervals. Each interview shall not take more than half an hour.

7. Children with diarrhoea will be provided with ORS and followed by depot holders, interviewers, and physicians if necessary at households. They will also be referred to the appropriate health facilities if required. The results of the study will help to formulate future health policy in diarrhoeal disease control and management, and will have far reaching implications for child survival efforts.

8. The study will not use records, organs, tissues, body fluids, fetus or the abortus.

CONSENT FORM

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

The International Centre for Diarrhoeal Disease Research, Bangladesh is planning to undertake a study in your community to know the role of precooked ready to use packaged rice ORS in reducing duration of diarrhoea and in improving weight gain in children 3-47 months.

Your child will receive * glucose/rice powder ORS for diarrhoeal episodes based on random allocation. Both ORS formulations are being used in ICDDR,B hospital. We will collect information related to health problem, take weight and measure length. Your child will be followed for at least 12 months.

We believe better knowledge of precooked ready to use rice ORS will bring benefit to the children. The results may help in designing future action programme for control of diarrhoeal disease.

During diarrhoea the child will be home visited and relevant health information will be collected.

The study involves no risk. We will maintain confidentiality of the information given to us. If you do not agree, your child will still get ORS for diarrhoeal episodes. At any stage of the study, you may withdraw your child, but his treatment with ORS will not be hampered.

If you agree to participate in this study then please sign below.

Signature of the Principal Investigator	Date	Signature or left thumb impression of the legal guardian

* The consent form for the community assigned to glucose ORS will only mention glucose ORS and the form for the community assigned to rice ORS will mention rice-ORS.

সম্মতি পত্র

(সম্মতি নেওয়ার আগে পড়ে শুনানো হবে এবং বিস্তারিত ভাবে ব্যাখা করা হবে)

আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র, বাংলাদেশ আপনার এলাকায় একটি গবেষণার মাধ্যমে জানতে চাচ্ছে চাউলের গুড়া দিয়ে তৈরী খাবার স্যালাইন যে রান্না করার প্রয়োজন হবে না) ডায়রিয়ার মেয়াদ কমাতে এবং বাচ্চার (৩-৪৭ মাস বয়স) ওজন বৃদ্ধিতে কেমন কাজ করে ।

আপনার বাচ্চাকে ডায়রিয়া হলে গ্লুকোজ স্যালাইন/চাউলের গুড়ার স্যালাইন দেয়া হবে । এ স্যালাইন আমাদের হাসপাতালে ব্যবহার করা হয় । আমরা আপনার বাচ্চার স্বাস্থ্য সমস্যার তথ্য নেবো । ওজন ও উচ্চতা মাপবো । আমরা এ ভাবে ১ বৎসর আপনার বাচ্চাকে পর্যবেক্ষণ করবো ।

আমরা মনে করি চাউলের গুড়া থেকে তৈরী খাবার স্যালাইন সম্পর্কে বিস্তারিত ধারণা পেলে উন্নতমানের স্বাস্থ্য ব্যবস্থা চালু করতে আমরা সক্ষম হবো ফলে বাংলাদেশের শিশুরা বিশেষ ভাবে উপকৃত হবে ।

ডায়রিয়া চলাকালীন সময় আমাদের গ্রাম্য মহিলা কর্মীরা আপনার বাড়ীতে আসবে এবং বাচ্চার সেবা করবে ।

এই ধরণের গবেষণায় কোন ঝুঁকি নাই । আপনি যে সমস্ত তথ্য আমাদেরকে জানাবেন আমরা তা গোপন রাখবো । আপনি যদি এই গবেষণায় রাজী না থাকেন তবুও আপনার শিশুর জন্য চাহিলে খাবার স্যালাইন দেবো । গবেষণা চলাকালীন সময় আপনি ইচ্ছা করলে আপনার শিশুকে এই গবেষণা থেকে প্রত্যাহার করতে পারবেন, তবে তার চিকিৎসা ব্যাহত হবে না ।

যদি আপনি এই গবেষণায় অংশ গ্রহণ করতে রাজী থাকেন তবে নীচে স্বাক্ষর কিংবা টিপ সই দিন ।

গবেষকের স্বাক্ষর

তারিখ----------

অভিভাবকের স্বাক্ষর/বৃদ্ধাংগুলির ছাপ

তারিখ----------

স্বাক্ষীর স্বাক্ষর

তারিখ----------

** যাদেরকে গ্লুকোজ স্যালাইন দেয়া হবে তাদের সম্মতি পত্রে কেবলমাত্র গ্লুকোজ স্যালাইনের কথা লেখা থাকবে । একই ভাবে যাদেরকে চাউলের গুড়ার স্যালাইন দেয়া হবে তাদেরকে কেবল মাত্র চাউলের গুড়ার স্যালাইনের কথা বলা হবে ।

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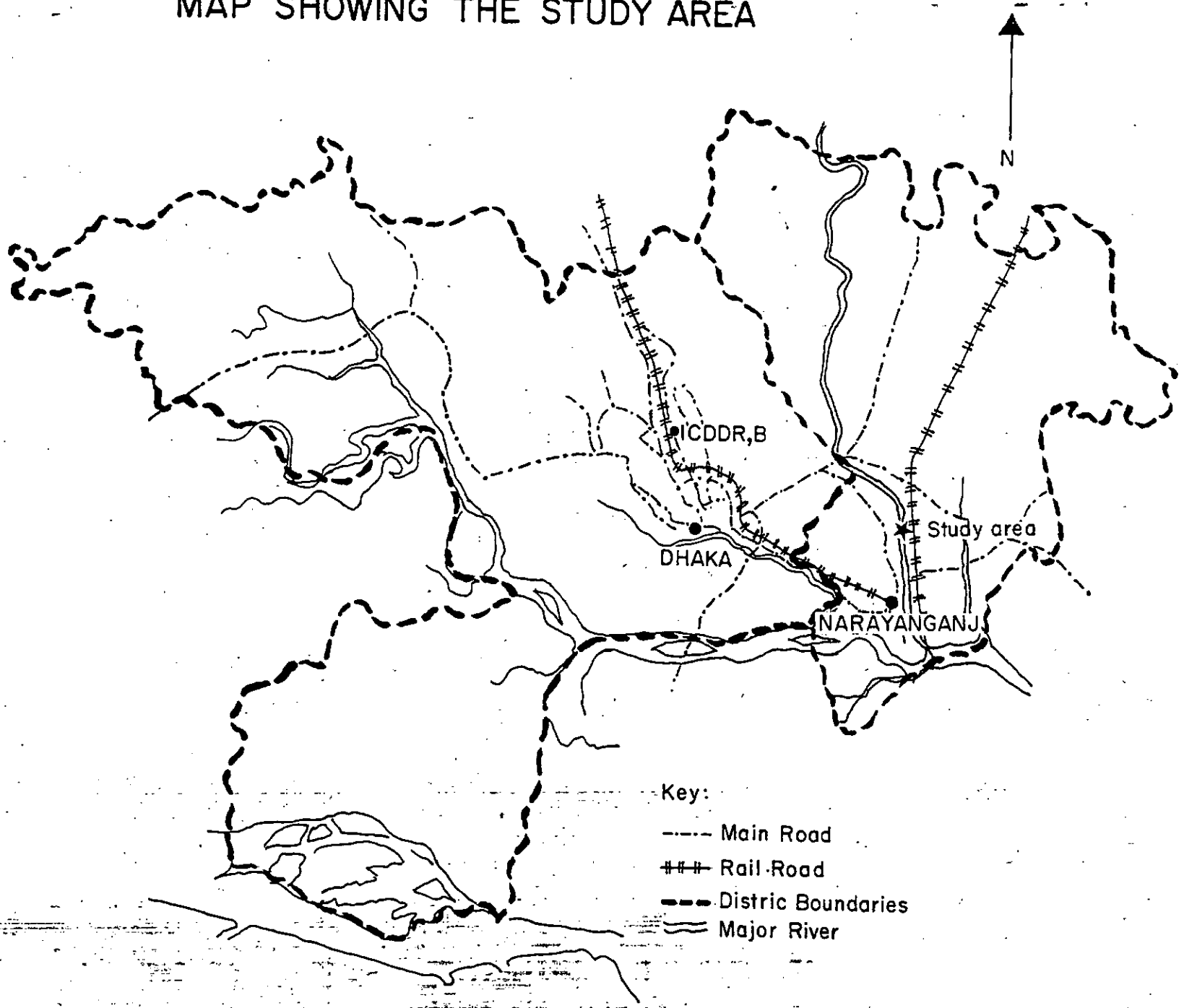
MAP SHOWING THE STUDY AREA



HOUSEHOLD INFORMATION

Village _____ Bari _____

Sl. No.	N a m e	Relation	Age	Sex	I.D. No.	Education	Occupation	Land holding
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								

Source of water: Drinking : Tubewell /___/ Pond /___/ Canal /___/ River /___/ Well /___/ Other /___/

Cooking : Tubewell /___/ Pond /___/ Canal /___/ River /___/ Well /___/ Other /___/

Washing : Tubewell /___/ Pond /___/ Canal /___/ River /___/ Well /___/ Other /___/

Bed-room floor : Cemented /___/ Non-cemented /___/

Electricity : Yes /___/ No /___/

Animals : Cow : Yes /___/ No /___/ # /_____/

Goat : Yes /___/ No /___/ # /_____/

Chicken : Yes /___/ No /___/ # /_____/

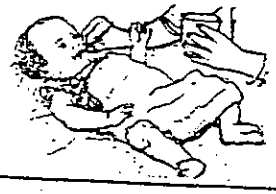
Duck : Yes /___/ No /___/ # /_____/

Name of the worker----------

Date----------

APPENDIX-III

ছবি পঞ্জিকা কোথায়ঃ হাসপাতালে _____ বাড়ীতে _____

প্রতিবার পায়খানা হলে এক বার দাগ দিন	তারিখ- .... বার				তারিখ- .... বার				তারিখ .... বার				তারিখ- .... বার			
	সকাল	দুপুর	সন্ধ্যা	রাত্র	সকাল	দুপুর	সন্ধ্যা	রাত্র	সকাল	দুপুর	সন্ধ্যা	রাত্র	সকাল	দুপুর	সন্ধ্যা	রাত্র
																

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যদি এই সময়ের মধ্যে স্যালাইন খাওয়ায়ে থাকেন তবে প্রতি ঘরে একবার দাগ দিনঃ

সকাল ঃ সকাল ৬টার পর থেকে দুপুর ১২টা
দুপুর ঃ দুপুর ১২টার পর থেকে সন্ধা ৬টা
সন্ধা ঃ সন্ধা ৬টার পর থেকে রাত ১২টা
রাত্র ঃ রাত ১২টার পর থেকে সকাল ৬টা পর্যন্ত

রোগীর নাম ঃ _____
গবেষণা নং ঃ _____
আই, ডি নং ঃ _____

DAILY DISEASE SURVEILLANCE
(Long term cohort follow-up; only for those who have illness)

Name of the worker: _____

Date of visit: _____

1. Child I.D. # ___/___/___/___/___/___/

2. Age (months) ___/___/ 3. Sex (Male=1, Female=2) ___/

4. Any diarrhoea between last visit and this visit ___/
(Yes=1, No=2)

5. If yes date of onset: ___/___/___/___/___/___/
D D M M Y Y

6. Time of onset: ___/

6 AM - 12 Noon=1, 12 Noon - 6 PM=2,
6 PM - 12 MN=3, 12 MN - 6 AM=4

7. If yes character of stool: ___/
(Watery/loose=1, bloody=2, mucoid=3)

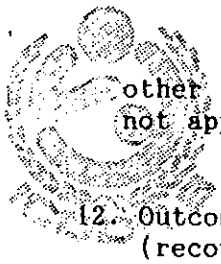
8. If yes, use of ORS: ___/
(Yes=1, No=2)

9. If yes, type of ORS: ___/
(Glucose=1, Rice 50 g=2,
Rice 80 g=3)

10. Use of any drug: ___/
(Allopathic=1, Homoeopathic=2, Herbal=3)

11. Drug received from:

Drug store [Yes=1, No=2] ___/
Qualified physician [Yes=1, No=2] ___/
non qualified physician [Yes=1, No=2] ___/
Kabiraj [Yes=1, No=2] ___/
health complex [Yes=1, No=2] ___/
MCH clinic [Yes=1, No=2] ___/
health subcentre [Yes=1, No=2] ___/
government health worker [Yes=1, No=2] ___/
homoeopath [Yes=1, No=2] ___/
district hospital [Yes=1, No=2] ___/
ICDDR,B hospital [Yes=1, No=2] ___/



other [Yes=1, No=2] ___/
not applicable [Yes=1, No=2] ___/

12. Outcome: ___/
(recovered=1, died=2,
still continuing=3

13. If recovered, date of recovery ___/___/___/___/___/___/
D D M M Y Y

14. If recovered, time of recovery: ___/ ___/

6 AM - 12 Noon=1, 12 Noon - 6 PM=2,
6 PM - 12 MN=3, 12 MN - 6 AM=4

15. Any ARI between last visit and this visit ___/
(Yes=1, No=2)

16. If yes date of onset: ___/___/___/___/___/___/
D D M M Y Y

17. Time of onset: ___/

6 AM - 12 Noon=1, 12 Noon - 6 PM=2,
6 PM - 12 MN=3, 12 MN - 6 AM=4

18. If yes, main clinical features of ARI were:

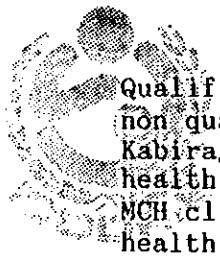
Fever [Yes=1, No=2] ___/
Cough [Yes=1, No=2] ___/
runny or blocked nose [Yes=1, No=2] ___/
Hoarseness of voice [Yes=1, No=2] ___/
Rapid breathing [Yes=1, No=2] ___/
Breathing difficulty [Yes=1, No=2] ___/
Visible sucking in of ribs [Yes=1, No=2] ___/
Very rapid breathing [Yes=1, No=2] ___/
Ear discharge or pain in the ear [Yes=1, No=2] ___/
Unable to drink [Yes=1, No=2] ___/

19. Type of ARI ___/
(Mild=1, moderate=2, severe=3)

20. Use of any drug: ___/
(Allopathic=1, Homoeopathic=2, Herbal=3)

21. Drug received from:

Drug store [Yes=1, No=2] ___/



Qualified physician [Yes=1, No=2] ___/
non qualified physician [Yes=1, No=2] ___/
Kabiraj [Yes=1, No=2] ___/
health complex [Yes=1, No=2] ___/
MCH clinic [Yes=1, No=2] ___/
health subcentre [Yes=1, No=2] ___/
government health worker [Yes=1, No=2] ___/
homoeopath [Yes=1, No=2] ___/
district hospital [Yes=1, No=2] ___/
ICDDR,B hospital [Yes=1, No=2] ___/
other [Yes=1, No=2] ___/
not applicable [Yes=1, No=2] ___/

22. Outcome: ___/
(recovered=1, died=2,
still continuing=3

23. If recovered, date of recovery ___/___/___/___/___/___/
D D M M Y Y

24. If recovered, time of recovery: ___/ ___/

6 AM - 12 Noon=1, 12 Noon - 6 PM=2,
6 PM - 12 MN=3, 12 MN - 6 AM=4

25. Any illness:

Measles	[Yes=1, No=2]	___/
Scabies	[Yes=1, No=2]	___/
Conjunctivitis	[Yes=1, No=2]	___/
Night blindness	[Yes=1, No=2]	___/
Stomatitis	[Yes=1, No=2]	___/
Marasmus	[Yes=1, No=2]	___/
Kwashiorkor	[Yes=1, No=2]	___/
Impetigo	[Yes=1, No=2]	___/
Sore throat	[Yes=1, No=2]	___/
Mumps	[Yes=1, No=2]	___/
TB	[Yes=1, No=2]	___/
Other	[Yes=1, No=2]	___/

MONTHLY SUMMARY FORM
(Long term cohort follow-up)

1. Name of the child: _____

2. Father's name: _____

3. Age(months) _____ 4. Sex: Male_____ Female_____

5. Child I.D. # _____

6. Name of the month _____ Year _____

7. Number of diarrhoeal episodes in this month: _____

8. If any diarrhoea:

Stool character for first episode:

watery/loose_____ bloody_____ mucoid_____

ORS use: Yes_____ No_____

If yes, glucose_____ Rice 50 g_____ Rice 80 g_____

Duration of diarrhoea(# 6 hourly completed period) _____

Use of any drug: Allopathic _____ Homoeopathic_____ Herbal_____

Source of drug:

Drug store_____ Qualified physician _____

Non qualified physician_____ Kabiraj_____

health complex_____ MCH clinic_____

health subcentre_____ homoeopath_____

district hospital_____ ICDDR,B hospital_____

other_____

Stool character for second episode:

watery/loose_____ bloody_____ mucoid_____

ORS use: Yes_____ No_____

If yes, glucose_____ Rice 50 g_____ Rice 80 g_____

Duration of diarrhoea(# 6 hourly completed period) _____

Use of any drug: Allopathic _____ Homoeopathic_____ Herbal_____

Source of drug:

Drug store_____ Qualified physician _____

Non qualified physician_____ Kabiraj_____

health complex_____ MCH clinic_____

health subcentre_____ homeopath_____

district hospital_____ ICDDR,B hospital_____

other_____

Stool character for third episode:

watery/loose_____ bloody_____ mucoid_____

ORS use: Yes_____ No_____

If yes, glucose_____ Rice 50 g_____ Rice 80 g_____

Duration of diarrhoea(# 6 hourly completed period) _____

Use of any drug: Allopathic _____ Homoeopathic_____ Herbal_____

Source of drug:

Drug store_____ Qualified physician _____

Non qualified physician_____ Kabiraj_____

health complex_____ MCH clinic_____

health subcentre_____ homoeopath_____

district hospital_____ ICDDR,B_____

other_____

9. Outcome of diarrhoeal episode: recovered_____ Died_____ Unknown_____

10. Number of diarrhoeal episodes in this month: _____

11. If any ARI:

Clinical features for first ARI episode:

Fever_____ cough_____ runny or blocked nose_____

Hoarseness of voice_____ rapid breathing_____

breathing difficulty_____ visible sucking in of ribs_____

very rapid breathing_____ ear discharge or pain in the ear_____

Unable to drink_____

Duration of ARI (# 6 hourly completed period) _____

Use of any drug: Allopathic _____ Homoeopathic_____ Herbal_____

Source of drug:

Drug store_____ Qualified physician _____

Non qualified physician_____ Kabiraj_____

health complex_____ MCH clinic_____

health subcentre_____ homoeopath_____

district hospital_____ ICDDR,B hospital_____

other_____

Type of ARI: Mild_____ Moderate_____ Severe_____

Outcome of ARI: recovered_____ Died_____ unknown_____

Clinical features for second ARI episode:

Fever_____ cough_____ runny or blocked nose_____

Hoarseness of voice_____ rapid breathing_____

breathing difficulty_____ visible sucking in of ribs_____

very rapid breathing_____ ear discharge or pain in the ear_____

Unable to drink_____

Duration of ARI (# 6 hourly completed period) _____

Use of any drug: Allopathic _____ Homoeopathic_____ Herbal_____

Source of drug:

Drug store_____ Qualified physician _____

ICDDR,B LIBRARY
DHAKA 1212

Non qualified physician_____ Kabiraj_____

health complex_____ MCH clinic_____

health subcentre_____ homoeopath_____

district hospital_____ ICDDR,B hospital_____

other_____

Type of ARI: Mild_____ Moderate_____ Severe_____

Outcome of ARI: recovered_____ Died_____ unknown_____

Clinical features for third ARI episode:

Fever_____ cough_____ runny or blocked nose_____

Hoarseness of voice_____ rapid breathing_____

breathing difficulty_____ visible sucking in of ribs_____

very rapid breathing_____ ear discharge or pain in the ear_____

Unable to drink_____

Duration of ARI (# 6 hourly completed period) _____

Use of any drug: Allopathic _____ Homoeopathic_____ Herbal_____

Source of drug:

Drug store_____ Qualified physician _____

Non qualified physician_____ Kabiraj_____

health complex_____ MCH clinic_____

health subcentre_____ homoeopath_____

district hospital_____ ICDDR,B hospital_____

other_____

Type of ARI: Mild_____ Moderate_____ Severe_____

Outcome of ARI: recovered_____ Died_____ unknown_____

12. Any other illness:

Measles_____ Scabies_____ Conjunctivitis_____

Night blindness_____ Stomatitis_____ Marasmus_____

Kwashiorkor_____ Impetigo_____ Sore throat_____

Mumps_____ TB_____ Other(_____)_____

13. Weight:_____ Kg 14. Length:_____ Cm 15. MUAC:_____ Cm

PRECOOKED READY TO USE RICE ORS STUDY
(Short term diarrhoea follow-up)

Name of the child:_____

Father's name: _____

Village:_____

1.I.D. # ___/___/___/___/___/___/

2.Age(months) ___/___/ 3.Sex : ___/
(Male=1,Female=2)

HISTORY:

4.Date of onset of diarrhoea ___/___/___/___/___/___/
D D M M Y Y

5.Date of onset of vomiting ___/___/___/___/___/___/
D D M M Y Y

6.Time of onset of diarrhoea ___/ 7.Time of onset of vomiting ___/

(6 AM-12 noon=1,12 noon-6 PM=2
6 PM-12 MN=3,12 MN=6 AM=4)

8.Duration of diarrhoea ___/___/ 9.Duration of vomiting ___/___/

(# 6 hourly completed period)

10.Any sickness in last one month: Fever Cough ___/
(Yes=1, No=2)

runny or blocked nose ___/ hoarseness of voice ___/

rapid breathing ___/ Breathing difficulty ___/

Visible sucking in of ribs ___/ very rapid breathing ___/

ear discharge or pain in the ear ___/ Unable to drink ___/

Measles ___/ Scabies ___/ Conjunctivitis ___/

Night blindness ___/ Stomatitis ___/ Marasmus ___/

Kwashiorkor ___/ Impetigo ___/ Sore throat ___/

Mumps ___/ TB ___/ Other ___/

11. Any diarrhoea in last one month: ___/ 12. If yes, duration in days ___/___/
(Yes=1, No=2)

13. Any diarrhoea in last three months: ___/14. If yes, duration in days___/___/
other than # 11 & 12)
(Yes=1, No=2)

15. Feeding at the onset of present diarrhoea: BM ___/ Water ___/
(Yes=1, No=2)

Unbranded powder milk ___/ Commercial baby food ___/

Cow's milk ___/ Goat's milk ___/ Buffalo's milk ___/

Unbranded powder milk + suji ___/ Commercial baby food + suji ___/

Cow's milk + suji ___/ Goat's milk + suji ___/

Buffalo's milk + suji ___/ Solid ___/ Other ___/

16. Feeding before the onset of present diarrhoea: BM ___/ Water ___/
(Yes=1, No=2)

Unbranded powder milk ___/ Commercial baby food ___/

Cow's milk ___/ Goat's milk ___/ Buffalo's milk ___/

Unbranded powder milk + suji ___/ Commercial baby food + suji ___/

Cow's milk + suji ___/ Goat's milk + suji ___/

Buffalo's milk + suji ___/ Solid ___/ Other ___/

17.Completed years of schooling of mother ___/___/

18.Completed years of schooling of father ___/___/

19.Family income (last month) ___/___/___/___/___/ 20.Cemented floor ___/
(Yes=1, No=2)

21.Family landholding ___/___/___/

22.Are you (mother) involved in any income earning job (Yes=1, No=2) ___/

23.If yes, the job is (full-time=1, part time=2) ___/

24.Base line weight (Kg) ___/___/.___/___/ 25.Base line length ___/___/.___/

26.Base line mid arm circumference ___/___/.___/

27.Prior treatment: none ___/ Antibacterial drug ___/
(Yes=1,No=2)

Anthelmentic drug ___/ Antiprotozoal ___/ Antiperistaltic ___/

Other ___/

28.Time of starting of ORS at household ___/___/.___/___/

29.Type of ORS received (Glucose=1, Rice 50 g=2, Rice 80 g=3) ___/

Name of the worker: _____

Date: _____

DAILY FOLLOW-UP VISIT AT HOUSEHOLD
(Short term diarrhoea follow-up)

Name of interviewer:_____

Date: _____

1. Child ID # ___/___/___/___/___/___/

2.Time of visit ___/

(6 AM-12 Noon=1, 12 Noon-6 PM=2,
6 PM-12 MN=3, 12 MN-6 AM=4)

3.Duration between discharge and first visit ___/
(# 6 hourly completed period)

4.Diarrhoea stopped at the time of visit or before ___/
(Yes=1; No=2)

IF DIARRHOEA STOPPED AFTER LAST VISIT:

5.Date of recovery ___/___/___/___/___/___/

6.Time of recovery ___/

(6 AM-12 Noon=1, 12 Noon-6 PM=2,
6 PM-12 MN=3, 12 MN-6 AM=4)

7.Duration of diarrhoea between start of ORT and recovery ___/___/
(# 6 hourly completed period):

8.# stool ___/___/ 9.# vomit ___/___/

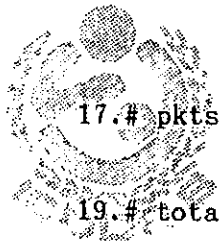
10.ORS use at home: ___/
(Yes=1,No=2)

11.Total quarters of mug taken between discharge and recovery ___/___/

12.Duration of ORS use(# 6hr)___/

13.ORS preparation: # pkts ___/ 14.Dissolved in # mugs ___/

15.# pkts received at hospital ___/ 16.# pkts used ___/



17.# pkts remaining with family ___/ 18.# pkts resupplied ___/

19.# total pkts remaining with family ___/

20.Did you (mother) feel preparation of ORS too bothersome (Yes=1, No=2) ___/

21.If yes, why _____

22.Did you(mother) feel administration of ORS too difficult (Yes=1, No=2) ___/

23.If yes, why _____

24.Did you(mother) have any problem in giving ORS in small quantities at ___/ regular intervals throughout the day at home (Yes=1, No=2)

25.If any problem, what were they _____

_____

26.Feeding at home: BM ___/ Water ___/
(Yes=1,No=2)

Unbranded powder milk ___/ Commercial baby food ___/

Cow's milk ___/ Goat's milk ___/ Buffalo's milk ___/

Unbranded powder milk + suji ___/ Commercial baby food + suji ___/

Cow's milk + suji ___/ Goat's milk + suji ___/

Buffalo's milk + suji ___/ Solid ___/ Other ___/

27.Treatment at home: None ___/ Antibacterial ___/
(Yes=1,No=2)

Anthelmentic ___/ Antiprotozoal ___/

Antiperistaltic ___/ Other ___/

28.Any other illness at home: ___/
(Yes=1,No=2)

specify: _____

_____

IF DIARRHOEA STILL CONTINUING:

29. Duration of diarrhoea between start of ORT and first visit (# 6 hourly completed period): ___/___/

30. # stool ___/___/

31. # vomit ___/___/

32. ORS use at home: (Yes=1,No=2) ___/

33. Total quarters of mug taken between discharge and first visit ___/___/

34. Duration of ORS use (# 6 hr) ___/

35. ORS preparation: # pkts ___/

36. Dissolved in # mugs ___/

37. # pkts received at hospital ___/

38. # pkts used ___/___/

39. # pkts remaining with family ___/

40. # pkts resupplied ___/

41. # total pkts remaining with family ___/

42. Did you (mother) feel preparation of ORS too bothersome=1, No=2) ___/

43. If yes, why _____

44. Did you(mother)feel administration of ORS too difficult (Yes=1, No=2) ___/

45. If yes, why _____

46. Did you(mother) have any problem in giving ORS in small quantities at regular intervals throughout the day at home (Yes=1, No=2) ___/

47. If any problem, what were they _____

_____

48. Feeding at home: BM ___/ Water ___/

(Yes=1,No=2)

Unbranded powder milk ___/ Commercial baby food ___/

Cow's milk ___/ Goat's milk ___/ Buffalo's milk ___/

Unbranded powder milk + suji ___/ Commercial baby food + suji ___/

Cow's milk + suji ___/ Goat's milk + suji ___/

Buffalo's milk + suji ___/ Solid ___/ Other ___/

49. Treatment at home: None (Yes=1,No=2) ___/ Antibacterial ___/

Anthelmentic ___/ Antiprotozoal ___/ Antiperistaltic ____/

Other ___/

50. Any other illness at home (Yes=1,No=2) ___/

Specify:_____

_____

_____

51. Any unschedule visit to other health personnel or facility: ___/
(Yes=1, No=2) ___/

52. If yes, to whom or where:

Drug store	[Yes=1, No=2]	___/
Qualified physician	[Yes=1, No=2]	___/
non qualified physician	[Yes=1, No=2]	___/
Kabiraj	[Yes=1, No=2]	___/
health complex	[Yes=1, No=2]	___/
MCH clinic	[Yes=1, No=2]	___/
health subcentre	[Yes=1, No=2]	___/
government health worker	[Yes=1, No=2]	___/
homoeopath	[Yes=1, No=2]	___/

district hospital [Yes=1, No=2] ___/

ICDDR,B hospital [Yes=1, No=2] ___/

Other [Yes=1, No=2] ___/

53.Reason for that: ___/

(Inadequate hydration requiring I.V.F=1, Excess purging or vomiting=2, Bloody-mucoid stool=3, Severe systemic illness=4, other=5_____)

FOLLOW-UP VISIT AT HOUSEHOLD ON DAY 16 OF ILLNESS
(Short term diarrhoea follow-up)

Name of interviewer:_____

Date of interview: _____

1.Child I.D. # ___/___/___/___/___/___/

2.Time of visit ___/

(6 AM-12 Noon=1, 12 Noon-6 PM=2,
6 PM-12 MN=3, 12 MN-6 AM=4)

IF DIARRHOEA STOPPED AFTER LAST VISIT:

3.Date of recovery ___/___/___/___/___/___/

4.Time of recovery ___/

(6 AM-12 Noon=1, 12 Noon-6 PM=2,
6 PM-12 MN=3, 12 MN-6 AM=4)

5.Duration of diarrhoea between start of ORT and recovery ___/___/
(# 6 hourly completed period):

6.# stool ___/___/ 7.# vomit ___/___/

8.ORS use at home: ___/
(Yes=1,No=2)

9.Total quarters of mug taken between discharge and recovery ___/___/

10.Duration of ORS use(# 6hr)___/

11.ORS preparation: # pkts ___/ 12.Dissolved in # mugs ___/

13.# pkts received at hospital ___/ 14.# pkts used ___/

15.# pkts remaining with family ___/ 16.# pkts resupplied ___/

17.# total pkts remaining with family ___/

18. Did you (mother) feel preparation of ORS too bothersome (Yes=1, No=2) ___/

19. If yes, why _____

20. Did you(mother) feel administration of ORS too difficult (Yes=1, No=2) ___/

21. If yes, why _____

22. Did you(mother) have any problem in giving ORS in small quantities at regular intervals throughout the day at home (Yes=1, No=2) ___/

23. If any problem, what were they _____

_____

24. Feeding at home: (Yes=1,No=2)

BM ___/ Water ___/

Unbranded powder milk ___/ Commercial baby food ___/

Cow's milk ___/ Goat's milk ___/ Buffalo's milk ___/

Unbranded powder milk + suji ___/ Commercial baby food + suji ___/

Cow's milk + suji ___/ Goat's milk + suji ___/

Buffalo's milk + suji ___/ Solid ___/ Other ___/

25. Treatment at home: None ___/ (Yes=1,No=2)

Antibacterial ___/

Anthelmentic ___/ Antiprotozoal ___/

Antiperistaltic ___/ Other ___/

26. Any other illness at home: ___/ (Yes=1,No=2)

specify:_____

IF DIARRHOEA STILL CONTINUING:

27. Duration of diarrhoea between last visit and this visit (# 6 hourly completed period) ___/___/

28. ORS use at home: ___/
(Yes=1,No=2)

29. Total quarters of mug taken between last and this visit ___/___/

30. Duration of ORS use between last and this visit (# 6 hr) ___/___/

31. ORS preparation: # pkts ___/___/ 32. Dissolved in # mugs ___/___/

33. # pkts used ___/___/ 34. # pkts remaining with family ___/

35. # pkts resupplied ___/ 36. # total pkts remaining ___/

37. Did you(mother) feel preparation of ORS too bothersome (Yes=1, No=2) ___/

38. If yes, why _____

39. Did you(mother) feel administration of ORS too difficult (Yes=1, No=2) ___/

40. If yes, why _____

41. Did you(mother) have any problem in giving ORS in small quantities at regular intervals throughout the day at home (Yes=1, No=2) ___/

42. If any problem, what were they _____

_____

43. Feeding at home: BM ___/ Water ___/
(Yes=1,No=2)

Unbranded powder milk ___/ Commercial baby food ___/

Cow's milk ___/ Goat's milk ___/ Buffalo's milk ___/

Unbranded powder milk + suji ___/ Commercial baby food + suji ___/

Cow's milk + suji ___/ Goat's milk + suji ___/

Buffalo's milk + suji ___/ Solid ___/ Other ___/

44. Treatment at home: None ___/ Antibacterial ___/
(Yes=1, No=2)

Anthelmentic ___/ Antiprotozoal ___/ Antiperistaltic ____/

Other ___/

45. Any other illness at home: ___/
(Yes=1,No=2)

Specify:_____

IF NEW EPISODE OF DIARRHOEA:

46. Date of onset ___/___/___/___/___/___/
D D M M Y Y

47. Time of onset ___/

(6 AM-12 Noon=1, 12 Noon-6 PM=2,
6 PM-12 MN=3, 12 MN-6 AM=4)

48. Duration of diarrhoea between onset and this visit (# 6 hourly completed period) ___/___/

49. ORS use at home: ___/
(Yes=1, No=2)

50. Total quarters of mug taken between onset and this visit ___/___/

51. Duration of ORS use between onset and this visit (# 6 hr) ___/___/

52. ORS preparation: # pkts ___/___/ 53. Dissolved in # mugs ___/___/

54. # pkts used ___/___/ 55. # pkts remaining with family ___/

56.# pkts resupplied ___/ 57.# total pkts remaining ___/

58.Did you(mother) feel preparation of ORS too bothersome (Yes=1, No=2) ___/

59.If yes, why _____

60.Did you(mother) feel administration of ORS too difficult (Yes=1, No=2) ___/

61.If yes, why _____

62.Did you(mother) have any problem in giving ORS in small quantities at ___/
regular intervals throughout the day at home (Yes=1, No=2)

63.If any problem, what were they _____

_____

64.Feeding at home: BM ___/ Water ___/
(Yes=1,No=2)

Unbranded powder milk ___/ Commercial baby food ___/

Cow's milk ___/ Goat's milk ___/ Buffalo's milk ___/

Unbranded powder milk + suji ___/ Commercial baby food + suji ___/

Cow's milk + suji ___/ Goat's milk + suji ___/

Buffalo's milk + suji ___/ Solid ___/ Other ___/

65.Treatment at home: None ___/ Antibacterial ___/
(Yes=1,No=2)

Anthelmentic ___/ Antiprotozoal ___/ Antiperistaltic ___/

Other ___/

66.Any other illness at home: ___/
(Yes=1,No=2)

Specify:_____

67. Any unschedule visit to other health personnel or facility: ___/
(Yes=1, No=2) ___/

68. If yes, to whom or where:

Drug store	[Yes=1, No=2]	___/
Qualified physician	[Yes=1, No=2]	___/
non qualified physician	[Yes=1, No=2]	___/
Kabiraj	[Yes=1, No=2]	___/
health complex	[Yes=1, No=2]	___/
MCH clinic	[Yes=1, No=2]	___/
health subcentre	[Yes=1, No=2]	___/
government health worker	[Yes=1, No=2]	___/
homoeopath	[Yes=1, No=2]	___/
district hospital	[Yes=1, No=2]	___/
ICDDR,B hospital	[Yes=1, No=2]	___/
Other	[Yes=1, No=2]	___/

69. Reason for that: ___/

(Inadequate hydration requiring I.V.F=1, Excess purging or vomiting=2,
Bloody-mucoid stool=3, Severe systemic illness=4,
unnecessary prolongation of the illness=5,
other=6_____)

PHYSICAL EXAMINATION:

70. Weight ___/___/.___/___/ kg

71. Length ___/___/.___/ cm

72. MUAC ___/___/.___/ cm

73. Pre-packaged ORS Used before starting of this project: ___/
(Yes=1,No=2)

74. What type of ORS: ___/
Glucose=1,
Sugar=2,
Rice=3
Not applicable=9

75. What was the source: ___/___/
Drug store=1,
district hospital=2,
Qualified physician=3,
Government health worker=4,
non qualified physician=5,
Homoeopath=6,
health complex=7
MCH clinic=8
health subcentre=9
ICDDR,B hospital=10
Other=11 _____
Not applicable=99

76. Did you like the ORS given to your child ___/
(Yes=1, No=2)

77. If yes what did you like about it ___/
(Let the mother answer spontaneously.
At the end ask if there is any thing else)

	Mentioned	Not mentioned
- Child's diarrhoea stopped		
- Child liked it		
- It is free		
- Other		

78. If no, what did you not like about it ___/
(Let the mother answer spontaneously.
At the end ask if there is any thing else)

	Mentioned	Not mentioned
- Child's diarrhoea did not stop		
- Child did not like it		
- This is not a medicine		
- Other		

79. Have you ever used other types of ORS?
(Yes=1, No=2)

80. If yes, what kind of packets was this?

(Show the different packets to the mother)

---

81. Tell the mother:
(I want to know what your opinion is regarding these things which you have tried)

	Surely	Partly	Not at all	DK	NA
(A) Can stop diarrhoea					
Study ORS					
ORS used before					
	Surely	Partly	Not at all	DK	NA
(B) Can help cure the child					
Study ORS					
ORS used before					
	Surely	Partly	Not at all	DK	NA
(C) Taste good					
Study ORS					
ORS used before					

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	Surely	Partly	Not at all	DK	NA
(D) Can lessen weakness					
Study ORS					
ORS used before					

	Surely	Partly	Not at all	DK	NA
(E) Difficult to have					
the child drink it					
Study ORS					
ORS used before					

82. Will you use the ORS we gave you again ___/
(Yes=1, No=2)

83. Would you recommend it to your friends/neighbours ___/
(Yes=1, No=2)

84. Which ORS would you prefer? ___/
(Present one=1, past one=2)

85. Why?

_____

_____

86. Any illness between second and third visit ___/
(Yes=1, No=2)

87. Re ID # ___/___/___/___/