

Principal Investigator R.E. Black, M.D. Trainee investigator (if any) \_\_\_\_\_

Application No 78-014 Supporting Agency (if Non-CRL) \_\_\_\_\_

Title of study Diarrhea and Growth Study Project status:  
 New Study  
 Continuation with change  
 No change (do not fill out rest of form)

- Circle the appropriate answer to each of the following (If Not Applicable write NA):
- Source of Population:
    - Ill subjects  Yes  No
    - Non-ill subjects  Yes  No
    - Minors or persons under guardianship  Yes  No
  - Does the study involve:
    - Physical risks to the subject  Yes  No
    - Social risks  Yes  No
    - Psychological risks to subjects  Yes  No
    - Discomfort to subjects  Yes  No
    - Invasion of Privacy  Yes  No
    - Disclosure of information possibly damaging to subject or others  Yes  No
  - Does the study involve:
    - Use of records (hospital, medical, death, birth or other)  Yes  No
    - Use of fetal tissue or abortus  Yes  No
    - Use of organs or body fluids  Yes  No
  - Are subjects clearly informed about:
    - Nature and purposes of study  Yes  No
    - Procedures to be followed including alternatives used  Yes  No
    - Physical risks  Yes  No
    - Sensitive questions  Yes  No
    - Benefits to be derived  Yes  No
    - Right to refuse to participate or to withdraw from study  Yes  No
    - Confidential handling of data  Yes  No
  - Will signed consent form be required:
    - From subjects  Yes  No
    - From parent or guardian (if subjects are minors)  Yes  No
  - Will precautions be taken to protect anonymity of subjects:  Yes  No
  - 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:
- 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.
  - Examples of the type of specific questions to be asked in the sensitive areas.
  - An indication as to when the questionnaire will be presented to the Board for review.

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

P. Kelly MD R. Black  
Principal Investigator

\_\_\_\_\_  
Trainee

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

78-014  
Recd 10/4/78

SECTION I - RESEARCH PROTOCOL

1. Title: Diarrhea and Growth Study.
2. Principal Investigator: Robert E. Black M.D.
3. Starting Date: March 1, 1978.
4. Completion Date: June 30, 1979.
5. Total Direct Cost: \$102, 173
6. Abstract Summary: A cohort of 200 children (age 3 months - 4 years) from 2 villages will be studied for 1 year to determine the relationship of serum and breastmilk antibodies to protection from enteric infection and the effect of diarrhea on growth, lactose malabsorption, and food intake. Studies of water use, defecation behavior and environmental microbiology are being planned in the same villages.  
  
In one village (100 children) oral glucose-electrolyte solution will be provided to determine if use of this solution for all diarrhea results in enhanced growth compared with children treated with conventional therapy.
7. Reviews:
  - a) Research Involving Human Subjects: \_\_\_\_\_
  - b) Research Committee: \_\_\_\_\_
  - c) BNRC: \_\_\_\_\_
  - d) Director: \_\_\_\_\_
  - e) Controller/Administrator: \_\_\_\_\_

## SECTION II - RESEARCH PLAN

### A. INTRODUCTION

#### 1. Objective

The objectives of this study are 1) to identify the etiologic agents of diarrhea episodes in the first 5 years of life. 2) to learn the relationship of serum and breast milk antibody titers to specific enteric pathogens to the risk and severity of diarrhea caused by these agents. 3) to learn the effect of diarrheal episodes on food intake, absorption of lactose and growth, 4) to determine if oral glucose electrolyte solution taken for all cases of diarrhea has a beneficial effect on growth. Studies of water use, defecation behavior and environmental microbiology are being planned.

#### 2. Background

Diarrheal diseases are a major cause of morbidity and mortality in developing countries, both through their direct impact on the host and through their adverse effect on nutrition. Until recently, the etiology of most of these diarrheal episodes could not be determined however, within the past several years techniques have become available to detect bacterial and viral agents which have heretofore been overlooked. The application of these techniques in Bangladesh and in other countries has led to recognition of rotaviruses and enterotoxin producing Escherichia coli (ETEC) as important pathogens in many countries (1-8). Other recently discovered agents such as parvovirus have yet to be studied in developing countries.

Studies currently in progress to determine the age-specific incidence of diarrhea in the Matlab field area suggest that rotavirus and ETEC are the most important pathogens in infantile diarrhea. In the <2 year age group the estimated annual incidence of hospital visits for ETEC-associated diarrhea is 67 per 1000, while the incidence of rotavirus-associated diarrhea may be even higher. Rotavirus has been sought in the stool of Matlab hospital patients since November 1977. Between November and February rotavirus has been found in over 60% of children less than 2 years of age. Since rotavirus infections may be seasonal, the annual incidence cannot be determined until children are tested during additional months of the year. After 2 years of age the incidence of these 2 infections decreases. For ETEC the annual incidence after age 2 years ranges from 2-7 per 1000 persons and for rotavirus the drop in incidence is even more marked. Very few rotavirus infections have been found in persons over 2 years of age.

The declining incidence of these two infections with age suggests acquired immunity; however this has been studied to only a limited extent. In Bangladesh, serologic studies have revealed that 67% of children by age 4 and 95% of adults have demonstrable CF antibody titer to rotavirus (7, 8). However, recent information suggests that detectable serum levels of antirotavirus IgG are not protective against symptomatic infection and that development of anti-rotavirus IgM correlates with the presence of symptomatic infection (9). Likewise with ETEC mean antitoxin titers increase with clinical infection and with increasing age, but it is not clear if this heat-

labile enterotoxin neutralizing antibody is related to protection from ETEC disease (10). Serum bactericidal and anti-adhesive antibodies are also being studied for their role in protection from illness; but, as appears to be the case with cholera, local intestinal immunity may be primarily responsible for immunity to enteric diseases (11-13). Since breast milk may be important for transferring intestinal immunity from mother to child in the early months of life, it must be studied as well as serum to elucidate the role of immunoglobulin specific immunity in enteric infections (13-14).

It is the young children also who appear to suffer nutritionally because of diarrhea. Previous studies have documented a drop in weight and an alteration in the growth of children because of diarrhea (15-17). However, the mechanism by which diarrhea acts is not well understood. Possible contributing factors may be 1) withdrawal of food or alteration in food given to an ill child, 2) anorexia and vomiting, 3) catabolic losses from the illness, and 4) malabsorption of nutrients. Although comprehensive studies have not been done to evaluate the importance of each of these factors, analysis of data from available studies suggests that altered food intake is more important than catabolism, at least for diarrheal illnesses (18-19). Altered food intake is often related to cultural practices, beliefs and taboos relevant to illness, but may also be due to anorexia, vomiting or malaise. One study found reduced intake associated with illness in the second year of life but not the first or third year (19). The role of malabsorption is difficult to assess with available evidence.

Malabsorption during and following illness from a wide variety of infectious agents has been documented (20-24). The largest number of studies refer to malabsorption of sugars which are the predominant source of dietary calories. Most studies have used the non-dietary pentose, xylose, as the test sugar and have confirmed malabsorption in a variety of types of enteritis as well as in a large proportion of residents of many developing countries. However, recent investigations cast some doubt on the relationship between xylose malabsorption and altered absorption of dietary nutrients. On the other hand, malabsorption of lactose may be a problem of more importance, since it is the major carbohydrate in human and cow milk, and is the most poorly absorbed of all disaccharides (24). Furthermore, intestinal lactose is the most sensitive of the intestinal disaccharides to infectious or toxic injury and therefore lactase activity is one of the most sensitive indicators of intestinal insult. A study in Mexico of 50 infants with severe diarrhea found 46% with lactose intolerance and the authors suggested that sugar malabsorption may not only worsen diarrhea symptoms but also contribute to intestinal bacterial overgrowth (25). Unabsorbed lactose exerts an osmotic effect, drawing water into the intestine and hastening transit time. This increased transit time is hypothesized to be a mechanism for secondary malabsorption of other nutrients.

The etiology of the diarrheal episode may be an important determinant of the severity and duration of malabsorption. Various enteric pathogens have been demonstrated to cause decreased disaccharidase activity.

or lactose malabsorption either during or after illness. In a study of both cholera and non-cholera enteritis jejunal sucrase, maltase, palatinase, and lactase were depressed in 14 patients during diarrhea (26).. Even in convalescence hydrolysis of lactose and lactase activities remained abnormally low in 13 of 14 patients. Volunteer studies with the Norwalk agent showed similar results (21). Of 5 subjects tested 2, both of whom had minimal lactase deficiency before infection, became ill. While they were ill, lactase deficiency became much worse and in convalescence there was some improvement, although absorption remained abnormal. One subject who did not become ill nonetheless developed lactose malabsorption after the virus challenge.

Animal studies support the importance of rotavirus infection as a threat to normal growth. After challenge of either pigs or calves with either human or bovine rotavirus, malabsorption of xylose and lactose developed. The period of diarrhea was short, however malabsorption and weight loss persisted for 6-8 weeks. These changes correlated with a reduced villus to crypt ratio after illness (27).

It is likely that some children with acute diarrheal disease develop persistent carbohydrate malabsorption and therefore undergo a nutritional deficit. A comprehensive study is needed to define the relative importance of this factor and others, such as altered food intake, as determinants of malnutrition.

It has been suggested that rapid and complete replacement of water

and electrolyte losses during diarrhea will result in an earlier return of appetite than would otherwise occur (28). One study in the Philippines tested the hypothesis that the use of an oral glucose-electrolyte solution in an outpatient clinic and at home would result in improved growth (29). In spite of the provision of nutrition education and stress on feeding and provision of fluids during diarrhea in both the study and control communities, the children in the study community (oral solution treated) had a higher relative weight gain than children in the control community. By 1-2 months following diarrhea study children gained weight and control children lost weight. In 7 months there was a 3% difference in the study children compared with the control children.

If these results can be confirmed they may provide strong justification for provision of oral replacement solution at the village level. However, if growth is enhanced, the mechanism for this effect is still unclear. The explanation that appetite is enhanced by correction of electrolyte imbalance is suggested by the authors of the previous study. On the other hand, they mention in the report that there were "no differences between the groups as to appetite during attacks". An alternative explanation is that mothers changed their attitudes and practices concerning feeding children during diarrhea. Even if the instructions on feeding during diarrhea were comparable in the 2 groups, the mothers in the oral fluid community may have practised more aggressive feeding during illness, possibly because they recognized that oral fluids were well tolerated during diarrhea and were being encouraged as a medicine. If a positive



effect on growth can be demonstrated, the mechanism of this effect is important. If it is due to enhanced appetite from normalization of hydration and electrolytes, the appropriate intervention in provision of oral solution at the village level. On the other hand, if the mechanism is enhanced feeding based on changes in mothers' beliefs and behavior, nutrition education may be a more appropriate intervention.

3. Rationale

In many developing countries, like Bangladesh, diarrheal diseases and growth retardation are important problems. Although the inter-reactions between nutrition and infection have been recognized, a more complete understanding of the mechanism by which diarrhea affects nutrition is critical to developing appropriate interventions to enhance growth and decrease morbidity and mortality. One such intervention - the provision of oral glucose-electrolyte solution to 50% of the study children - will be utilized. It is hoped that study of this intervention will provide additional information on the adverse effects of diarrhea, as well as test the intervention itself.

B. SPECIFIC AIMS

1. We will attempt to identify the etiology of all diarrheal episodes occurring in 2 groups of children (all children in 2 villages up to and including 4 years old) using rectal swabs and serology. From this we hope to learn the relationship of serum antibody titers to the risk of clinical illness and subclinical infection caused by specific enteric agents.
2. We will attempt to relate the titer of antibodies to enteric pathogens in breast milk with the occurrence and severity of diarrheal episodes

- in their breast fed (or partially breast-fed) children.
3. We will determine the effect of diarrheal episodes on food intake, absorption of lactose, and nutritional status. By assessing intake of nutrients and absorption, we hope to determine the importance of each in the detrimental effect of diarrhea on growth. Furthermore, by combining this information with the etiology of the diarrheal episode we can determine which enteric pathogens are the most important in altering growth and the mechanisms by which this occurs.
  4. We will determine the effect of oral glucose-electrolyte treatment of diarrhea on the nutrition of children.
  5. We will plan future studies of water use, sanitation and environmental microbiology in the same two villages.

C. METHODS OF PROCEDURE

1. Location - Villages Enayet Nagar (V14) and Sepai Kandi (F) in the Matlab Field Surveillance Area. These villages are comparable as illustrated in Appendix I.
2. Time Period - The study will begin March 1, 1978 and end June 30, 1979.
3. Study Subjects - At the beginning of the study 100 children will be selected from each of the 2 villages, these children will be between 3 months and 4 years of age.
4. Study Procedures
  - a. Disease Surveillance - A field worker will visit each child every other day to enquire about illness on that day or the preceding day. At each visit information on study children will include presence of diarrhea (4 loose or watery stools

in the previous 24 hours), dysentery (bloody stool), vomiting, fever, skin rash, nasal discharge, cough, draining ears and anorexia. The form to be used to record this is included as Appendix IIa. During weekly visits, a physician will obtain the history in more detail, examine the ill persons, and provide a diagnosis (including no illness) for each person each day (Appendix IIb.)

Persons with diarrhea for more than 14 days will be taken to Matlab hospital for a more complete evaluation including repeat rectal culture, stool examination for parasites, etc. and for appropriate treatment.

- b) Medical Services - The physician will also provide simple treatment when appropriate. The physicians treatment may consist of aspirin, scabies lotion, vitamins (for vitamin deficiency), eye ointment, topical anti-fungal and antibiotic ointments etc. A two day course of ampicillin will be given for dysentery and antibiotics may be provided for pneumonia. Children with a hematocrit <25 will be given iron. Routine DPT and measles immunization will be offered. Ill persons needing more extensive treatment e.g. for moderate to severe dehydration or other severe illness will be referred to the appropriate facility (CRL or thana health center).
- c) Rectal cultures - When a study child has diarrhea or vomiting, 2 rectal swabs will be taken. One swab will be placed in Cary-Blair transport media and the other in phosphate buffered saline. Swabs will also be obtained every 2 weeks regardless of illness and processed as above. All swabs will be taken to Matlab on the day of collection.

- d) Processing of rectal cultures - Each time rectal swabs are taken, one swab will be plated on Monsur's agar (the swab will be plated again on Monsur's after 6 hour enrichment in bile peptone broth) SS and MacConkey agars and the plates incubated for 18-24 hours. The plates will be examined for vibrios, shigella and salmonella. From the MacConkey plate, 5 lactose positive colonies that are typical of E. coli and a pool of 10 other lactose positive colonies will be picked to nutrient agar slants (for routine cultures only the pool of 10 colonies will be obtained). These will be stored for testing for LT by the CHO assay (30) and ST by the infant mouse assay (31). The second swab will be inserted into a vial containing phosphate buffered saline (PBS) pH 7.4 and frozen for subsequent testing for rotavirus by the ELISA assay (32) and possibly for parvovirus (Norwalk agent).
- It is anticipated that vibrios, salmonella, shigella and rotavirus and ETEC would be sought on all cultures (estimated 600 diarrhea episodes and 4800 routine bi-monthly cultures). (Laboratory record form is Appendix III). Swabs in PBS will be preserved frozen until they can be tested for known etiologic agents for which a test is not currently available at CRL or for agents not yet discovered.
- e) Blood specimens - At the time of admission to the study and at subsequent 4 monthly intervals a fingertip blood specimen will be obtained from study children. A Natelson microblood collection tube (resulting in approximately 100 ul of plasms) will be used. Plasma will be separated in Matlab and frozen. A microhematocrit tube will also be obtained at 4 monthly intervals to permit testing for hematocrit and plasma proteins.

- f) Serological tests - Sera will be examined for IgG and IgM rotavirus antibody by the ELISA assay (35). Sera will also be tested for E. coli antitoxin titers by the adrenal cell assay system and stored for subsequent antibody determinations to known etiologic agents for which an antibody test is not presently available (e.g. ST only E. coli, parvovirus) and to agents which will be discovered at a later date.
- g) Breast Milk - a lcc breast milk sample will be obtained from lactating mothers each month and this will be tested for total and antirotavirus IgA and IgG, anti-LT by the Y1 adrenal cell assay and IgA anti-LT by ELISA assay and for IgA anti-colonization factor by ELISA assay (the anti-LT and CF tests will probably be done by collaboration).
- h) Tests for Malabsorption - In each village 20 children (6-18 months) will be selected for breath hydrogen testing. At four monthly intervals they will be studied for intestinal function and lactose malabsorption by means of a breath hydrogen test (BHT). Parents will be questioned to assure that the children have taken no medications during the week prior to testing. Following an overnight fast, a baseline breath sample will be collected. Then a 2 gm/Kg dose of lactose will be given as a 20% solution in water. Additional breath samples will be collected at 30 minutes and 1,

2, 3, 4, and 5 hours after ingestion of the sugar and signs indicative of lactose intolerance will be recorded. The expired breath samples will be collected either by face-mask and anesthesia bag or directly into the bag, and the sample will be stored in a plastic syringe for no more than 24 hours before the subsequent determination of hydrogen concentration. The gas analyses will be performed in Matlab on the Quintron gas chromatograph and compared to a commercially prepared standard containing 55 PPM hydrogen in air. Results of the test will be presented on the basis on PPM rise in H concentration above the baseline sample, an increase of 20 or more being considered indicative of malabsorption.

In addition to the scheduled breath testing, children will be studied at ten days and four weeks (if the 10 day test was abnormal) after the onset of each episode of acute diarrhea. Following each period of diarrhea, the timing for the next four monthly routine study will be reset so that they occur at four monthly intervals following the most recent diarrhea episode.

i) Diet Studies

Usual dietary intakes during periods of health and illness will be determined for 25-50 children per village whose ages range from 6-18 months at the beginning of the study. Most children in this age group will be breastfeeding as well as taking some supplementary foods. Thus, intake surveys will include assessments of daily breastmilk consumption in addition to weighed determinations of other foods taken.

Twenty-four hour breast milk consumption will be extrapolated from nine-hour "test feedings". During test-feeding periods the diapered infants will be weighed by trained female field workers immediately before and after each breast feed and the difference in weight will be recorded as milk consumed. Previous studies at the Children's Nutrition Unit (CNU) have indicated that an infant's twenty-four hour intake can be predicted within about 13% from a nine-hour study of test feeds. Therefore, nine-hour studies will be performed and then corrected to 24-hour consumption estimates by a regression equation. Approximately 12 24-hour studies will be performed in selected village households to test the applicability of the regression equation obtained at the CNU with that observed in the village. Previous data from CNU further suggests that approximately ten individual study days are required to estimate an infants usual intake with 10% accuracy (see Appendix IV for summary of previously collected data relating to these decisions and a brief discussion of the regression model).

The food intakes will be measured at the subject's home by a trained female dietician. Studies will take place once each month according to the protocol suggested by the Nutrition Section of the N.I.H. The child's entire intake for the day will be observed; all food items (that is, individual foodstuffs) will be weighed as they are included in the preparation of each homogeneous menu item (e.g. rice, dal, or curry) at each meal. The completed menu items will be weighed after cooking and the child's portion of the menu items will be weighed before and after consumption. The child's actual intake will be expressed as a percent of the post-cooking weight of each of the menu items and it will then be assumed that

the child ate that same percent of the weight of each of the individual food items in the given menu item (example Appendix V). This procedure will be repeated for each menu item and for each meal or snack during the day. A similar but less complicated procedure will be followed for single-food menu items such as fruit, meat, or fish etc., which are consumed as individual pieces. In this case, each food item will be weighed before and after consumption, and the difference will be recorded as actual intake. All of the individual food items consumed during the day will then be totalled and the actual nutrient intake will be calculated from food composition tables.

Since the desired numbers of breastmilk-consumption and food-consumption studies for each individual subject are similar, breast feeds will be test-weighed on each day of diet weighment studies. Thus total dietary intake for these days can be estimated.

Each of the dietary studies will be repeated in relation to specific periods of illness. Thus, intakes will be determined during two or three days of illness and during two days of convalescence for each of two episodes of diarrhea and for one episode of non-diarrhea related fever in every subject for whom usual daily intakes are available.

j.) Anthropometrics

Study subjects will be weighed and measured (length, arm circumference and skin fold thickness) at monthly intervals in their village homes. They will also be weighed on the first or second day after onset of and recovery from each episode of diarrhea as well as on day 14 after



onset of diarrhea. Illness-related weights will also be determined for one non-diarrhea-related febrile episode in those children on diet studies. All results will be compared to appropriate international standards. (Data forms Appendix VIa. b)

1. Weights will be determined on Salter (spring) scales calibrated in 50 gram intervals to a 25 Kg capacity. Subjects will be weighed unclothed.
2. All subjects will have their length measured to the nearest 0.1 cm in recumbency on a portable measuring board.
3. Upper arm circumference to the nearest 0.1 cm and triceps skin fold thickness to the nearest 0.1 mm will be determined according to the techniques suggested by Jelliffe.

k) Evaluation of the effect of oral glucose-electrolyte solution taken for all diarrhea on the nutritional status of children.

The study is planned as a controlled trial in 2 similar (Appendix Ia -d) villages. Residents of one village will receive conventional treatment for diarrhea (kaolin mixture) and residents of the other village will be provided glucose-electrolyte solution for all episodes of watery diarrhea. Residents in both villages will receive education on nutrition and appropriate feeding practices during diarrhea.

Before the study begins (i.e. March 1978) a Knowledge, Attitude and Practices (KAP) survey will be done. This will include questions on the usual practices of feeding children during diarrhea. (Form included as Appendix VII). This KAP survey will be repeated in 1 year at the conclusion of the study (April 1979).

After completion of the KAP survey the resident female field assistant in each village will provide information to each study

family concerning appropriate feeding of children during diarrhea. Mothers will be instructed not to interrupt breastfeeding during illness. The education will encourage provision of any well tolerated foods during illness and will stress the necessity of fluids given by mouth.

In April 1978, oral glucose-electrolyte solution will be made available in one village through the CRL resident field assistant (FA). Packets of Oralyte\* will be carried by the FA on her routine surveillance visits in the village every other day. On the alternate days, the packets and instructions for mixing will be available at the home of the FA or from the dai in that village. Mixing of the packets will be demonstrated to the ill child's mother in the home. A vessel from the home will be calibrated to 1 liter by the FA. One additional packet will be left in the home. Mothers will be told to provide as much Oralyte solution as the child will drink but to offer generally 1 cupful (200 ml) after each loose motion. The volume will be reduced appropriately for very small infants. The kaolin mixture will also be prescribed for use after each loose stool, but will be given a standard dose based on age and weight.

The procedures for managing a case in each village are included as Appendix VIII. As indicated cases with severe dehydrating diarrhea or other complications will be referred to Matlab Hospital. Cases with bloody diarrhea will be treated with ampicillin in addition to Oralyte. Transportation may be provided by country boat (most

\* (Na<sup>+</sup>90, K<sup>+</sup>20, HCO<sub>3</sub><sup>-</sup>30, Cl<sup>-</sup>80, glucose 110)

likely 1-2 country boats will go to Matlab Bazar each day with specimens and field workers) or by speedboat ambulance. The study physician will evaluate children with diarrhea during routine weekly visits and during periodic visits specifically to evaluate the oral rehydration. Complications such as hypernatremia and carpopedal spasm will be sought clinically. The first fifty ill children with no to mild dehydration from each village will have a finger tip blood (serum sodium and specific gravity) drawn on day 1 and day 3 of their illness to determine if Oralyte treated children develop hypernatremia and if they return to normal hydration faster than children not treated with Oralyte. A sample of oral solution mixed by each mother will be tested for sodium concentration.

#### Data analysis

It is anticipated that the following analyses and others will be performed:

- a. Incidence of infection by various enteric pathogens during the first 5 years of life.
- b. Incidence of re-infection by specific agents.
- c. Whether serum or breast milk antibody to specific enteric pathogens and quantity of breast milk consumed is related to the subsequent risk of infection or illness (or severity of illness) with these agents.
- d. Which etiologic agents of diarrhea have the most profound effect on nutrition.
- e. How diarrhea caused by different agents affects lactose malabsorption.
- f. How diarrhea caused by different agents affects food intake.
- g. Can oral glucose-electrolyte solution (Oralyte) be safely mixed and administered by mothers in the home under non-medical supervision?
- h. If oral glucose-electrolyte solution taken for all watery diarrhea has a beneficial effect on nutrition.

- i. If Oralyte has a beneficial effect, is it because correction of dehydration improves the child's appetite.
- j. Is the beneficial effect of Oralyte (if any) on nutrition due to encouragement of feeding during diarrhea and not to rehydration per se.
- k. How does the provision of Oralyte and nutrition education change mothers' knowledge, attitude and practices on care of their children during diarrhea.

#### 6. Future Studies

After the diarrhea surveillance and other studies are initiated it would be desirable that these 2 villages be utilized for additional studies of water, sanitation and environmental microbiology. In anticipation of these studies accurate maps of the villages will be drawn and will include houses, water sources, and fixed latrine sites.

These 2 villages each consist of a row of houses arranged perpendicular to the riverside. Some houses on one end of each village are adjacent to the major river (and in one village a canal) while houses on the other end are distant from the river. Water use differs in different areas of the village based on data collected in 1974. Persons living adjacent to the river or canal use river or canal water for all purposes, while persons in the middle of the village use water carried from the river for drinking but use less distant tank or ditch water for other purposes. Persons in the area most distant from the river or canal use tank or ditch water for all purposes (Appendix Id is a tabulation of water use habits in 1974 by section of the villages. A similar survey of water use will be done at the onset of the study). Based on interviews in the villages, households should be selected for intensive study of actual water use, perceptions about water use, and defecation behaviour. Ideally these

studies would be combined with intensive environmental microbiology studies in the same villages. Expertise in these areas either does not exist at CRL now or will not exist in a few months. Therefore, it seems appropriate to establish collaborative arrangements with institutions, such as the Ross Institute, UK, which have the needed expertise. The cost of such collaboration has been included in this protocol to facilitate making the necessary contacts with other institutions.

D. SIGNIFICANCE

See Rationale.

E. FACILITIES REQUIRED

1. Office Space - one room in the Matlab facility with desk, table, and file cabinet.
2. Laboratory Space - already exists in CRL Matlab and Dacca.
3. Hospital Resources - none.
4. Animal Resources - 17,000 suckling mice.
5. Logistical Support - Data processing and computer support from Statistics Branch.
6. Major Items of Equipment - Quintron gas chromatograph.
7. Other - none.

F. COLLABORATIVE ARRANGEMENTS

Collaborative arrangements will be sought in the area of water use, sanitation, and environmental microbiology.

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## SECTION III - BUDGET

## A. DETAILED BUDGET

PERSONNEL SERVICES

| <u>Name</u>         | <u>Position</u>                              | <u>% or #<br/>of days</u> | <u>Annual<br/>Salary</u> | <u>Project Requirements<br/>Taka</u> | <u>Requirements<br/>\$</u> |
|---------------------|--|---------------------------|--------------------------|--------------------------------------|----------------------------|
| r. Robert Black     | Investigator                                 | 50%                       | \$ 46,000                | -                                    | 23,000                     |
| r. Kenneth Brown    | Investigator                                 | 20%                       | \$ 16,200                | -                                    | 3,240                      |
| r. Stan Becker      | Investigator                                 | 20%                       | \$ 12,000                | -                                    | 2,400                      |
| r. Michael Merson   | Investigator                                 | 20%                       | \$ 42,000                | -                                    | 8,400                      |
| s Lynn Parry        | Investigator                                 | 80%                       | Tk 9,400                 | 7,680                                | -                          |
| r. Md. Yunus        | Investigator                                 | 40%                       | Tk56,430                 | 22,572                               | -                          |
| r. M. Rahaman       | Investigator                                 | 20%                       | Tk70,330                 | 14,066                               | -                          |
| mdadul Huq          | Supervisor                                   | 100%                      | Tk30,100                 | 30,100                               | -                          |
| huria Begum         | Sr. Field Assistant                          | 50%                       | Tk15,030                 | 7,515                                | -                          |
| o be named          | Female field assistants(7)                   | 100%                      | Tk17,730                 | 124,110                              | -                          |
| o be named          | Male field assistant (1)                     | 30%                       | Tk18,739                 | 5,622                                | -                          |
| o be named          | Dais (2)                                     | 50%                       | Tk 6/day                 | 2,190                                | -                          |
| o be named          | Boatmen/porters (6)                          | 100%                      | Tk 11/day                | 24,090                               | -                          |
| r. Golam Kibriya    | Sr. Res. Assistant                           | 40%                       | Tk35,820                 | 14,328                               | -                          |
| r. Al-Mahmud        | Head, Animal Resources                       | 50%                       | Tk45,470                 | 22,735                               | -                          |
| r. Rezaur Rahman    | Res. Tech.                                   | 50%                       | Tk20,484                 | 10,242                               | -                          |
| r. Anisur Rahman    | Glasswasher (Dacca)                          | 10%                       | Tk 9,696                 | 970                                  | -                          |
| o be named          | Glasswasher (Matlab)                         | 20%                       | Tk 9,696                 | 1,840                                | -                          |
| r. Aleem            | Senior Research Assist.                      | 30%                       | Tk36,012                 | 10,804                               | -                          |
| r. Shiraj Sardar    | Research Technician                          | 30%                       | Tk16,044                 | 4,813                                | -                          |
| o be named          | Sr. Res. Tech. (for rota<br>and LT serology) | 20%                       | Tk37,500                 | 7,500                                | -                          |
| o be named (Dacca)  | Statistical Assist.                          | 50%                       | Tk19,681                 | 9,840                                | -                          |
| o be named (Dacca)  | Key punch operator                           | 50%                       | Tk11,448                 | 5,724                                | -                          |
| o be named (Dacca)  | Computer programmer                          | 50%                       | Tk42,000                 | 21,000                               | -                          |
| o be named (Matlab) | Tech. (for gas chromatograph)                | 50%                       | Tk10,000                 | 5,000                                | -                          |
|                     |  |                           | Sub total                | 352,741.                             | 37,040                     |

2. SUPPLIES

| <u>Items</u>                                  | <u>Unit Cost</u> | <u>Amount Required</u> | <u>Project Requirement:</u> |           |
|---|------------------|------------------------|-----------------------------|-----------|
|   |                  |                        | <u>Taka</u>                 | <u>\$</u> |
| Rectal swab for <u>V. cholerae</u>            | Tk. 3.28         | 5600                   | 18,368                      | -         |
| Rectal swab for Sal/Shig                      | Tk. 2.5          | 5600                   | 14,000                      | -         |
| Biochem tests for <u>V. cholerae</u>          | Tk. 1.02         | 5600                   | 5,712                       | -         |
| Biochem tests for Sal/Shig                    | Tk. 0.8          | 5600                   | 4,480                       | -         |
| Cultures for <u>E. coli</u>                   | Tk. 2.0          | 5600                   | 11,200                      | -         |
| Stock culture vials                           | Tk. 0.5          | 9000                   | 4,500                       | -         |
| CHO assay                                     | Tk. 3.0          | 8600                   | 25,800                      | -         |
| ST assay (supplies)                           | \$ 0.11          | 8600                   | -                           | 946.00    |
| ST assay (mice)                               | Tk. 3.0          | 8600                   | 25,800                      | -         |
| <u>E. coli</u> antitoxin titer (adrenal cell) | Tk. 10.00        | 800                    | 8,000                       | -         |
| Rotavirus antibody titer                      | Tk. 2.0          | 1000                   | 2,000                       | -         |
| Rotavirus (ELISA)                             | Tk. 1.5          | 5600                   | 8,400                       | -         |
| Stool M/E                                     | Tk. 2.0          | 100                    | 200                         | -         |
| Plasma sp. gravity                            | Tk. 0.25         | 100                    | 25                          | -         |
| Lancets                                       | \$ 9.72          | 1000                   | -                           | 9.72      |
| Natelson tubes                                | \$ 0.13          | 1000                   | -                           | 130.00    |
| Microhematocrit tubes                         | \$ 2.18/1000     | 3000                   | -                           | 65.40     |
| Serum storage vials                           | Tk. 0.6          | 1000                   | 600                         | -         |
| Tab. aspirin                                  | Tk. 90/1000      | 5000                   | 450                         | -         |
| Benzyl benzoate                               | Tk. 30/lb        | 20 lbs                 | 600                         | -         |
| DPT   | Tk. 6/dose       | 600                    | 3,600                       | -         |
| Skin ointment                                 | Tk. 5/tube       | 100                    | 300                         | -         |
| Ophthalmic ointment                           | Tk. 3/tube       | 100                    | 800                         | -         |
| Kaolin powder                                 | Tk. 300/50 lb    | 300 lbs                | 1,800                       | -         |
| Ampicillin syrup                              | \$ 15.80 liter   | 5 liters               | -                           | 79.00     |

| Items                            | Unit Cost    | Amount<br>Required | Project Requirement |        |
|----------------------------------|--------------|--------------------|---------------------|--------|
|                                  |              |                    | Taka                | \$     |
| ORS Packets                      | donated      | -                  | -                   | -      |
| Tabs multivit                    | Tk. 90/1000  | 7,500              | 1,075               | -      |
| Syrup multivit                   | Tk. 20.8/1b  | 20 lbs             | 416                 | -      |
| Tab. fersolate                   | Tk. 120/1000 | 5,000              | 600                 | -      |
| Cough syrup                      | Tk. 8.5      | 75                 | 637                 | -      |
| Cotton                           | Tk. 20/1b    | 5 lb               | 100                 | -      |
| Spirits                          | Tk. 4/1b     | 5 lb               | 20                  | -      |
| Ice chests                       | \$ 24.65     | 4                  | -                   | 98.60  |
| Towel                            | Tk. 16       | 8                  | 128                 | -      |
| Soap                             | Tk. 2.7      | 100                | 270                 | -      |
| Candy                            | Tk. 150/1000 | 2,500 pcs          | 375                 | -      |
| Balloons                         | Tk. 24/gross | 10 gross           | 240                 | -      |
| Thermometers - oral              | Tk. 5        | 20                 | 100                 | -      |
| rectal                           | \$ 0.55      | 20                 | -                   | 11.00  |
| IBM cards                        | \$ 48/10,000 | 60,000             | -                   | 288.00 |
| IBM tapes                        | \$ 8.19/tape | 8                  | -                   | 65.52  |
| Pens, paper etc                  |              |                    | 1,500               | -      |
| Salter scales                    | \$ 25.00     | 4                  | -                   | 100.00 |
| Ohaus solution (food)balance     | \$231.75     | 3                  | -                   | 695.25 |
| Ohaus Dial-o-gram balance        | \$ 80.00     | 1                  | -                   | 80.00  |
| Lange skinfold caliper           | \$125.00     | 2                  | -                   | 250.00 |
| Length board                     | \$ 20.00     | 2                  | -                   | 40.00  |
| Recording paper                  | \$ 8/roll    | 10                 | -                   | 80.00  |
| Masks and bags (for breath test) | \$ 20 each   | 12                 | -                   | 240.00 |

| <u>Items</u>                                    | <u>Unit Cost</u>         | <u>Amount Required</u> | <u>Project Requirements Taka</u> | <u>Requirements \$</u> |
|---|--------------------------|------------------------|----------------------------------|------------------------|
| Lactose   | \$1950/lb                | 50 lb                  | -                                | 975.00                 |
| Plastic syringe                                 | \$ 6.90/20               | 500                    | -                                | 172.50                 |
| Stopcocks                                       | \$ 0.54                  | 500                    | -                                | 270.00                 |
| Argon gas                                       | Tk3000/1000 <sup>3</sup> | 1 tank                 | 3,000                            | -                      |
| Supplies for dietary histories (cups etc)       | -                        | -                      | 3,000                            | -                      |
| Protein electrophoresis                         | Tk 17.5                  | 400                    | 7,000                            | -                      |
| Diapers   | \$ 35/box                | 5 boxes                | -                                | 175.00                 |
| Plastic pants                                   | \$2/20                   | 500                    | -                                | 50.00                  |
| Boxes for scales                                |                          |                        | 1,000                            | -                      |
| Miscellaneous (figured at 5% of other supplies) |                          | -                      | 7,981                            | 241.00                 |
|   |                          | Sub total              | 167,596                          | 5,062.00               |

EQUIPMENT

|                             |  |           |  |          |
|-----------------------------|--|-----------|--|----------|
| Quintron gas chromatograph* |  |           |  | 1,500.00 |
| Air conditioner             |  |           |  | 500.00   |
| Calculators (6)             |  |           |  | 150.00   |
|                             |  | Sub total |  | 2,150.00 |

PATIENT HOSPITALIZATION

|   |  |           |        |   |
|---|--|-----------|--------|---|
| Number of patient days - 200 at Tk. 150/day |  |           | 26,000 | - |
|   |  | Sub total | 26,000 | - |

OUTPATIENT CARE

|  |  |           |         |   |
|--|--|-----------|---------|---|
| one  |  |           |         |   |
| <u>CRL TRANSPORT</u>   |  |           |         |   |
| Dacca/Matlab/Dacca 1 per week for 50 weeks at Tk. 300/round trip |  |           | 15,000  | - |
| Speedboat (Tk. 100/hour)   |  | 1000 hr   | 100,000 | - |
| Country boatmen (under personnel)                                |  |           |         |   |
|  |  | Sub total | 115,000 |   |

TRAVEL AND TRANSPORTATION OF PERSONS

Project Requirements  
Taka            \$

|   |   |        |
|---|---|--------|
| Local travel - none   | - | -      |
| International travel (attendance at meetings)                                   | - | 2,500  |
| Baltimore-Dacca-Baltimore (for Dr. Brown to work on study for 2 months in 1979) | - | 2,500  |
| Consultant on water/sanitation studies  | - | 5,000  |
| Sub total   | - | 10,000 |

TRANSPORTATION OF THINGS

|                                     |  |          |
|-------------------------------------|--|----------|
| Import of Supplies (25% of \$ cost) |  | 1,265.50 |
| Sub total                           |  | 1,265.50 |

RENT, COMMUNICATION AND UTILITIES

|                  |       |   |
|------------------|-------|---|
| Postage          | 500   | - |
| Telephone - none | 1,500 | - |
| Rent - none      | -     | - |
| Sub total        | 2,000 | - |

PRINTING AND REPRODUCTION

|                      |       |     |
|----------------------|-------|-----|
| Forms, record sheets | 5,000 | -   |
| Publication costs    |       | 500 |
| Sub total            | 5,000 | 500 |

CONTRACTUAL SERVICES

|  |        |   |
|--|--------|---|
| Computer time (30 hours at Tk. 800/hour) | 24,000 | - |
| Sub total                                | 24,000 | - |

B. BUDGET SUMMARY

|                            | <u>Taka</u> | <u>Dollars</u> |
|----------------------------|-------------|----------------|
| 1. Personnel               | 352,741     | 37,040         |
| 2. Supplies                | 167,597     | 5,062          |
| 5. Equipment               | -           | 2,150          |
| 4. Patient Hospitalization | 26,000      | -              |
| 5. Outpatient care         | -           | -              |
| 6. CRL Transport           | 115,000     | -              |
| 7. Travel - Persons        | -           | 10,000         |
| 8. Transportation - Things | -           | 1,265.50       |
| 9. Rent/Communications     | 2,000       | -              |
| 10. Printing/Reproduction  | 5,000       | 500            |
| 11. Contractual Services   | 24,000      | -              |
| 12. Construction           | -           | -              |
|                            | <hr/>       | <hr/>          |
| Total                      | 692,338     | 56,017.50      |
|                            | <hr/>       | <hr/>          |

Dollar total (Tk.15/\$) = \$102,173

Table 1

Breastmilk Intake (9m) of 10 Infants on Several Days  
at Child Nutrition Unit (CNU)

|                 |     | D   | A   | Y   |     |     |     |     |
|-----------------|-----|-----|-----|-----|-----|-----|-----|-----|
| Woman 1         | 1   | 2   | 3   | 4   | 5   | 6   | 7   |     |
| 24 hrs.         | 540 | 466 | 379 | 485 | 373 | 482 |     |     |
| 9 a.m. - 6 p.m. | 224 | 123 | 94  | 175 | 140 | 177 |     |     |
| Woman 2         |     |     |     |     |     |     |     |     |
| 24 hrs.         | 620 | 619 | 777 | 682 | 655 | 786 | 790 |     |
| 9 a.m. - 6 p.m. | 230 | 258 | 302 | 260 | 260 | 316 | 290 |     |
| Woman 3         |     |     |     |     |     |     |     |     |
| 24 hrs.         | 590 | 537 | 456 | 645 | 390 |     |     |     |
| 9 a.m. - 6 p.m. | 199 | 242 | 170 | 300 | 135 |     |     |     |
| Woman 4         |     |     |     |     |     |     |     |     |
| 24 hrs.         | 637 | 550 | 795 | 678 |     |     |     |     |
| 9 a.m. - 6 p.m. | 257 | 255 | 260 | 293 |     |     |     |     |
| Woman 5         |     |     |     |     |     |     |     |     |
| 24 hrs.         | 635 | 600 | 695 | 565 |     |     |     |     |
| 9 a.m. - 6 p.m. | 295 | 205 | 235 | 205 |     |     |     |     |
| Woman 6         |     |     |     |     |     |     |     |     |
| 24 hrs.         | 655 | 608 | 720 | 700 | 700 | 943 |     |     |
| 9 a.m. - 6 p.m. | 220 | 230 | 210 | 295 | 290 | 365 |     |     |
| Woman 7         |     |     |     |     |     |     |     |     |
| 24 hrs.         | 365 | 480 | 575 | 545 |     |     |     |     |
| 9 a.m. - 6 p.m. | 150 | 220 | 160 | 285 |     |     |     |     |
| Woman 8         |     |     |     |     |     |     |     |     |
| 24 hrs.         | 645 | 545 | 320 | 600 | 660 |     |     |     |
| 9 a.m. - 6 p.m. | 425 | 270 | 440 | 255 | 295 |     |     |     |
| Woman 9         |     |     |     |     |     |     |     |     |
| 24 hrs.         | 595 | 275 | 475 | 545 | 690 | 675 | 710 | 815 |
| 9 a.m. - 6 p.m. | 250 | 135 | 205 | 260 | 250 | 260 | 310 | 355 |
| Woman 10        |     |     |     |     |     |     |     |     |
| 24 hrs.         | 595 | 555 | 690 |     |     |     |     |     |
| 9 a.m. - 6 p.m. | 175 | 220 | 290 |     |     |     |     |     |

APPENDIX Ia

Diarrhea/Growth Study - Characteristics of Study Villages

|                               | <u>Enayet Nagar (V 14)</u>      | <u>Sepaikandi (F)</u> |
|-------------------------------|---------------------------------|-----------------------|
| Population*:                  | 896                             | 1175                  |
| Number of households*:        | 147                             | 194                   |
| Persons per household:        | 6.1                             | 6.1                   |
| Religion*:                    |                                 |                       |
|                               | Islam 830 (93%)                 | 996 (85%)             |
|                               | Hindu 66 (7%)                   | 179 (15%)             |
| Schools**:                    | Primary 1                       | 1                     |
| Tubewells**:                  | 1                               | 5                     |
| Latrines **                   |                                 |                       |
|                               | Pucca (cement walls and roof) 2 | 0                     |
|                               | Tin and wood 10                 | 10                    |
|                               | Bamboo and nara fencing 29      | 57                    |
| Annual birth rate (1976-77) * | 28.1                            | 39.2                  |
| Annual death rate (1976-77)*  | 14.3                            | 16.7                  |

\* Based on Matlab 1974 Census and Demographic Surveillance

\*\* Based on village observation (February 1978).



APPENDIX 1b

Diarrhea/Growth Study - Characteristics of Study Areas - Educational Level

| Educational level **<br>(of head of Household<br>(years) | <u>Enayet Nagar (V14)</u> |           | <u>Sepaikandi (F)</u> |          |
|--|---------------------------|-----------|-----------------------|----------|
|  | <u>Households</u>         | <u>%*</u> | <u>Households</u>     | <u>%</u> |
| 0  | 79                        | 56.4      | 92                    | 60.9     |
| 1  | 0                         | -         | 3                     | 2.0      |
| 2  | 5                         | 3.6       | 14                    | 9.3      |
| 3  | 9                         | 6.4       | 9                     | 6.0      |
| 4  | 7                         | 5.0       | 7                     | 4.6      |
| 5  | 13                        | 9.3       | 12                    | 7.9      |
| 6  | 9                         | 6.4       | 7                     | 4.6      |
| 7  | 3                         | 2.1       | 1                     | 0.7      |
| 8  | 5                         | 3.6       | 1                     | 0.7      |
| 9  | 1                         | 0.7       | 1                     | 0.7      |
| 10   | 2                         | 1.4       | 3                     | 2.0      |
| >10  | 7                         | 5.0       | 1                     | 0.7      |
| Unknown  | <u>7</u>                  | <u>-</u>  | <u>0</u>              | <u>-</u> |
|  | 147                       | 99.9      | 151                   | 100.1    |

percentage of those with known status

1974 Matlab Socioeconomic Census

APPENDIX Ic

Diarrhea/Growth Study - Characteristics of Study Areas - House Size

|                                | <u>Enayet Nagar (V14)</u> |          | <u>Sepaikandi (F)</u> |            |
|--------------------------------|---------------------------|----------|-----------------------|------------|
|                                | <u>Households</u>         | <u>%</u> | <u>Households</u>     | <u>%</u>   |
| House size **<br>(square feet) |                           |          |                       |            |
| <150                           | 11                        | 7.5      | 16                    | 10.6       |
| 150-199                        | 20                        | 13.6     | 28                    | 18.5       |
| 200-249                        | 30                        | 20.4     | 26                    | 17.2       |
| 250-299                        | 51                        | 21.1     | 31                    | 20.5       |
| 300-349                        | 12                        | 8.2      | 20                    | 13.2       |
| 350-399                        | 18                        | 12.2     | 12                    | 7.9        |
| 400-499                        | 6                         | 4.1      | 1                     | 0.7        |
| 450-499                        | 6                         | 4.1      | 5                     | 2.0        |
| >500                           | 13                        | 8.8      | 7                     | 4.6        |
| Unknown                        | <u>0</u>                  | <u>-</u> | <u>7</u>              | <u>4.6</u> |
|                                | 147                       | 100.0    | 151                   | 99.8       |

percentage of those with known status

1974 Matlab Socioeconomic Census

APPENDIX Id

7 - Characteristics of Study Areas\* - Water Use\*\*

| b) | F                           |                             | V14                         |                             | F                           |                         | V14                     |                         | F                       |                         |
|----|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
|    | Section 2<br>Households (%) | Section 3<br>Households (%) | Section 3<br>Households (%) | Section 3<br>Households (%) | Section 3<br>Households (%) | Total<br>Households (%) | Total<br>Households (%) | Total<br>Households (%) | Total<br>Households (%) | Total<br>Households (%) |
|    | 17 (23.5)                   | 7 (19.4)                    | -                           | 34 (87.2)                   | 87 (59.2)                   | 70 (17.3)               |                         |                         |                         |                         |
|    | -                           | -                           | 1 (2.6)                     | 1 (2.6)                     | -                           | 34 (25.0)               |                         |                         |                         |                         |
|    | 39 (76.5)                   | 22 (61.1)                   | -                           | 6 (16.7)                    | 39 (26.5)                   | 40 (27.0)               |                         |                         |                         |                         |
|    | -                           | 6 (16.7)                    | -                           | 1 (2.6)                     | 6 (4.1)                     | -                       |                         |                         |                         |                         |
|    | -                           | 1 (2.8)                     | 1 (2.6)                     | 3 (7.7)                     | 15 (10.2)                   | 1 (0.7)                 |                         |                         |                         |                         |
|    | -                           | -                           | 3 (7.7)                     | -                           | -                           | 3 (2.0)                 |                         |                         |                         |                         |
|    | 51 (100)                    | 36 (100)                    | 39 (100.1)                  | 39 (100.1)                  | 147 (100)                   | 148 (100)               |                         |                         |                         |                         |
|    | -                           | -                           | -                           | -                           | -                           | -                       |                         |                         |                         |                         |
|    | -                           | -                           | -                           | -                           | -                           | -                       |                         |                         |                         |                         |
|    | 51 (100)                    | 22 (61.1)                   | 9 (23.1)                    | 27 (69.2)                   | 34 (25.1)                   | 10 (6.8)                |                         |                         |                         |                         |
|    | -                           | 14 (38.9)                   | -                           | -                           | 62 (42.2)                   | 16 (10.8)               |                         |                         |                         |                         |
|    | -                           | -                           | -                           | -                           | 51 (34.7)                   | 119 (80.4)              |                         |                         |                         |                         |
|    | -                           | -                           | 3 (7.7)                     | 3 (7.7)                     | -                           | 3 (2.0)                 |                         |                         |                         |                         |
|    | 51 (100)                    | 36 (100)                    | 39 (100)                    | 39 (100)                    | 147 (100)                   | 148 (100)               |                         |                         |                         |                         |

tudy area.  
nomic Census

Diarrhea/Growth Study Illness Surveillance Form

TS Number (1-6) \_\_\_\_\_ Card#2 (7) \_\_\_\_\_ Week (8-10) \_\_\_\_\_ Name \_\_\_\_\_

| Diagnosis | Date:          | Day1 (11) | Day2 (21) | Day3 (31) | Day4 (41) | Day5 (51) | Day6 (61) | Day7 (71) |
|-----------|----------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Diarrhea  | जुलै १५        |           |           |           |           |           |           |           |
| Stool     | मकखंडका        |           |           |           |           |           |           |           |
| Stool     | पातला          |           |           |           |           |           |           |           |
| Stool     | पानीरस         |           |           |           |           |           |           |           |
| Stool     | कठोर पायस      |           |           |           |           |           |           |           |
| Stool     | रक्त           |           |           |           |           |           |           |           |
| Stool     | खून            |           |           |           |           |           |           |           |
| Stool     | बिंदु          |           |           |           |           |           |           |           |
| Duration  | ३-४ दिवस       |           |           |           |           |           |           |           |
| Stool     | खुर            | (12)      | (22)      | (32)      | (42)      | (52)      | (62)      | (72)      |
| Stool     | जायदा          |           |           |           |           |           |           |           |
| Stool     | नकमला          |           |           |           |           |           |           |           |
| Stool     | कमि            |           |           |           |           |           |           |           |
| Stool     | खुरीर दाना उठा |           |           |           |           |           |           |           |
| Pus       | का (न खून)     |           |           |           |           |           |           |           |
| Stool     | खुरा मला       | (13)      | (23)      | (33)      | (43)      | (53)      | (63)      | (73)      |
| Stool     | खुर            |           |           |           |           |           |           |           |
| Stool     | नेउया टाट्ट    |           |           |           |           |           |           |           |
| Stool     | डिफिड्या       |           |           |           |           |           |           |           |
| Stool     | पारिधान        |           |           |           |           |           |           |           |
| Diagnosis |                | D(14)     | D(24)     | D(34)     | D(44)     | D(54)     | D(64)     | D(74)     |
|           |                | Dx(15-16) | Dx(25-26) | Dx(35-36) | Dx(45-46) | Dx(55-56) | Dx(65-66) | Dx(75-76) |
|           |                | Dx(17-18) | Dx(27-28) | Dx(37-38) | Dx(47-48) | Dx(57-58) | Dx(67-68) | Dx(77-78) |
|           |                | Dx(19-20) | Dx(29-30) | Dx(39-40) | Dx(49-50) | Dx(59-60) | Dx(69-70) | Dx(79-80) |

APPENDIX IIb

Diarrhea/Growth Study - Classification of Illness

|               |                                   |      |
|---------------|-----------------------------------|------|
| Form Space D  | No diarrhea                       | = 0  |
|               | Diarrhea - no dehydration         | = 1  |
|               | Diarrhea - mild dehydration       | = 2  |
|               | Diarrhea - mod. dehydration       | = 3  |
|               | Diarrhea - severe dehydration     | = 4  |
|               | Dysentery - no dehydration        | = 5  |
|               | Dysentery - with dehydration      | = 6  |
|               | Vomiting - no diarrhea            | = 7  |
|               | Unknown                           | = 9  |
| Form Space Dx | Measles                           | = 01 |
|               | Mumps                             | = 02 |
|               | Chickenpox                        | = 03 |
|               | "Viral" exanthem unknown etiology | = 04 |
|               | Scabies                           | = 05 |
|               | Impetigo                          | = 06 |
|               | Cellulitis                        | = 07 |
|               | Eczema                            | = 08 |
|               | Miscellaneous skin lesions        | = 10 |
|               | URT Infection                     | = 11 |
|               | Conjunctivitis                    | = 12 |
|               | Otitis                            | = 13 |
|               | Whooping cough                    | = 14 |
|               | Tonsillitis                       | = 15 |
|               | Stomatitis                        | = 16 |
|               | Diphtheria                        | = 17 |
|               | Pneumonia                         | = 18 |

|                         |      |
|-------------------------|------|
| Bronchitis/croup        | = 19 |
| Asthma                  | = 20 |
| Tuberculosis            | = 21 |
| Hepatitis               | = 22 |
| Meningitis              | = 23 |
| Tetanus                 | = 24 |
| Malaria                 | = 25 |
| Typhoid fever           | = 26 |
| Urinary tract infection | = 27 |
| Unknown                 | = 99 |

APPENDIX III

Diarrhea/Growth Study Laboratory Record Form

Number (1-6) \_\_\_\_\_

#3 (7)                      Week (8-10) \_\_\_\_\_

|              | Day 1(11) | Day 2(21) | Day 3(31) | Day 4(41) | Day 5(51) | Day 6(61) | Day 7(71) |
|--------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| date         |           |           |           |           |           |           |           |
| culture      |           |           |           |           |           |           |           |
| ure-Diarrhea | _____(12) | _____(22) | _____(32) | _____(42) | _____(52) | _____(62) | _____(72) |
| ure-Routine  | _____(13) | _____(23) | _____(33) | _____(43) | _____(53) | _____(63) | _____(73) |
| LT           |           |           |           |           |           |           |           |
| rio          | _____(14) | _____(24) | _____(34) | _____(44) | _____(54) | _____(64) | _____(74) |
| onella       | _____(15) | _____(25) | _____(35) | _____(45) | _____(55) | _____(65) | _____(75) |
| yella        | _____(16) | _____(26) | _____(36) | _____(46) | _____(56) | _____(66) | _____(76) |
| coli         | _____(17) | _____(27) | _____(37) | _____(47) | _____(57) | _____(67) | _____(77) |
| seirus       | _____(18) | _____(28) | _____(38) | _____(48) | _____(58) | _____(68) | _____(78) |
|              | _____(19) | _____(29) | _____(39) | _____(49) | _____(59) | _____(69) | _____(79) |
|              | _____(20) | _____(30) | _____(40) | _____(50) | _____(60) | _____(70) | _____(80) |

MODELS AND STATISTICAL CONSIDERATIONS IN DESIGNS  
OF NUTRITION-INTAKE STUDY

- I. Prediction of 24-hour breastmilk consumption from 9-hour studies utilizing method of weighing the infant.

Data:

Data on milk consumption of infants (age 2 to 8 months) for 10 women (selected at random) on several days were calculated. The data are recorded in 3-hour intervals for an entire 24-hour period at the CNU.

The objective of the analysis was to determine how accurately the total 24-hour intake can be predicted from a 9-hour study. (Several time periods were studied but only the 9 a.m. to 6 p.m. results are shown here). The data for this analysis are shown in Table 1.

Model

Notation:

$T_{ij}$  = total breast milk intake of  $i$ th child on  $j$ th day.

$X_{ij}$  = observed intake of  $i$ th child on  $j$ th day in the period 9-6.

$T_{ij}$  = predicted total intake of  $i$ th child on  $j$ th day.

$\epsilon_{ij}$  = error term.

The simple regression model  $T_{ij} = \beta X_{ij} + \epsilon_{ij}$  was studied where the coefficient  $\beta$  is an easily interpreted multiplication factor for the 9 hour value of intake.



However, this was found inferior to the model:

$$T_{ij} = \alpha + \beta (X_{ij} - \bar{X}) + \epsilon_{ij}$$

where  $\alpha$  represents the mean daily intake in the population and  $\bar{X}$  is an average across both days and individuals.  $\beta$  is no longer a simple multiplication factor, however. For the 50 days of observation described above the estimates were  $\hat{\alpha} = \bar{T} = 609.8$ ,  $b = \hat{\beta} = 1.4275$ . The accuracy of the individual predictions for this model is judged with several statistics. First the mean deviation was 61.7 or 10% of the mean level. Second the standard error of the deviations was 77.8 giving a coefficient of variation of 14%. Finally the actual percentages of predictions which were more than 10%, 15% and 20% off from the actual totals, were 42, 29, and 15 respectively. These results indicate that fairly good prediction of total intake from a 9-hour study is possible.

- I. Determination of validity of regression equation estimated from CNU data, for Matlab analysis. How many 24-hour studies in Matlab are required?

Before obtaining regression predictions for 24-hour intakes in Matlab with the equation above it is essential to determine if the parameters ( $\bar{T}$  and  $b$ ) are the same in Matlab as at CNU. Twenty-four hour studies in Matlab are required to make this determination. From these data comparisons of  $\bar{T}$  and  $b$  will be made. Differences will appear if either the overall mean intake ( $\bar{T}$ ) is different or if the pattern of feeding during the 24-hours

is different (b). From a brief consideration of the standard error of b in the CNU data and the percentage errors in the predictions which result if the estimate of b is one or two standard errors off from its actual value in the data, it appears that a sample of size 12 is sufficient to compare the  $\bar{T}$  and b of the CNU and Matlab.

III. How many studies are required to establish the mean level of a child's intake?

Here we consider day-to-day variation in the milk intake of one child. The purpose of the actual study is to measure differences in milk consumption between normal and sick days. Comparisons for individual children may be desired.

As a first approximation we assume that there is no upward or downward trend in the consumption level of infants during well periods over the time of the study. In this case the analysis would involve a comparison of means (mean intake on well days vs. mean intake on sick days) so the usual methods are appropriate for estimating sample size. (Snedecor and Cochran, Statistical Methods, 1976 edition, p. 113). The variance of the estimated daily variation of a child has two components: 1) the daily variation from the child's overall mean intake; 2) the variance introduced by the regression method of estimation (discussed above). These variances

are assumed additive and identical on well and sick days. An estimate of the second component is  $(77.8)^2$  as given in I above. An estimate of the first component comes from an analysis of the daily variation for the 10 CNU infants (Table 1). The simple pooled (mean) estimate of the daily variance from the infants is  $(90.6)^2$ . With these two variance estimates, and  $\alpha = .10$ ,  $\beta = .10$  and  $\delta = 200$  (i.e. we wish to detect a true difference between intake during well periods and sick periods of 200 grams) then we find  $n = 5.5$  for each sample, or 10 or 12 observation days are required.

In actuality, the breastmilk intake of children changes over time with increasing age and the periods of sickness cannot be predicted. Thus the mean intake level at the time immediately preceding sickness will be estimated from another regression equation for the mean intake of the one child over time. This line (assuming the trend in intake is linear with time) is best predicted by doing 4-5 studies for each child at the beginning of the period and 4-5 studies at the end of the study period (after one year). The variance of the predicted intake at times immediately before sickness is of the same magnitude as the sum of the two variances given above.

| VTS #: X-100-40 AGE: (27:28) 3yr 2 mo DATE OF STUDY: (08:05) |                       | NO. OF MEALS COOKED/DAY: 3 NO. OF MEALS/SNACKS CONSUMED/DAY: 3/2 NO. OF PEOPLE SHARING MEALS: 4 ADULTS 3 |                  | NO. OF MEALS COOKED/DAY: 3 NO. OF MEALS/SNACKS CONSUMED/DAY: 3/2 NO. OF PEOPLE SHARING MEALS: 4 ADULTS 3 |                           |
|--|-----------------------|--|------------------|--|---------------------------|
| Band Time (approx. 92. 7:00-7:30)                            | Food Item (M.I.)      | Breakfast (8.00am)   | Snack (10.00 am) | Lunch (1.00pm)   | Dinner (6.00pm)           |
| ESTIMATED AMOUNT   | ESTIMATED AMOUNT      | ESTIMATED AMOUNT   | ESTIMATED AMOUNT | ESTIMATED AMOUNT   | ESTIMATED AMOUNT          |
| 3  | Tare (T) + F.I. (3-4) | 1045   | 130              | 71   | 1490                      |
| 4  | Tare (T) + F.I. (3-4) | 125  | 106              | 65   | 480                       |
| 5  | Weight F.I. (3-4)     | 920  | 24               | 6  | 1010                      |
| 6  | T. + M.I. p cook.     | 1265   |                  |  | 1713                      |
| 7  | T. (6-7)              | 160  |                  |  | 220                       |
| 8  | M.I. p cook.          | 1105   |                  |  | 1493                      |
| 9  | T. + portion of M.I.  | 157  |                  |  | 247                       |
| 10   | T. (6-7)              | 65   |                  |  | 205                       |
| 11   | Portion of M.I.       | 42   |                  |  | 42                        |
| 12   | T. + portion of M.I.  |  |                  |  | 19                        |
| 13   | T. (11-13)            |  |                  |  | 65                        |
| 14   | Waste (11-13)         | 0  | 16               | 0  | 4*                        |
| 15   | Description waste     |  | (paul)           |  | 2 pieces<br>Potatoes only |
| 16   | Conspect. (11-13)     | 42   | 79               | 140  | 42*                       |
| 17   | Conspect. (11-13)     | (1/2 paul)   |                  |  |                           |
| 18   | Conspect. (11-13)     | 3.8  |                  | 4.3  | 2.8                       |
| 19   | Conspect. (11-13)     | 3.5  |                  | 50   | 14.4                      |

1. Paratha  
 2. Oil  
 3. Whole wheat flour  
 4. Ghee  
 5. Unrefined sugar  
 6. Banana  
 7. Rice  
 8. Potato  
 9. Cabbage  
 10. Onion  
 11. Chili  
 12. Oil







Diarrhea/Growth Study - KAP Survey

Interviewer \_\_\_\_\_

Number 

|  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|

(1) (2) (3) (4) (5) (6) (7) (8)

Age (child) 

|  |  |
|--|--|
|  |  |
|--|--|

 yrs 

|  |  |
|--|--|
|  |  |
|--|--|

 mo Sex 

|  |
|--|
|  |
|--|

 M=1 F=2

(10) (11) (12) (13) (14)

Age (mother) 

|  |  |
|--|--|
|  |  |
|--|--|

 yrs Mother's name: \_\_\_\_\_

(15) (16)

When your child has diarrhea do you  
 ਜਦੋਂ ਤੁਹਾਡਾ ਬੱਚਾ ਦਿਹੀਜ਼ਾ ਹੋਵੇ ਤਾਂ ਤੁਹਾਡੀ

a. Treat him/her yourself?  
 ਤੁਹਾਡੇ ਬੱਚੇ ਦਿਹੀਜ਼ਾ ਹੋਵੇ ਤਾਂ ਤੁਹਾਡੇ ਕੋਲੋਂ ਕਰਵਾਏ ?

No = 0 

|  |
|--|
|  |
|--|

 17

Yes: Sometimes = 1 Always = 2 NA = 9  
 ਕਦੇ-ਕਦੇ (ਕਦੇ-ਕਦੇ) ਹਮੇਸ਼ਾ (ਹਮੇਸ਼ਾ) ਨਹੀਂ

b. Take him/her to health practitioner?  
 ਤੁਹਾਡੇ ਬੱਚੇ ਦਿਹੀਜ਼ਾ ਹੋਵੇ ਤਾਂ ਤੁਹਾਡੇ ਨਾਲੋਂ ਜਾਣ ?

No = 0 

|  |
|--|
|  |
|--|

 18

Yes: Sometimes = 1 Always = 2 NA = 9  
 ਕਦੇ-ਕਦੇ (ਕਦੇ-ਕਦੇ) ਹਮੇਸ਼ਾ (ਹਮੇਸ਼ਾ) ਨਹੀਂ

c. (If taken to health practitioner) what type of practitioner?  
 (ਜੇ ਤੁਹਾਡੇ ਬੱਚੇ ਨਾਲੋਂ ਜਾਣ ਤਾਂ) ਤੁਹਾਡੇ ਬੱਚੇ ਦਿਹੀਜ਼ਾ ਹੋਵੇ ?

No = 0 

|  |
|--|
|  |
|--|

Yes: Sometimes = 1 Always = 2 NA = 9  
 ਕਦੇ-ਕਦੇ (ਕਦੇ-ਕਦੇ) ਹਮੇਸ਼ਾ (ਹਮੇਸ਼ਾ) ਨਹੀਂ

|                                       |   |  |                    |   |  |
|---------------------------------------|---|--|--------------------|---|--|
| Qualified physician<br>ਕੌਮੋਡਿਟੀ ਡਾਕਟਰ | <table border="1" style="width: 30px; height: 30px;"><tr><td></td></tr></table><br>19 |  | Aurvedey<br>ਅਰੁਯੋਗ | <table border="1" style="width: 30px; height: 30px;"><tr><td></td></tr></table><br>24 |  |
|                                       |   |  |                    |   |  |
|                                       |   |  |                    |   |  |
| Quack<br>ਟਰੈਲੋ ਪੁਰੋਹਿਤ                | <table border="1" style="width: 30px; height: 30px;"><tr><td></td></tr></table><br>20 |  | Kabiraj<br>ਕਬਿਰਾਜ  | <table border="1" style="width: 30px; height: 30px;"><tr><td></td></tr></table><br>25 |  |
|                                       |   |  |                    |   |  |
|                                       |   |  |                    |   |  |
| Homeopath<br>(ਟਰੈਲੋ ਪੁਰੋਹਿਤ)          | <table border="1" style="width: 30px; height: 30px;"><tr><td></td></tr></table><br>21 |  | Hakim<br>ਟਰੈਲੋ     | <table border="1" style="width: 30px; height: 30px;"><tr><td></td></tr></table><br>26 |  |
|                                       |   |  |                    |   |  |
|                                       |   |  |                    |   |  |
| CRL Worker/Dai<br>ਕੌਮੋਡਿਟੀ ਡਾਕਟਰ/ਦਾਈ  | <table border="1" style="width: 30px; height: 30px;"><tr><td></td></tr></table><br>22 |  | Other<br>ਦੂਜੇ      | <table border="1" style="width: 30px; height: 30px;"><tr><td></td></tr></table><br>27 |  |
|                                       |   |  |                    |   |  |
|                                       |   |  |                    |   |  |
| CRL Hospital<br>ਕੌਮੋਡਿਟੀ ਹਸਪਿਟਲ       | <table border="1" style="width: 30px; height: 30px;"><tr><td></td></tr></table><br>23 |  |                    |   |  |
|                                       |   |  |                    |   |  |



Why do some children die from diarrhea?

କାହିଁକି କିଛି ଶିଶୁମାନଙ୍କୁ (କେମିତି କେମିତି କିଛି ଶିଶୁମାନଙ୍କୁ ମରିଯାଇଥାଏ (କାହିଁକି)

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28

What is the usual diet of this child?

ଏହି ଶିଶୁର ସାଧାରଣ ଖାଦ୍ୟ କିପରି ଥାଏ ?

a. Only breast milk (0)  
କେବଳ ସ୍ତନ୍ନ ପୁରୁ ?

b. Breast milk and water (1)  
ସ୍ତନ୍ନ ଓ ପାଣି ?

c. Breast milk and other liquids (2)  
ସ୍ତନ୍ନ ଓ ଅନ୍ୟ ଉପକରଣ ?

d. Breast milk and solid food supplement (3)  
ସ୍ତନ୍ନ ଓ କଠିନ ଖାଦ୍ୟ ?

e. No breast milk - using other liquid diet or formula  
କେବଳ ସ୍ତନ୍ନ ନାହିଁ - ଅନ୍ୟ ଉପକରଣ ବା ସିଲିକା ଖାଦ୍ୟ ?

f. Mostly solid food with less frequent breast feeding than previously (5)  
କଠିନ ଖାଦ୍ୟ ଅଧିକାଂଶ ଉପକରଣ କମ୍ ସ୍ତନ୍ନ ପୁରୁ ?

g. No breast milk - using solid foods with or without animal milk or formula (6)  
କେବଳ ସ୍ତନ୍ନ ନାହିଁ - କଠିନ ଖାଦ୍ୟ ସହିତ ବା ବିନା ପ୍ରାଣୀ ମିଶ୍ରଣ ବା ସିଲିକା ଖାଦ୍ୟ ?

h. NA (9)

29

List foods other than breast milk and ask the following question for each food stuff:

କଠିନ ଖାଦ୍ୟ ଛଡ଼ା ଅନ୍ୟ ଖାଦ୍ୟ ପଦାର୍ଥଗୁଡ଼ିକ ପାଇଁ ନିମ୍ନଲିଖିତ ପ୍ରଶ୍ନ ପଚାରିବାକୁ କୁହନ୍ତୁ:

When your child has diarrhea what do you do with that food, I mean, whether you

ଶିଶୁର କିଛି ଖାଦ୍ୟ ଥିବା ସମୟରେ କିପରି କରନ୍ତି ତାହା କହିବାକୁ କୁହନ୍ତୁ, ଅର୍ଥାତ୍, କିପରି କରନ୍ତି ତାହା କହିବାକୁ କୁହନ୍ତୁ

eliminate/decrease/keep same/increase/other?

ଉପକରଣ କମ୍/ଅଧିକ କମ୍/ସମାନ ରଖିବା/ଅଧିକ କମ୍/ଅନ୍ୟ ?

List of food

১৯ খাদ্য

Response

উত্তর

elim decr same incr other NA  
 বাদ করা হ্রাস একই বৃদ্ধি (কোনো) অন্যান্য

|    |    |    |
|----|----|----|
|    |    |    |
| 30 | 31 | 32 |

elim decr same incr other NA

|    |    |    |
|----|----|----|
|    |    |    |
| 33 | 34 | 35 |

elim decr same incr other NA

|    |    |    |
|----|----|----|
|    |    |    |
| 36 | 37 | 38 |

elim decr same incr other NA

|    |    |    |
|----|----|----|
|    |    |    |
| 39 | 40 | 41 |

elim decr same incr other NA

|    |    |    |
|----|----|----|
|    |    |    |
| 42 | 43 | 44 |

elim decr same incr other NA

|    |    |    |
|----|----|----|
|    |    |    |
| 45 | 46 | 47 |

List the same foods and ask: In the week after the recovery of your child from diarrhea what do you do with this food?

এই খাদ্যগুলি তালিকাভুক্ত করুন এবং জিজ্ঞাসা করুন: ডায়েরিয়া থেকে সুস্থ হওয়ার পরে সপ্তাহের মধ্যে এই খাদ্যগুলি নিয়ে আপনি কি করেন? (কোনো/অন্যান্য) (হ্রাস/একই/বৃদ্ধি/বাদ করা/অন্যান্য) - (কোনো/অন্যান্য) কি করেন?

List of food

খাদ্য তালিকা

Response

উত্তর

elim decr same incr other NA  
 বাদ করা হ্রাস একই বৃদ্ধি (কোনো) অন্যান্য

|    |    |    |
|----|----|----|
|    |    |    |
| 48 | 49 | 50 |

elim decr same incr other NA

|    |    |    |
|----|----|----|
|    |    |    |
| 51 | 52 | 53 |

elim decr same incr other NA

|    |    |    |
|----|----|----|
|    |    |    |
| 54 | 55 | 56 |

elim decr same incr other NA

|    |    |    |
|----|----|----|
|    |    |    |
| 57 | 58 | 59 |

elim decr same incr other NA

|    |    |    |
|----|----|----|
|    |    |    |
| 60 | 61 | 62 |

elim decr same incr other NA

|    |    |    |
|----|----|----|
|    |    |    |
| 63 | 64 | 65 |

Do you offer any new food/medicine specially during diarrhea of your child?  
 කුඩා (බාල) දහමක් වශයෙන් විශේෂ කෘත (කොටස් හෝ ඖෂධ) ඔබ දුන්නේ කොහොමද?

What food/medicine? \_\_\_\_\_ Why?  
 කුඩා (බාල) / දුන්නේ? \_\_\_\_\_ (කොහොමද?)

|    |    |
|----|----|
|    |    |
| 66 | 67 |

What food/medicine? \_\_\_\_\_ Why?  
 කුඩා (බාල) / දුන්නේ? \_\_\_\_\_ (කොහොමද?)

|    |    |
|----|----|
|    |    |
| 68 | 69 |

Do you offer any new food/medicine specially in the week following recovery from diarrhea?  
 කුඩා (බාල) දහමක් වශයෙන් ප්‍රති-දහමෙන් පසුව සති 7ක් තුළ විශේෂ කෘත (කොටස් හෝ ඖෂධ) දුන්නේ කොහොමද?

What food/medicine? \_\_\_\_\_ Why?  
 කුඩා (බාල) / දුන්නේ? \_\_\_\_\_ (කොහොමද?)

|    |    |
|----|----|
|    |    |
| 70 | 71 |

What food/medicine? \_\_\_\_\_ Why?  
 කුඩා (බාල) / දුන්නේ? \_\_\_\_\_ (කොහොමද?)

|    |    |
|----|----|
|    |    |
| 72 | 73 |

If breast feeding then ask: When your child has diarrhea do you  
 කුඩා කුඩා දුන්නේ නම් ඇහීම: කුඩා කුඩා කුඩා (බාල) දහමක් වශයෙන් දහම දීමේ කොහොමද?

Stop breast milk? (0)  
 කුඩා දුන්නේ නැති කොහොමද?

Reduce breast milk? (1)  
 කුඩා දුන්නේ අඩු කොහොමද?

|    |
|----|
|    |
| 74 |

Increase breast milk? (2)  
 කුඩා දුන්නේ වැඩි කොහොමද?

Make no change in breast milk? (3)  
 කුඩා දුන්නේ වෙනස් නොකොහොමද?

NA (9)

If there is a change in breast feeding pattern during diarrhea is the change determined by mother or child?  
 දහම දීමේ කොහොමද වෙනස් වන්නේ කුඩා හෝ මව්ගේ (කොහොමද) (මව්ගේ - කුඩා හෝ මව්ගේ කොහොමද?)

Mother (0) Child (1) Both (2) Other (3) Unknown (4)  
 මව් කුඩා දෙදෙනාම වෙනත් අනෙක් කොහොමද

|    |
|----|
|    |
| 75 |

If breast feeding then ask: In the week following recovery from diarrhea do you  
 කුඩා කුඩා දුන්නේ නම් ඇහීම: කුඩා කුඩා (බාල) දහමක් වශයෙන් ප්‍රති-දහමෙන් පසුව සති 7ක් තුළ කුඩා කුඩා දුන්නේ කොහොමද?

a. Stop breast milk? (0)

ସ୍ତନପାନ ବନ୍ଦ କରିବା (ନା)?

b. Reduce breast milk?(1)

ସ୍ତନପାନ କମାଇବା (ନା)?

c. Increase breast milk? (2)

ସ୍ତନପାନ ବୃଦ୍ଧି କରିବା (ନା)?

d. Make no change in breast milk? (3)

ଅବସ୍ଥା ବଦଳାଇବା (ନା)?

What is the best treatment for diarrhea in children?

ସନ୍ତାନଙ୍କ (ପାଳକ) ଅସ୍ତମାଧିକ ପତରାଣର ଉତ୍ତମ ଚିକିତ୍ସା କି?

76

77

During diarrhea is it good for a child to drink fluids?

(ପାଳକ) ଅସ୍ତମାଧିକ ସମୟ ପାଳି ଶାନ୍ତିର ସମୟ (ନିଷ୍ପତ୍ତି କି ଉତ୍ତମ)?

a. No (0) or Yes: What quantity?

ନା ଉତ୍ତର ସ୍ତମାଧିକ କି ପରିମାଣ?

b. Less volume than usual (1)

ଅସ୍ତମାଧିକତର (ଘଟି) କମ ପରିମାଣ?

c. Same volume as usual (2)

ଅସ୍ତମାଧିକ ପରିମାଣ?

d. More volume than usual (3)

e. NA = (9)

ଅସ୍ତମାଧିକତର (ଘଟି) (କମି) ପରିମାଣ?

During diarrhea is it good for a child to eat solid food?

(ପାଳକ) ଅସ୍ତମାଧିକ ସମୟ କଠିନ ଖାଦ୍ୟ (ନିଷ୍ପତ୍ତି କି ଉତ୍ତମ)?

a. No (0) or Yes: What quantity?

ନା ଉତ୍ତର ସ୍ତମାଧିକ କି ପରିମାଣ?

b. Less quantity than usual (1)

ଅସ୍ତମାଧିକତର (ଘଟି) କମ ପରିମାଣ?

c. Same quantity as usual (2)

ଅସ୍ତମାଧିକ ପରିମାଣ?

d. More quantity than usual (3)

ଅସ୍ତମାଧିକତର (ଘଟି) (କମି) ପରିମାଣ?

e. NA = (9)

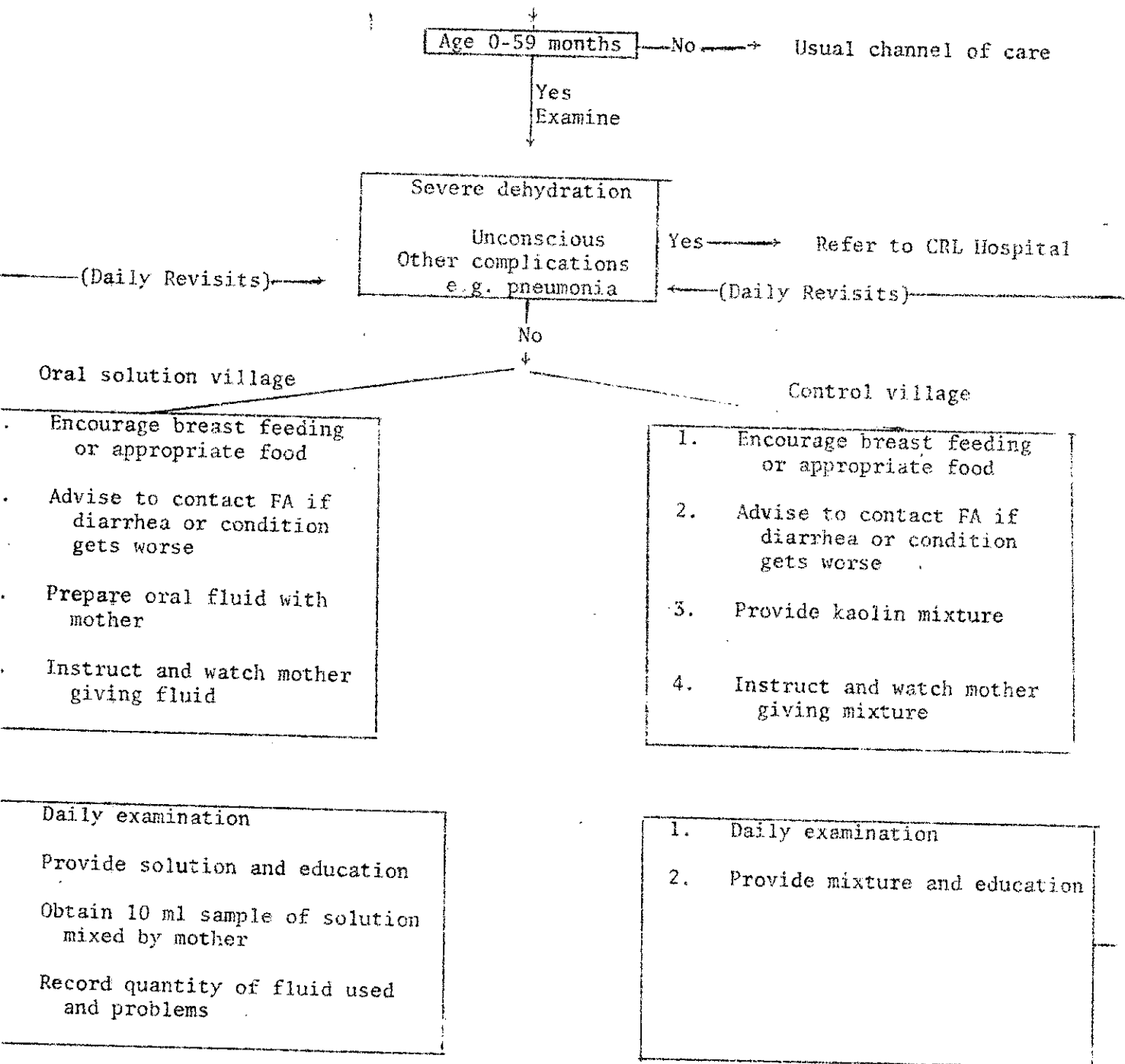
79

80

APPENDIX VIII

Management of Diarrhea Cases in Study and Control Villages

Child with diarrhea



Abstract - Cohort Study of Diarrhea, Nutrition and the Effect of Oral  
Glucose-Electrolyte Solution on Nutrition

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TIENZ

A cohort of 200 children (age 3 months to 4 years) from 2 villages will be studied for one year to determine the relationship of serum and breastmilk antibodies to protection from enteric infection and the effect of diarrhea on growth, lactose malabsorption, and food intake. Furthermore we will try to determine if the use of oral glucose-electrolyte solution for all diarrhea has a beneficial effect on growth of children.

1. Since it is growing children who appear to suffer stunted growth and poor nutrition as a result of illness, the study will be done on children,
2. There are no significant risks to persons in this study. The collection of rectal swabs and fingertip blood specimens from children and 1 cc samples of breastmilk from women should not result in serious side effects. Some individuals with lactose malabsorption may develop temporary cramping and diarrhea after ingesting a test dose of lactose. The hydrogen breath test is the best non-invasive technique available to test for lactose malabsorption. Approximately 300 Bangladeshi children have been studied by this technique without harmful effects.
3. Does not apply.
4. All study subjects will be assigned a study number at the beginning of the study. The subjects' names will then remain locked in a file until completion of the study. All data will be recorded by study number only and will be published without reference to subjects' names.
5. A signed (thumb print) consent will be obtained from all study subjects or their guardian or parent (for children). In each case the information provided will include

- a) the nature and purpose of the study
  - b) the procedures to be used
  - c) the physical risks
  - d) the benefits to be derived
  - e) the right to refuse to participate and
  - f) the confidential handling of data.
6. Families will be questioned about illness 3-4 times per week for 1 year. They will also be asked about water use and other exposures periodically during the study. At the beginning and end of the study a survey will be done asking about knowledge, attitudes and practices concerning the feeding of children during diarrhea and the treatment of diarrhea.
7. Children will benefit from the study in that many illnesses will be treated by the study physician. The cause of diarrhea will be determined and appropriate treatment utilized. The individual subject will receive information regarding his ability to absorb lactose. At the end of the study we will discuss appropriate alterations in feeding and care of children. Based on the information collected during the study. The potential future benefits of the study to society could be information critical to planning appropriate interventions to control diarrheal diseases and to reduce malnutrition and improve growth.
8. The study requires the use of Matlab Treatment Center records.

Diarrhea/Growth Study Consent Form

The doctors at the Cholera Hospital are studying the illnesses of children and how these illnesses affect growth of children. During the next year a female field worker will be visiting your house 3-4 times per week and a doctor will visit once per week to check your child's health. They will provide treatment for illness when possible.

As part of the study of illnesses, rectal swab cultures will be done during diarrhea and every 2 weeks regardless of illness. Also fingertip blood samples will be done 4 times in the year. We will also collect a very small amount of breastmilk (1 cc) from mothers who are breastfeeding their babies. This will help us find out what protects babies from diarrhea. Children will be weighed and measured each month and after diarrhea to find out if they are growing normally.

Some children will have a test to find out if they can absorb sugar and milk properly. For this test children cannot eat for 6 hours during the night nor during the test. After the night-time fast they will drink a sugar-containing solution. A sample of their breath will be collected 8 times in the following 5 hours. This will be done by having them blow into a rubber bag or breathe through a face mask for 15-30 seconds. There are no seriously harmful side effects but some children may develop gas, cramping or temporary diarrhea after the test.

Each month and after diarrhea a female field worker will visit the home for 12 hours to find out what food your child is eating. This will be done by weighing and measuring the food during preparation. Also for babies who are eating breastmilk, the child will be weighed before and after eating to find out how much milk was eaten.

Information collected will not be given to anyone other than yourself. You can ask any questions you want and are not required to take part in the study. The subject is free to withdraw from the study and will still be treated at the Cholera Hospital in the future.

Child's name: \_\_\_\_\_ VTS Number: \_\_\_\_\_

Child's name: \_\_\_\_\_ VTS Number: \_\_\_\_\_

Child's name: \_\_\_\_\_ VTS Number: \_\_\_\_\_

Date: \_\_\_\_\_ Mother/Guardian's name: \_\_\_\_\_



## উদারাময়/পারীক্ষিক বৃদ্ধি গবেষণামূলক নিরীক্ষার জন্য

### সম্মতি পত্র

কলেজ হাসপাতালের চিকিৎসকগণ শিশুরোগ এবং শিশুদের পারীক্ষিক বৃদ্ধির উপর এই সব রোগের প্রভাব সম্পর্কে গবেষণা করিতেছেন। আগামী এক বৎসর একজন মহিলা কর্মী প্রতি সপ্তাহে ৩।৪ দিন এবং একজন চিকিৎসক একদিন আপনার বাড়ীতে আসিয়া আপনার শিশুদের স্বাস্থ্য পরীক্ষা করিবেন এবং যথা সম্ভব চিকিৎসার ব্যবস্থা করিবেন।

রোগ পরীক্ষার অংশ হিসাবে, পেটের অসুখের সময় এবং প্রতি দুই সপ্তাহে কোন অসুখ থাক বা না থাক, এক বার রেকর্ড সোয়াব পরীক্ষা করা হবে। এছাড়া বৎসরে ৪ বার গাঞ্জলের ডগা হইতে রক্ত পরীক্ষা করা হইবে। যে সব মায়েরা বাচ্চাকে বুকের দুধ খাওয়ান, তাদের থেকে অতি সামান্য পরিমাণ (১ সিঃসিঃ) বুকের দুধ পরীক্ষার জন্য নেওয়া হইবে যাহা আমাদেরকে জানতে সাহায্য করবে কি তাতে বাচ্চার পেটের অসুখ হইতে রক্ষা পাইতে পারে। শিশুরা প্রাতিবিক তাতে বাড়ছে কিনা জানার জন্য প্রতি মাসে এবং পেটের অসুখের পর তাদের ওজন ও মাপ পরীক্ষা করা হইবে। কোন কোন শিশুকে পরীক্ষা করে দেখা হবে সে ঠিক মত দুধ ও চিনি হضم করতে পারে কিনা। এই পরীক্ষার জন্য শিশুকে শেষ রাতে ৬ ঘণ্টা না খাইয়া থাকিতে হইবে। সকল বেলায় শিশুকে চিনির সরবত খাওয়ানো হবে এবং পরবর্তি ৫ ঘণ্টা সময়ে আটবার তার প্রশ্বাসের বাতাস সংগ্রহ করা হবে। এই বাতাস সংগ্রহের জন্য বাচ্চাকে একটি রাবার ব্যাগের মধ্যে ফুঁ দেওয়ানো হবে অথবা একটি কেস মাস্কের তিতর দিয়া শ্বাস প্রশ্বাস গ্রহণ করানো হবে। এই পরীক্ষার মধ্যে কোন গুরুতর খারাপ প্রতিক্রিয়ার সম্ভাবনা নাই। তবে কোন কোন বাচ্চার পেটে হাওয়া জমা বা সামান্য অসুস্থি বা রূগস্থায়ী পাতলা পায়খানা হতে পারে।

প্রতি মাসে এবং পেটের অসুখের পর একজন মহিলা কর্মী আপনার বাড়ীতে ১২ ঘণ্টা বাল অপেক্ষা করে দেখবেন আপনার বাচ্চা কি কি খাবার খায়। খাবার তেরীর সময় ওজন করিয়া ও মাপিয়া তাহা নির্ধারন করা হবে। যে সব বাচ্চা দুধ খায়, তাহাকে দুধ খাওয়ান আগে ও পরে ওজন করিয়া ঠিক করা হবে সে কতটা পরিমাণ দুধ খাইয়াছে। আপনি ছাড়া এ সকল সংগৃহীত তথ্য আর কাউকে দেওয়া হইবেনা। আপনার কোন জানার থাকিলে জিজ্ঞাসা করিতে পারেন এবং এই পরীক্ষায় অংশ গ্রহনে কোন বাধ্য বাধকতা নাই। অংশ গ্রহনকারী যে কোন সময় এই গবেষণামূলক পরীক্ষা থেকে বিরত থাকিতে পারিবে এবং ভবিষ্যতে কলেজ হাসপাতালে চিকিৎসার সুযোগ লাভ করিবে।

শিশুর নাম: \_\_\_\_\_ ভি, টি, এস নং \_\_\_\_\_

শিশুর নাম: \_\_\_\_\_ ভি, টি, এস নং \_\_\_\_\_

শিশুর নাম: \_\_\_\_\_ ভি, টি, এস নং \_\_\_\_\_

তারিখ: \_\_\_\_\_

মা/অভিভাবকের স্বাক্ষর/চিহ্নসহ \_\_\_\_\_

১ নাবালক ছেলে বা মেয়ের পক্ষে পিতা/মাতা/আইনগত অভিভাবকের সম্মতি পত্র

আমাদের সমাজের ছেলে-মেয়েরা : (১) কি পশ্চাত্তম মেয়ে বা পুরুষের কর্ম সম্মানে জরান গ্রহণ, অভিজ্ঞতা অর্জন এবং (২) কিভাবে একজন অপরিজ্ঞানের সংগে উঠা-বসা, মেজাজমোশা ও খেলা-খুলা করে থাকে তাহা সম্পর্কে সরাসরি ছেলে-মেয়েদের নিকট হতে পাওয়া তথ্যের খুবই অভাব রয়েছে। মেয়ের আচার ব্যবহার ও ছেলের আচার ব্যবহার কিভাবে শিখা দেওয়া হয়ে থাকে এবং কিভাবে এরূপ শিখা গ্রহণ ও পালন করা হয়ে থাকে বিশেষ করে তাহার বর্ণনা ছেলে-মেয়েদের নিজ মুখ হতে জানতে ও লিখতে চাই। আলোচ্য বিষয়ে নাবালক ছেলে বা মেয়ের ব্যক্তিগত শিখা ও অভিজ্ঞতা গভীর ভাবে তলাইয়া বিবেচনা করাও তাহা পরিবারের সদস্য সংখ্যা সীমিত রাখার পরিকল্পনার কাজে নাগানোর চেষ্টা আমাদের দেশে এই প্রথম।

একজন নাবালক ছেলে বা মেয়ের নিকট হতে প্রয়োজনীয় তথ্য সংগ্রহ করতে এক ঘন্টার বেশী সময় ব্যবহার করা হবে না। একজন ছেলে বা মেয়ের নিকট হতে এক ঘন্টা সময়ের জন্য প্রশ্নোত্তর পেতে হলে এক হতে দুই বার তার সংগে বসতে হবে। ছেলে বা মেয়ের নাম ঠিকানা এবং তাহার দেওয়া প্রশ্নোত্তর লেখারও নিকট কোন অবস্থাতেই প্রকাশ করা হবে না তাহা উত্তর প্রদানকারী বা অভিভাবকের সামাজিক ও আর্থিক কতির কারন হতে পারে।

কলেজ গবেষণাগার ও রাজধানী ইউনিভারসিটির যৌথ কর্মসূচী অনুযায়ী উচ্চ ডিগ্রী (পি-এইচ, ডি) লাভের জন্য এই সব প্রশ্নোত্তরগুলি গবেষণা মূলক বইয়ে বর্ণনা করা হবে।

এই প্রশ্নোত্তর সমূহ নাবালক ছেলে বা মেয়ের নিকট হতে সংগ্রহ করতে দিতে রাজী হলে নীচে সই / টিপ সই দিন। এই কাজে অংশ গ্রহণ করতে দিতে রাজী না হলেও কলেজ হাসপাতালে চিকিৎসা বা অন্য সুবিধাদি পেতে কোন অসুবিধা হবে না। এই কাজে অংশ গ্রহণ এবং তাহা চলু রাখা না রাখা পুরাপুরি ভাবে আপনার ও উত্তর প্রদানকারী নাবালকের ইচ্ছাধীন।

আমি আমার সন্মান বা নাবালকের পক্ষে স্বেচ্ছায় সই দিলাম।

নাম সই \_\_\_\_\_

টিপ সই \_\_\_\_\_

ঠিকানা \_\_\_\_\_

তারিখ \_\_\_\_\_