<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Trainee Investigator (if any)</th>
</tr>
</thead>
<tbody>
<tr>
<td>K. Zaman</td>
<td></td>
</tr>
<tr>
<td>J. Chakraborty</td>
<td></td>
</tr>
</tbody>
</table>

**Patient Number:** 95-031

**Title of Study:** Children's fluid intake during diarrhoea: a comparison of questionnaire response with data from observations

**Supporting Agency (if Non-ICDRR,B):** WHO

**Project Status:**
- ( ) Continuation with change
- ( ) No change (do not fill out rest of form)

**Date:** Oct. 31, 1995

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

| Source of Population: |  
|-----------------------|------------------|
| (a) Ill subjects     | Yes No |
| (b) Non-ill subjects | Yes No |

**Does the study involve: (a)**
- 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 damaging to subject or others: Yes No

**Does the study involve: (a)**
- 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: (a)**
- 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 withdraw from study: Yes No
- Confidential handling of data: Yes No
- Compensation &/or treatment where there are risks or privacy is involved in any particular procedure: Yes No

**5. Will signed consent form be required?**
- (a) From subjects Yes No
- (b) From parent or guardian (if subjects are minors) Yes No

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

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

---

**Questionnaire or interview schedule:**

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

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

**Principal Investigator:**

**Trainee:**
CHECK-LIST FOR SUBMISSION OF PROPOSALS
TO THE RESEARCH REVIEW COMMITTEE (RRC)
[Please tick (✓) the appropriate box]

1. Has the proposal been reviewed, discussed and cleared at the Division level?
   Yes [✓]
   No [ ]

   If 'No', please clarify the reasons: _____________________________
   _____________________________
   _____________________________

2. Has the proposal been peer-reviewed externally?
   Yes [✓]
   No [ ]

   If the answer is 'NO', please explain the reasons: _____________________________
   _____________________________
   _____________________________

3. Has the proposal scope to address gender issues?
   Yes [ ]
   No [✓]

   If the answer is 'YES', have these been adequately incorporated in the proposal. Please indicate: _____________________________
   _____________________________
   _____________________________

4. Has a funding source been identified?
   Yes [✓]
   No [ ]

   If the answer is 'YES', please indicate the name of the donor: _____________________________
   WHO
5. Whether the proposal is a collaborative one?

Yes [✓]  

No [ ]

If the answer is 'YES', the type of collaboration, name and address of the institution and name of the collaborating investigator be indicated:

Dr. Jose Martinez

WHO

6. Has the budget been cleared by Finance Division?

Yes [✓]  

No [ ]

If the answer is 'NO', reasons thereof be indicated:


7. Does the study involve any procedure employing hazardous materials, or equipments?

Yes [ ]  

No [✓]

If 'YES', fill the necessary form.

Oct 31, 1995

Date

Signature of the Principal Investigator
RESEARCH PROTOCOL

1. Title: Children's fluid intake during diarrhoea: a comparison of questionnaire responses with data from observations

2. Principal Investigators: K. Zaman
   J. Chakraborty

   Co Investigators: Md. Yunus
                    A. de Francisco

4. Starting date: As soon as the protocol is approved

5. Completion date: 18 months from the date of start

6. Total Budget: US $ 72,075

7. Funding source: WHO

8. Division Director: Division Director
                     Community Health Division
ABSTRACT SUMMARY

Since its inception, WHO's Diarrhoeal Disease Control Programme (CDD) has laid much emphasis on improving the case management of children with diarrhoea, both in health facilities and in the home. A key element of correct case management in the home is the giving of "increased amounts of fluids" during the episode. In order to evaluate the effectiveness of CDD programmes in promoting correct case management in the home, CDD (WHO) has developed standard household surveys. However, the validity of questions regarding changes in children's fluid intake during diarrhoea has never been systematically assessed. This is, perhaps in part, because no "gold standard" for measuring changes in fluid intake exists. In the absence of a gold standard, the proposed study has the following aim:

To assess the use of simple questions to child caretakers to estimate the proportion of young children being offered/receiving increased quantities of fluids during diarrhoeal episodes, by comparing caretaker responses to questionnaires with data obtained by direct observation.

The study will be performed in Matlab, a rural area of Bangladesh. Two groups of children/caretakers (A and B) will be recruited by active surveillance. Children aged 4 to 35 months and having diarrhoea starting in the last 24 hours at the time of surveillance will be recruited into Group A. The following day (Day 2) and 2 weeks later (Day 15) these children will be observed during 12 hour periods (approx. 6 am to 6 pm) to evaluate practices and behaviours related to fluid intake. On the day following the second observation (Day 16) the caretakers will be interviewed using a standard questionnaire. Children aged 4 to 35 months at surveillance, with diarrhoea at any time in the past two weeks will be recruited into Group B. The same questionnaire as for Group A will be administered to the caretaker on the day of surveillance. A total of 195 children will be recruited into Group A and 390 into Group B.

Agreement, at the individual level, between questionnaire and observation will be assessed using the data from Group A children. At the population level, agreement will be assessed by comparing the observational data from group A with the questionnaire data from group B.

This study will contribute to the development of guidelines for conducting future surveys of home management of diarrhoea.
SECTION II : RESEARCH PLAN

A. Purpose of the study

1. General objectives:

To assess the use of simple questions to child caretakers to estimate the proportion of young children being offered/receiving increased quantities of fluids during diarrhoeal episodes.

2. Background

Diarrhoeal diseases have long been recognized as a major cause of morbidity and mortality in developing countries like Bangladesh [1,2]. Loss of fluids and electrolytes leading to dehydration is the major cause of this morbidity and mortality [3]. The development of inexpensive and simple oral rehydration therapy (ORT) has greatly simplified the treatment of diarrhoea, regardless of etiology or patient age [4,5].

Since its inception, WHO’s Diarrhoeal Disease Control Programme (CDD) has concentrated most of its efforts on improving the case management of children with diarrhoea, both in health facilities and in the home. One of the key elements of correct ‘case management in the home’ is the giving of “increased amounts of fluids” during the episode. In recent years CDD programmes have developed the concept of "recommended home fluids" suitable for this purpose, and many countries have identified locally available fluids that may be given during diarrhoeal episodes [6,7]. In Bangladesh "lobon-gur" (lobon = common salt, gur = molasses), packeted ORS and salt-sugar solution are all commonly recommended to mothers.

In order to evaluate the effectiveness of national and local CDD programmes in promoting correct case management in the home, CDD (WHO) developed a standard household survey [8]. This survey collects data on important programme indicators such as the proportion of all diarrhoea episodes in which ORS is used, the proportion of mothers who report continuing feeding the child during diarrhoea, the proportion of mothers who report offering the child increased quantities of fluid, and the use of drugs during diarrhoea.

Estimates of ORS and ORT use rates are of limited use to CDD programme managers in the sense that they give no indication of whether a sufficient (clinically important) quantity of fluid has been offered to and actually taken by the child. Similarly the responses concerning increased fluids offered/drunk, while perhaps appearing to address this issue of quantity, may fail to do so. When a caretaker replies that she has given the child more fluids what does she mean? Two teaspoonfuls of ORS a day? One litre of ORS per day? What does she consider constitutes an increase? And how well can she judge whether such an increase occurred?
As an illustration of this point, a study of ORS use in Matlab, Bangladesh found that among diarrhoeal infants an average of only 400 ml of ORS was consumed during the first 2 days of the episode. The small amount of ORS used may explain, at least partly, why infant mortality from diarrhoea has not decreased in this area, despite high awareness of ORS (> 90%) and high ORS use rates (> 50%) [9].

During the period 1989-91, standard household surveys of home management were completed in 26 countries. The results, with few exceptions, show small proportions of caretakers reporting giving increased quantities of fluids to children with diarrhoea. In Bangladesh, 26% of diarrhoea cases were reported to have been given increased amounts of fluid [10]. What does this mean? Does it reflect what really happened or what caretakers perceive to be expected of them? How big was this increase?

In 1991 CDD (WHO) initiated a revision of the household survey with the aim of developing an integrated household survey covering diarrhoeal diseases, acute respiratory infections (ARI), and breast feeding practices. In the course of this revision, modifications to the questions concerning changes in fluid intake during diarrhoeal episodes were made. The new version of the survey is now undergoing field trials and will shortly be made available to national CDD programmes for routine use (Dr. Gottfried Hirschchall, personal communication, WHO).

The existing WHO household survey [8] assesses the change in fluid intake during a diarrhoeal episode by asking the caretakers of children under 5 with diarrhoea in the last 24 hours the following question:

"Since the diarrhoea started, have you given your child more, less or the same amount of all fluids (other than breast milk)".

In the revised questionnaire (revised CDD/ARI Household Survey Manual, 1992, unpublished) two questions regarding changes in fluid intake are directed towards caretakers of children under 5. The first one (Q.12) is directed to all caretakers of children under 5:

"When a child has diarrhoea, should the child be given much less, somewhat less, about the same, or more fluids".

The second one (Q.46) is directed to caretakers reporting a diarrhoeal episode in their child (under 5) during the last 2 weeks:

"During your child's diarrhoea did the child drink much less, somewhat less, about the same, or more total fluids (including breast milk and formula) than usual?"
Between the two approaches mentioned above the main differences are:

a) the recall period - a child with diarrhoea in the last 24 hours versus a child with diarrhoea at any time in the past two weeks;

b) the phrasing of the question - "given" versus "drunk";

c) the new survey asks a "knowledge/belief" question (Q.12) in addition to a "practice" question (Q.46);

d) the old question excludes breast milk while the new question includes it.

It is unclear what the effect of these changes will be, and whether the responses to the new questions will be "better" in some way than the responses to the old question. Similarly it is not known whether either of these questionnaire approaches permit the detection of an actual change in fluid intake.

CONCEPTUAL MODEL

Factors influencing a child's fluid intake during diarrhoea

- Perceived severity of episode
- Cultural context, local beliefs, cultural
- Caretaker behaviour (frequency/amount fluids offered, persistence, encouragement)
- Child factors (thirst, age, ...)  
- Fluid intake of child
- Type of fluid
- CDD programme encourages increased fluids
- Constraints on time, physical
- Caretaker factors (age, parity, etc)
3. Rationale

CDD programmes aim to increase children’s fluid intake during episodes of diarrhoea. The way in which they seek to do this is by altering caretakers' behaviour. A child’s fluid intake may depend on the following aspects of a caretaker’s behaviour: the frequency with which the caretaker offers the child fluids and the amounts that she offers; the types of fluids that she offers; the degree of persistence with which she offers the fluids; the help and encouragement to drink that she gives the child.

While CDD programmes may influence child’s fluid intake by altering caretaker behaviour, other factors may also play a role in determining caretaker behaviour and in determining the impact of CDD programme messages. Some of these factors are shown in the conceptual model above and include: availability of health services, proximity to water supply and other environmental resources, access to school and health information, local knowledge beliefs and practices.

The child’s fluid intake will depend not only on caretaker behaviour, but also on other factors - for example, the child’s age, how thirsty the child feels, whether s/he is vomiting, etc.. Thus the impact of the CDD programme will depend on the limits of its impact on caretaker behaviour and then, in turn, on the limits on caretaker behaviour to alter fluid intakes.
The mechanism by which CDD programmes may alter children’s fluid intake - via caretaker behaviour - raises an important issue when considering evaluation of the programme. Should the success of the programme be judged by its impact on its ultimate objective, child fluid intake, or by its impact on that which it seeks to change directly - caretaker behaviour? This choice corresponds to choosing between questions about whether the child drank more (new questionnaire) or whether the caretaker gave more (old questionnaire). While this choice should take account of what is considered the more appropriate criterion of programme success, it should also be a pragmatic choice. To which question can caretakers respond more accurately - "did you give more" or "did the child drink more" (if either) - and what do caretakers understand/mean by "more" in each context?

This study will attempt to answer these questions. However, actual changes in quantities of fluids offered to and drunk by the child during diarrhoeal episodes as compared with healthy periods are difficult, if not impossible, to measure precisely. No gold standard exists. This study will use measurements and estimates obtained through direct observation of caretakers and children over two 12-hour periods. We believe that such measurements and estimates represent a realistic proxy in the absence of a gold standard. The proposed study will contribute to the development of guidelines for evaluating the impact of CDD programmes on children’s fluid intake during diarrhoeal episodes. From the data obtained specific elements and instruments for the evaluation of changes in fluid intake can be selected and developed, and which will provide the basis for a simplified process for application in different cultural situation.

Research questions:

- Do mothers offer children more fluids during diarrhoeal episodes?

- By how much do young children’s fluid intakes change between healthy periods and diarrhoeal episodes?

- Can a simple questionnaire provide programme managers with a meaningful estimate of the proportion of mothers who increase the quantity of fluids offered to/drunk by young children during diarrhoeal episodes?

- Are there any changes in the types of fluid drunk by young children during diarrhoeal episodes as compared to healthy periods?

- What caretaker and child behaviours are associated with change in fluid intake between healthy and diarrhoea periods?
B. Specific objectives:

1. To measure, by direct observation, the frequency with which children aged less than three years are offered fluids when experiencing an episode of diarrhoea and when healthy.

2. To estimate, by observation, the quantity of fluids consumed by children aged less than three years when experiencing an episode of diarrhoea and when healthy.

3. To record, by observation, the persistence and degree of encouragement employed by the caretaker when offering fluids to diarrhoeal children and to healthy children.

4. To compare, at the individual level, caretaker behaviour and children’s observed fluid intakes (type and quantity) during diarrhoeal episodes with those during healthy periods.

5. To compare, at both the individual and population levels, observed changes in caretaker behaviour and children’s fluid intake with caretaker’s responses to simple questions concerning fluid intake.

6. To assess the day-to-day variability of type and amount of fluid intake of young children.

7. To document caretakers’ notions about fluids and foods.

C. METHODS

Study site and population

The study will be conducted in Matlab, a rural area of Bangladesh, where the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) has been maintaining a field research project since 1963. Matlab is a low lying riverine area which lies 45 km south east of Dhaka, the capital of Bangladesh. Since 1966 a Demographic Surveillance System (DSS), which consists of regular cross-sectional censuses and longitudinal registration of vital events, has been maintained in the area [11]. A central treatment facility, staffed by physicians and para-medics provides free therapy for 12,000-15,000 diarrhoea patients a year. A Maternal, Child Health & Family Planning Program (MCH-FP) has been in operation for half of the population of the DSS area (current population of DSS is about 200,000)
since 1978 and intensive research has been conducted in this population. The other half serves as a comparison area where regular government health care facilities are available. The proposed study will be conducted in the comparison area whose population has been less exposed to previous research and interventions and is thus more typical of the general population of Bangladesh than the population in the MCH-FP area.

The incidence of diarrhoea in a cohort of 705 children in the comparison area aged less than 5 years was 4.6 episodes per year [12]. Knowledge of ORS among caretakers is high (> 80%), with a use rate over 50% [13]. To gain further insight into fluid intake patterns among children with and without diarrhoea, a small survey was conducted among 22 mothers in the community (10 mothers of children with diarrhoea and 12 of children without diarrhoea). These mothers believed that breast milk was enough to satisfy their children’s needs up to 4 months of age. However, most of the mothers reported giving water and other fluids (e.g. animal milk, sucrose water, rice gruel) to their children within the first 4 months of life. The mothers said that they identified when their baby was thirsty and needed water and fluid by the baby’s restlessness, crying and dryness of mouth. Mothers perceived the child’s demand for fluids to increase during diarrhoea. Fluids were usually given using bottles or glasses. Mothers also reported that they gave more fluid and water to their children during the summer (hot) season and in the morning and at noon. Mothers were unable to estimate the amount of fluid that might be required by their children during an episode of diarrhoea. In a review of admission charts of 34 children (aged 6 months to 59 months) in Matlab diarrhoea treatment centre, it was found that on average children consumed 400 ml of ORS between 8 am and 4 pm.

Study design

During the main body of fieldwork two groups (A and B) of children aged 4 to 35 months will be recruited into the study. An upper age limit of 35 months has been chosen for the study because of the difficulty of observing (see below) children aged 3 years or more. A lower limit of 4 months has been chosen because most children below this age are predominantly breast fed and the incidence of diarrhoea is relatively low. Children will be identified for inclusion in the study by surveillance of a population of about 14000 individuals (about 1300 children aged less than 3). Group A will undergo observations and interviews while Group B will undergo interview only.

Fieldwork will be performed by ten fieldworkers who will be allocated in pairs to 5 areas. Fieldworkers will be women recruited from the study communities who have obtained their Secondary School Certificate (SSC). Before beginning the study they will be fully trained and standardised, and a pilot study will be performed to test the study instruments (see below). Fieldwork will follow a seven day cycle. On the first day, the fieldworkers will perform house-to-house surveillance until they identify two children, one with watery diarrhoea starting in the last 24 hours (child A), the other with watery diarrhoea at any time during
the last two weeks (child B). The caretaker's definition of diarrhoea will be used (14), and her classification of the diarrhoea according to the local taxonomy in Bangla will be recorded. If there is more than one child with diarrhoea in that family, alternately the younger and then the older child will be recruited. The caretakers of the children will have the study explained to them and will be asked if they agree to participate in the study (see attached informed consent form). The fieldworker will administer a questionnaire to the caretaker of child B on the spot. The questionnaire will be based on WHO's standard household questionnaires, with the focus on fluids given to and drunk by the child (old and new questions). This will conclude caretaker/child B's participation in the study. The fieldworker will arrange with the caretaker of child A to visit the household the next day to observe the child. The next day (the second day of the seven day cycle) the fieldworker will conduct a twelve hour observation of child A, from 6 am to 6 pm. (The timing of the observation may vary slightly from season to season). The observation will focus on the frequency with which fluids (including breast-milk and liquid-containing foods), are offered to the child, the degree of persistence with which they are offered, the degree of encouragement given to the child to drink, and the quantity of fluids offered to and consumed by the child. The third day will be a rest day. Days four, five and six will repeat the pattern of the first three days with surveillance recommencing where it last left off. On the seventh day there will be a team meeting at the Matlab field centre to review the week's work, validate procedures and discuss any problems which arose.

The second week will repeat the same cycle as the first. During the third and fourth weeks the cycle will change slightly. On the first day the fieldworkers will re-observe the diarrhoeal children they observed thirteen days previously. On the second day they will identify and recruit a group B child and they will interview the group A caretaker observed by their partner the day previously. The third day will be a rest day. This pattern will continue for weeks 3 and 4 with meetings on the seventh day. Week 5 will revert to the pattern of week 1. (See table at end of section). The involvement of the two groups of study participants is summarized below.

<table>
<thead>
<tr>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>(diarrhoea starting</td>
<td>(diarrhoea at any time</td>
</tr>
<tr>
<td>in last 24 hours)</td>
<td>in past two weeks)</td>
</tr>
<tr>
<td>Day 1 Identified</td>
<td>Identified and questionnaire</td>
</tr>
<tr>
<td>Day 2 12-hour observation</td>
<td>-</td>
</tr>
<tr>
<td>Day 15 12-hour observation</td>
<td>-</td>
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<tr>
<td>Day 16 Questionnaire</td>
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</tr>
</tbody>
</table>

In addition a sub-sample of 20% of caretakers of Group B children will be re-interviewed 7 days after the first interview to enable an assessment to be made of the reproducibility of
the questionnaire with difference in time of recall.

A minimum of 5 months is required to complete data collection. However, seven months is programmed to allow for possible difficulties in identifying diarrhoeal cases.

The data collected from Group A will allow a comparison of questionnaires and observations at the individual level. The observational data from group A will be compared with the questionnaire data from group B, thus evaluating, at the population level, differences in observed and reported data. All of the questionnaire data from Group A will have been collected following two days of observation (one diarrhoea and one healthy day) and it is possible that this may alter caretakers' responses. The comparison of the data from the questionnaires of groups A and B will enable an evaluation of this possible observation bias or "contamination" effect. Nevertheless there may be an effect due to the difference in recall period. Group A varies from group B in the recall period since the starting of the last episode of diarrhoea, being 16 days in the case of group A, and between 1 and 14 days for group B. If the questionnaire were applied earlier for group A (eg. 7 days after the diarrhoeal episode) this could introduce the "contamination" effect for the second observation. To explore any effect of the differences in recall time, the questionnaire results of group B with a recall period of 8 - 14 days will be compared with questionnaire responses of group A.

**Exclusion criteria**

Children with diarrhoea associated with other illnesses (eg. high fever, pneumonia), children with bloody stools, and children who have or who develop moderate or severe dehydration during the period of the observation will be excluded from the study and will be referred to Matlab hospital. Once a child has been recruited into either Group A or Group B s/he will not be eligible for further recruitment.

**A. Observations**

Observations will be performed over a 12-hour period, from 6 am to 6 pm. A record will be kept of all occasions on which the child was offered or took fluids, including breast-milk and semi-solids/solids. The latter is included as many of these preparations contain varying amounts of fluid. Caretaker behaviours with respect to the giving of fluids and foods will be measured. Twelve-hour observation periods are considered necessary to observe all the feeding and breast-feeding episodes of the young child during the day time, thus including most of the liquid intake. Previous dietary intake studies in this population have shown that this period of observation is feasible (15). A recall of the frequency of giving fluids and breast-milk during the 12-hours prior to the observation period (night-time) will allow an estimation of frequency of liquid intake during the 24-hour period.
1. **Behaviours**

The following Behaviours of caretakers and children and the physical accompaniments relating to fluid and food intake will be measured.

a. **Maternal behaviours:**

   i) Preparation of liquid or food

   1) Type of liquid or food prepared.
   2) Ingredients used in the preparation.

   ii) Serving and giving of liquid or food to the child.

   1) Frequency of feeding episodes during observation period.
   2) Time of initiation, ending and duration of each feeding episode.
   3) Who initiates the feeding episode, caretaker or child.
   4) Who gives the liquid or food to the child.
   5) Selection of the types of liquids or foods given to the child.
   6) Order of giving the different types of liquids/foods to the child.
   7) Utensil used
   8) From who's recipient is the liquid or food given to the child.
   9) Amounts of each type of liquid/food offered or given to the child.
   10) Degree of physical help given to the child during feeding.
   11) Degree of encouragement and persistence given to the child by caretaker.
   12) Interruption of feeding episode by breastfeed or other activity.
   13) Who terminated the feeding episode and why.
   14) Estimated total volume of fluid offered during the observation period.

b. **Child behaviours:**

   1) Order of consumption of liquids or foods.
   2) Child's preference for types of liquid or food.
   3) Child's acceptance/appetite for liquids/foods
   4) Child's refusal of any liquid or fluid.
   5) Amount of liquid/food consumed by the child.
   6) Location of child during feeding.
   7) Child's activity level during the feeding episode.
   8) Frequency of night-time liquid intake.
   9) Estimated total volume of fluid consumed during the
observation period.

c. Mother and child behaviour around breastfeeding episodes:

1) Frequency of breastfeeds during the observation period.
2) Time of initiation of breastfeeding episode and duration.
3) Who initiates the breastfeed.
4) Appetite of baby for breastmilk
5) One or both breasts given
6) Who terminated the breastfeed and why.
7) Frequency of breastfeeds during the night.
8) Estimated volume of breast-milk consumed by the child during the observation period.

d. Family behaviour:

1) Presence of family members during the feeding episode.
2) Family members' support or encouragement for caretaker feeding the child.

2. Operational Definitions

The preliminary Operational Definitions of the above behaviours for observation are listed. These will be defined, tested and coding scales developed during the pilot phase.

a. Term definitions:

Liquid/food "served" (caretaker):
    Refers to the liquid or food that is separated (or served) as a portion specifically for the child.

Liquid/food "given" or "offered" (caretaker):
    Refers to the liquid or food actually given to the child by caretaker. The caretaker, either using an utensil or hand.

Liquid/food "consumed" or "drunk" (child):
    Refers to the liquid or food the child actually receives in his mouth and swallows.

b. Maternal behaviour:

1) Type of food liquid/food.
The different food types used will be noted and coded according to
preparation and consistency. For example, consistencies will be: liquid, liquid with solid pieces, semi-solid, solid, etc.

2) Ingredients.
Each liquid or food preparation will be recorded and the ingredients used will be noted and coded. For the purposes of this study it is not considered necessary to estimate amounts of the individual ingredients.

3) Feeding episode.
Each feeding episode will be numbered in chronological order during the observation period. In the local cultural setting there are certain practices associated with the serving of a meal which indicate the initiation of a feeding episode. These include the bringing of the child and foods to the eating place, the preparing of the child for feeding, the bringing of utensils, etc. Similarly the end of a feeding episode is marked by the taking away of the liquid/food etc. If the food has been taken away and then brought out again to give the child, this will be considered a new feeding episode; if the food is left out temporary and the child then re-fed, this will be considered as the same feeding episode. These definitions are considered more appropriate than a simple time difference between feeding episodes in the local setting and have been used previously in this population (24). However, they will be tested in the pilot phase. The time of the initiation and termination of each feeding episode will be recorded, and the duration calculated.

4) Person initiating feeding episode.
The person who initiates the feeding episode (caretaker or child) will be noted. If the child is expressing demand through crying or making gestures or signs the feeding episode will be considered as child-initiated.

5) Person feeding the child.
The person who feeds the child, or whether the child feeds him/herself, will be noted.

6) Selection and order of offering foods/liquids.
The food or liquid preparations will be noted in order of serving to the child.

7) Utensil for serving the child.
The utensil used for serving food/liquid to the child, whether it is served specifically for the child or from the caretaker's or family plate/pot will be noted.

8) Utensil for giving liquids and food to the child.
The utensil used for giving the food/liquid to the child, whether a spoon, glass, cup, hands, etc. (of whom), will be noted.

9) Amounts of liquids or foods "offered".
The quantity of the food or liquid offered to the child will be estimated from the observation of household measurements converted into grams or mls. according
to previously standardised procedures (See: Estimation of fluid intake, page 19). This will be either:

i) the food or liquid served specifically for the child, or

ii) in the case of the food being given directly to the child from the family pot or a dish or cup shared with another person, estimated from the number of times and amounts the food is actually given to the child.

The liquid offered at each feeding episode will be summed to give total fluid offered during the 12 hours observation. The estimated total 12-hour fluid offered will be calculated from the sum of the fluid offered to the child plus breast-milk intake.

10) Degree of physical help given to the child.
The degree of physical help given to the child by the caretaker will be estimated by the number of times the child is helped for each preparation during the feeding episode.

11) Degree of encouragement or force by the caretaker for the feeding of the child.
The degree of encouragement or force will be estimated using the following criteria for each of the preparations given during the feeding episode, coded according to number of times occurring for each preparation:

- encourage the child verbally or by gestures to eat or drink.
- "pressure" the child verbally or by gestures to eat or drink
- "force" the child physically
- the time of the physical presence of the caretaker with the child during the feeding episode.

12) Termination of the feeding episode.
The person who terminates the feeding episode will be noted (caretaker or child) as well as the circumstances dictating this.

13) Interruption of feeding episode by breastfeed.
If the feeding episode is interrupted by a breastfeed this will be noted.

c. Child behaviours:

1) Order of consumption of the liquids or foods.
The order of the child's consuming the liquids or foods will be noted.

2) Child's acceptance for liquid or food.
This will be measured by the apparent degree of appetite or thirst of the child at the initiation of the feeding episode.
3) Child's preference for liquid or food.
The preference of the child will be estimated by the child's demanding of a particular liquid or food and whether the child appeared to prefer a food item.

4) Child's refusal of a liquid or food.
If the child specifically refused to drink or eat any of the items offered this will be noted, as well as which these items were.

5) Amount of liquid and food consumed.
This will be estimated through observation by evaluating quantities from household measurements and converted into grams or mls, using previously standardised techniques (See: Estimation of fluid intake, page 19). It will be measured by estimating:

   a) the amount offered for the child less the amount left after the child has eaten or drunk, (vomiting or spillage by the child will be taken into account), or

   b) in the case of a child who is given food or liquid directly from a receptacle shared with other family members, estimated from the number of "single-bite" portions of liquid or food are given to the child and consumed.

The liquid consumed at each feeding episode will be summed to give the total 12-hour intake. The estimated total 12-hour fluid intake will be calculated from the sum of the fluid consumed by the child plus breast-milk intake.

6) Location of child.
The location of the child will be noted, whether he/she is on the ground, on a seat, on the caretaker's lap, etc.

7) Child's activity level.
During the feeding episode the child's activity level as active, irritable or sleepy will be described.

8) Night-time fluid intake.
As liquids may be given during the night, thus affecting the total 24-hour intake, a 12-hour recall will be applied during the morning of the observation, to estimate type and frequency of liquids and foods given during the night prior to the observation day. No attempt will be made to estimate the quantity of liquids consumed during the night.

d. **Breastfeeding episodes:**

1) Initiation of the breastfeed.
Whether the mother or child initiates the breastfeed will be noted. The child will be considered as initiating the breastfeed if he/she is expressing demand through crying or making gestures.

2) Breastfeeding episode.
A new breastfeeding episode is classified as one that commences with a minimum of 10 minutes after the termination of the previous breastfeed. This definition has been used in other studies (16).

3) Duration of breastfeeding.
The time of initiation and termination of each breastfeeding episode will be recorded and total breastfeeding time summed for the 12-hour observation period. Breastfeeding will be considered for the time that the baby is at the breast and suckling. Time that the baby is sleeping at the breast, just playing with the nipple, or other interruptions of the breastfeed will be excluded.

4) Appetite of child for breastmilk.
The appetite of the child for breastmilk will be evaluated by observing whether on being put to the breast, the child commences suckling immediately.

5) Who terminates the breastfeed.
The person who terminates the breastfeed (caretaker or child), and the circumstances dictating this will be noted (eg. baby sleeps at the breast, etc.)

6) Estimated total breast-milk intake.
Breast-milk volumes will be estimated from previously reported data of measured (test-weighed) breast-milk intake during 12-hour observation periods in this population (17). From these studies mean breast-milk intake was calculated according to the age of the child, total time at the breast and frequency of feeding during the 12-hour period. Using this data the approximate breast-milk intake during the 12-hour observation period will be calculated.

7) Night-time breast-milk intake.
The number of night-time breastfeeds given during the 12-hours prior to the initiation of the observation will be recorded.

e. Family behaviour:

1) Presence of family members.
The presence of family members during the feeding episode other than the caretaker will be noted.

2) Family encouragement of giving food or liquid.
The degree of the family support of the members present will be estimated by noting whether they encourage, are indifferent to, or interrupt (detract the
caretaker from) the feeding of the child.

f. Observer effect:

1) Effect of the observer during the feeding episode.
Any felt effect on the part of the observer as to her influence on the infant's feeding behaviour will be noted.

2) Effect of the observer during the breastfeeding episode.
Any felt effect on the part of the observer as to her influence on the infant's breast-feeding behaviour will be noted.

3. Other events.

Other events relevant to fluid intake and diarrhoea which will be recorded include child defaecation and vomiting during the observation period.

B. Questionnaire

The questionnaire will be administered to caretakers in Bangla (Bengali). It will be based on the standard WHO questionnaires on home management but will include both the original form of the question concerning fluids ("give") and the new form ("drink"). A common recall period of two weeks will be applied and breast feeding will be included in the question.

Assistance will be sought from anthropologists within ICDDR,B in developing the structured observation forms, and in translating the questionnaire into Bangla. Previous studies have described the way in which caretakers in the study area classify diarrhoea episodes (14). The distinctions caretakers draw between fluids/drinks and foods will be explored during the pilot phase. Particular care will be taken over the the translation of the word "fluids" on the questionnaire, to ensure that there is no confusion between the investigators/interviewers and the caretakers over what is meant by and covered by this term. Draft forms to be used for the collection of data are included with this proposal. The observation forms and the translation of the questionnaire will be finalized during the initial phase of the study (training and pre-testing).
Recruitment, training and standardisation of fieldworkers

Fieldworkers will be recruited locally through advertisements. To standardize the interviews and observations the field workers will be trained at Matlab, both at the Matlab hospital and in the field during piloting, following standard guidelines. During training the use of the forms and the coding of the specific operational definitions for the observations, both the estimation of quantities of liquids and foods and behaviours, will be standardized between field workers through repeated observational exercises. The careful standardization and transference to the field workers are critical elements of the study, yet have been successfully implemented elsewhere (25) (J. Rivera, H. Creed, personal communications). The assistance of an anthropologist will be sought for the training in behavioural aspects, and that of a nutritionist for the standardization of the estimated fluid intakes.

Estimation of fluid intake

a) Estimation of volume and weights of liquids and foods.

Repeated standardisations will be conducted to train field workers to accurately estimate observed portion sizes of household measures of specific liquids and foods in grams or mls. The procedure used will be similar to that described previously (18). Local utensils used for giving fluid/food to children will be collected and the volumes and weights of different portion sizes of specific liquids and foods measured, using balances accurate to 5 grams. For example: the weights of 1/4, 1/2, 3/4 and full cup or glass of water will be measured, similarly 1/4, 1/2 etc. of a "dish" used for dal (pulses), etc. As the caretakers' hand is used for giving food, and also some liquids to the young child, portion sizes of "single-bites", "fingerfuls" or "handfuls" for different food preparations and liquids will be measured. This will be conducted with a number of mothers and children who feed themselves (5-8 in each case), and averaged to give standard values.

A series of group exercises in which the observers estimate different amounts of liquids and foods will be conducted to familiarize them with estimating weights, followed by individual evaluations and standardisations. For the purposes of this study the amounts of liquid and food will be estimated to the nearest 1/4, 1/2, 3/4 or full portion of the utensil used, which will probably give an accuracy of the observed estimated weight to within 20% of the actual weight, which will be considered acceptable. Correlations between estimated and actual weights for these portion sizes will be calculated for each observer. Those field workers who consistently vary from the accepted standard will not participate in the observational study.

b) Estimation of fluid content of food preparations.

Initially a list of the local fluid and food preparations will be compiled during the pilot
observations. These will be coded according to food type (e.g. dal, rice gruel) and consistency (liquid, liquid with solid, semi-solid, solid, etc.). During training the consistency of the different liquid and food preparations will be standardised between field workers. The proportion of fluid in the different types of preparations will be estimated using the following procedure:

i) Liquid preparations will be considered as 100% liquid.

ii) For liquid with solid preparations (e.g. dal), mothers will be observed preparing each of the recipes and after cooking, the proportion of liquid to solid will be measured by weighing. From the range of liquid content measured for around 5 samples of each preparation the mean proportion of liquid will be calculated, giving a factor for the estimation of liquid content for each type of preparation. If different consistencies are found for a specific type of preparation, these will be classified as "thick" or "thin", and respective factors developed.

iii) In the case of semi-solid preparations, such as rice powder-milk recipes, the different ingredients will be weighed as the mothers cook the preparation and the proportion of liquid calculated. Again, means will be calculated to arrive at the respective factors for estimation of fluid content of each of the preparations.

iv) Although most solid preparations contain liquid, this will not be considered in the estimation of liquid intake for the purpose of this study which focuses on the increase in fluid intake during diarrhoea.

It is recognised that the use of these factors is an approximation of the fluid content. However, more precise measurements could only be achieved through weighing each item or preparation during the observations and this is not considered necessary for the purposes of the present study.

A more detailed description of the process of estimating fluid intake and training of the field workers in these aspects is included in Appendix 1.

Quality control

A field supervisor, along with the PI's, will be responsible for quality control of the data collected, both through spot checks on fieldworkers and through checking of completed forms. The supervisor will repeat the questionnaire with some mothers (around 20%), selected at random, on the same day as the field worker's interview, and the results checked against the field worker's forms.

The standardisation of the estimation of amounts of fluids and foods and the definition of the behaviours observed will be repeated regularly with the field workers during the weekly team meetings in the centre. In addition, validation will be performed with the female supervisor, responsible for the observations, who will conduct spot checks consisting of 2-3 hour-periods of observation with each of the field workers during an observation day, once
every 2 weeks. The completed forms of the supervisor (the standard) for the feeding episodes observed will be compared with that of the field worker and adjustments made. The results will be discussed and applied in the team meetings to maintain precise measurement.

**Preparatory phase and Pilot study**

Two phases of the study will be conducted with the following objectives:

**Preparatory phase (4 weeks)**

1. Finalisation of the specification of operational definitions and coding scales, and instrument design.
2. Ethnography (about 25 caretakers) to describe distinctions on the part of the caretakers, between fluids and foods.

**Pilot study (10 weeks, including training)**

3. Pre-testing of instruments and procedures, including estimation of liquid content of food preparations.
4. Training and standardisation of field workers.
5. Explore intra- and inter-child variability in types and amounts of fluid intake. A small number of children (10 healthy and 10 with diarrhoea) will be observed over three days. This data will provide some information on the variability of children’s fluid intake from one day to another and between children.

Preparatory phase will be conducted with the supervisors and PIs with the assistance of an anthropologist, including the ethnography to describe the perceptions of the mothers as to which preparations are considered liquid and which solid. The pilot phase includes the initial training of the field workers and their testing and standardisation in the field. Once trained, they will conduct the study to explore daily variation in fluid intake.

**Sample size**

The study will aim to recruit 195 caretakers/children into group A and 390 children into group B. About 80 repeat interviews will be performed with Group B caretakers. The sample size calculation is based on the previous findings in children under 5, that about one quarter of caretakers report increased fluids given to/drunk by the child [10]. There are no figures available for specific age groups. This sample size will provide a precision of about
±5% for these proportions in Group B and of about ±7% in Group A. When comparing questionnaire responses in Group B with observed behaviours/intakes in Group A, the study will have a power of about 90% (at the 5% level of significance) to detect a difference of 15% in proportions [19,20]; i.e. if the proportion giving increased fluids in Group A is less than 10% or greater than 40%. While it might be argued that this is a rather large difference between the two methods, and that one would like to detect a smaller discrepancy than this, the study already requires about 400 observations each of 12 hours. It is felt that this sample size represents a reasonable compromise between what one might like to do and what one can afford to do. This sample size includes an additional 30% to allow exclusion of those children with a recurrent episode of diarrhoea, those with persistent diarrhoea, and loss to follow-up of children in Group A. Healthy day observations will be made only when the child is diarrhoea-free for a minimum of 7 days and without fever (<38°C) on the day of observation, which could affect fluid/food intake.

**Data entry and analysis**

Data will be single entered onto personal computers at the Matlab field station on a day to day basis, using the software package Fox Pro/DBase III. Range and consistency checks will be performed on a regular basis.

SAS and/or Epi-Info will be used to perform data analyses. Initially, simple one way tabulations of the data will be performed to provide a description of the study sample (age of children, age of mother, education of the mother, etc.). Group A will be compared with Group B with regard to these variables to identify whether the two groups differ in any important respects.

Objectives 1, 2 and 3 will be addressed by preparing summary tabulations (with confidence intervals or standard deviations) of observed practices surrounding fluid intake by the children. More detailed secondary analyses will examine how these practices vary according to the age, sex, etc.

Objective 4 will be addressed by comparing data from the "diarrhoea" observation with data from the "healthy" observation. Initially simple frequencies for practices and behaviours related to fluid intake during the diarrhoea and healthy observations will be examined. Formal statistical tests comparing the two observations will take account of the paired nature of the data (paired t-test, McNemar's test, etc.).

A comparison of observed with reported changes at the individual level (objective 5) will be based on the data from Group A. Initially the sensitivity and specificity of the caretaker’s ability to identify a change from usual intake will be determined using different cut-off levels of change in fluid intake between diarrhoea and healthy periods.

The Kappa statistic will be used to measure the degree of agreement between the two data
collection methods (observation versus questionnaire). At the population level, observation
data from Group A will be compared with questionnaire data from Group B. Proportions
of caretakers giving increased fluids will be calculated for each group and these proportions
compared. Formal statistical tests may be performed using the chi-squared statistic. The cut-
off point defining increased fluid will be derived from the data of fluid intake during the
healthy period and considering the appropriate amount of fluid to be consumed during
diarrhoea in different age groups. For example, 500ml. of ORT taken in 24 hours is
suggested as appropriate for children under 2 years of age to maintain hydration (21). The
daily variability in fluid intake which might be expected to occur normally will be assessed
using the data from the repeated observations in the pilot study and will be taken into
consideration.

A second phase of analysis will be the change in the caretaker’s and child’s behaviours
between the diarrhoeal and healthy observation days, and their relationship to fluid intake
for group A. For these analyses scores for caretaker’s feeding behaviour and child’s
acceptance of liquids will be developed and will be related to the feeding practices
concerning fluid intake and change in fluid intake with diarrhoea, similar to previously
described procedures (25). For these analysis consultant statistical assistance will be
necessary.

Ethical considerations

Informed consent will be obtained from the caretaker of each child prior to inclusion in the
study (see attached consent form). To observe an episode of illness for a certain period of
time may create ethical problems if the clinical picture of the diarrhoea deteriorates quickly.
Therefore, if at any time during the observation the child develops moderate dehydration,
s/he will be excluded from the study. The workers will be trained at Matlab diarrhoea
treatment centre to recognize dehydration according to WHO guidelines [22], and
appropriate measures (e.g. making ORS available and referral to health facilities) will be
taken when the child develops moderate dehydration.

Limitations of the study

We would like to validate the questions used by the CDD home management survey
concerning children’s fluid intake during diarrhoea. We cannot do this since we have no gold
standard measure with which to compare the performance of these questions. In place of
a gold standard we plan to observe children on two occasions, one with diarrhoea and one
without, for periods of twelve hours. We shall use these data as a measure of fluid intake
during diarrhoea and "normal" fluid intake respectively. By observing from 6 am to 6 pm we
shall miss fluid intake that occurs during the night. Nevertheless, we are including frequency
of consuming fluids and breastmilk during the night prior to the observation, to obtain
information of night-time intake. If "normal" fluid intake between 6 am and 6 pm varies substantially from one day to the next any comparison with a one-day intake during a diarrhoea episode will be unreliable, and will render the interpretation of the study's results very difficult. We shall assess the day-to-day variability of fluid intakes during the course of the pilot study and take this into account in the definition of increased fluid intake.

Fluid intake may well vary over the course of a diarrhoea episode. For example, during the first few hours the caretaker may not react to the diarrhoea, but wait to see whether it develops or ceases [23]. It may be only later in the course of the episode that she tries to increase the fluid intake of the child. Our observations will be performed the day after the identification of a new episode; ie starting between about 24 and 48 hours after the beginning of the episode. We do not know what proportion of caretakers wait longer than this before reacting to the episode. However, we believe that many caretakers will have begun to react to the child's illness by this time. Waiting until the third day (48 hours to 72 hours after the start of the episode) might cause us to "miss" many episodes; ie the episode might have finished before the observation begins.

In addition to the problem of "normal" variability in fluid intakes, we face the problem of trying to quantify fluid intakes. We would like to measure as accurately as is practical the actual fluid intake of children. We do not intend to use weighing to measure fluid intake but shall instead ask fieldworkers to estimate volumes of fluids consumed by the child. Clearly this will lead to some inaccuracies which may reduce the ability of the study to detect changes in fluid intake. Nevertheless, we feel that weighing is a much more "invasive" procedure and may affect caretakers' behaviour more than the presence of an observer who estimates fluid intake visually. These observation techniques have been used successfully in other studies (18), (personal communications: E. Hurtado, H. Creed).

This last point raises another limitation of the study, which is that the presence of the observer may alter the behaviour of the caretaker. We shall try to assess whether this is a major problem by performing repeat measurements during the pilot study and by discussing with these mothers afterwards whether they felt the presence of the observer altered their behaviour.

Finally we shall be observing only children with mild or no dehydration. Thus the findings of the study may only be applicable to mild (Type A) diarrhoea.

Timetable

Month 0 - 2  Staff recruitment
Preparatory phase - development of questionnaire and instruments
Small ethnographic study

Months 2 - 4.5  Training, pilot, testing & review of questionnaire and observation forms
Months 4.5 - 11.5  Main period of data collection, data entry and verification

Months 11.5 - 18  Data analyses and report writing

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<th>Work schedule for fieldworkers</th>
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<tr>
<td><strong>Week</strong></td>
</tr>
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</table>
Week 4 follows the pattern of week 3. After 4 weeks, each pair of fieldworkers will between them have observed and interviewed 8 group A caretakers/children and interviewed 16 group B caretakers.
REFERENCES


## BUDGET

### Personnel and salary costs

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<th>Name</th>
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### Operating expenses

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<td>Equipment maintenance</td>
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<td>Data analysis</td>
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*Speed boat costs calculated on the basis of 400 hours 8 $15/hour, equivalent to about 2 hour/d during training, pre-testing and fieldwork.*
**Travel**

- 30 return trips Dhaka-Matlab (@ $60) | 1800
- Country boat fares (for fieldworker transport) | 3025

Sub-total, transport | 4825

**Other expenditures**

- Training costs | 500
- Printing of forms | 750

Sub-total, other expenditures | 1250

**Major equipment**

- 1 personal computer with dot matrix printer | 4000

Sub-total, major equipment | 4000

**Budget summary**

- Personnel costs | 50300
- Operating expenses | 11700
- Travel | 4825
- Other expenditures | 1250
- Major equipment | 4000

Grand total | 72075
CONSENT FORM (Group A)

Matlab hospital treats many children coming with diarrhoea each day. We are trying to find out more about diarrhoea in children in order to prevent so many children suffering and dying in the future. Your child (name) has just begun to have diarrhoea. I would like to visit you tomorrow and spend the day watching the child, how s/he behaves, what s/he does. I do not wish to get in your way or stop you working, but simply to observe the child. If you agree I will come tomorrow, and then again in two weeks time, when the child is recovered, to watch the child. Afterwards someone else will come and ask you some questions about (name's) diarrhoea. If while I am here your child's condition gets worse, I will advise you about what should be done. All records will be kept confidential and there are no risks in this study. You are at liberty to withdraw your child from this study at anytime without any obligation and without jeopardizing your medical care at Matlab Treatment Centre. Would you be willing to help us in this work? Are there any questions that you would like to ask me about the work before you decide?

Signature of the interviewer
/observer

Signature or LTI of mother
/caretaker of the child
CONSENT FORM (Group B)

Matlab hospital treats many children coming with diarrhoea each day. We are trying to find out more about diarrhoea in children in order to prevent so many children suffering in the future. Your child (name) has had diarrhoea during the last two weeks and I would like to ask you some questions about your child’s diarrhoea. Your answers will be kept strictly confidential. Would you be willing to spend some time answering my questions? Are there any questions that you would like to ask me about the work before you decide?

If you are willing to participate in the study, then please sign your name or give left thumb impression below.

Signature of the interviewer /observer

Signature or LTI of mother /caretaker of the child

Date__________________
সামাজিকতা
( প্রণয় „এ”)

সামাজিকতা হলো শব্দাদিত্বের প্রতিদিন অনুষ্ঠান যেখানে শব্দ সিদ্ধির দিকে আসা হয়। তবিতে অনুষ্ঠান এর প্রতিদিন যে সুখ অনুভূতির মধ্য অস্ত্র সিদ্ধির সাক্ষরকে আরও বন্ধনী (কেন করা) অস্ত্র সিদ্ধির (নাম) তদন্তে অনুষ্ঠান সুখ হয়। অনন্য অস্ত্র গুরুত্ব অবহেলায় আসে এবং তদন্তে অস্ত্র সিদ্ধির সাক্ষরকে কি কি করে। অনন্য অস্ত্র দিনের কাজ কোনো স্থায়ীত্ব লাগে না। অনন্য অস্ত্রের প্রতিদিন কী করা। অনন্য যদি দিনের সাক্ষরকে অনন্য অস্ত্র গুরুত্ব অবহেলায় আসে এবং তদন্তে অস্ত্র সিদ্ধির সাক্ষরকে কি কি করে। অনন্য অস্ত্র দিনের কাজ কোনো স্থায়ীত্ব লাগে না। অনন্য অস্ত্রের প্রতিদিন কী করা। অনন্য যদি দিনের সাক্ষরকে অনন্য অস্ত্র গুরুত্ব অবহেলায় আসে এবং তদন্তে অস্ত্র সিদ্ধির সাক্ষরকে কি কি করে। অনন্য অস্ত্রের প্রতিদিন কী করা। অনন্য যদি দিনের সাক্ষরকে অনন্য অস্ত্র গুরুত্ব অবহেলায় আসে এবং তদন্তে অস্ত্র সিদ্ধির সাক্ষরকে কি কি করে। অনন্য অস্ত্রের প্রতিদিন কী করা। অনন্য যদি দিনের সাক্ষরকে অনন্য অস্ত্র গুরুত্ব অবহেলায় আসে এবং তদন্তে অস্ত্র সিদ্ধির সাক্ষরকে কি কি করে। অনন্য অস্ত্রের প্রতিদিন কী করা। অনন্য যদি দিনের সাক্ষরকে অনন্য অস্ত্র গুরুত্ব অবহেলায় আসে এবং তদন্তে অস্ত্র সিদ্ধির সাক্ষরকে কি কি করে। অনন্য অস্ত্রের প্রতিদিন কী করা। অনন্য যদি দিনের সাক্ষরকে অনন্য অস্ত্র গুরুত্ব অবহেলায় আসে এবং তদন্তে অস্ত্র সিদ্ধির সাক্ষরকে কি কি করে। অনন্য অস্ত্রের প্রতিদিন কী করা। অনন্য যদি দিনের সাক্ষরকে অনন্য অস্ত্র গুরুত্ব অবহেলায় আসে এবং তদন্তে অস্ত্র সিদ্ধির সাক্ষরকে কি কি করে।
বিশ্বাস রাখা হবে অনিবার্যতা রয়েছে বলে নিশ্চিত করা হয়। অনিবার্য হল এমন সব কিছু যার অবস্থার ছোট ছোট দৃষ্টিতে অদ্ভুত সৃষ্টি। একে পরামর্শের মাধ্যমে অনিবার্য হল অন্য কোনো কিছুর অবস্থার ভিত্তি।

এই দৃষ্টিতে আমরা বলি যে, আমাদের কাজ ও অবস্থার সাথে সাথে অনিবার্য সম্পর্কিত মন্তব্য করা যেতে পারে।

আমরা করে যে সমস্যার কারণে আমাদের প্রতিদিন চাপ ভাঙা হয়। তবে এটি অনিবার্য সমস্যা হলো না। তবে আমাদের জন্য আমরা প্রতিদিন কী করব তা স্পষ্ট করা যেতে পারে।

আমরা নিশ্চিত করে যে, আমরা আমাদের কাজ ও কল্যাণের জন্য সাবধান থাকি। তবে এটি অনিবার্য সমস্যা হল।

আমরা বলি যে, আমাদের কাজ ও কল্যাণ গড়ে তোলার জন্য আমরা প্রতিদিন চাপ ভাঙার চেষ্টা করি।


dated: ____________________

endorsement: ____________________

signature: ____________________
Appendix 1

Procedure for the estimating of fluid intake and standardization of field workers.

The process for the estimation of fluid intake and the necessary steps for the training of the field workers are outlined. The assistance of a nutritionist will be sought for this phase.

1. List of liquids and food preparations.

From the initial, pilot observations a list of all the fluid and semi-solid food items given to small children will be compiled. They will be coded according to type of preparation.

For example:

<table>
<thead>
<tr>
<th>Description</th>
<th>Code</th>
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</thead>
<tbody>
<tr>
<td>pure water</td>
<td>01</td>
</tr>
<tr>
<td>water with sugar</td>
<td>02</td>
</tr>
<tr>
<td>milk</td>
<td>03</td>
</tr>
<tr>
<td>lobon-gur</td>
<td>04</td>
</tr>
<tr>
<td>ORS</td>
<td>05</td>
</tr>
<tr>
<td>rice gruel</td>
<td>06</td>
</tr>
<tr>
<td>rice gruel w. milk</td>
<td>07</td>
</tr>
<tr>
<td>dal, thin</td>
<td>08</td>
</tr>
<tr>
<td>dal, thick</td>
<td>09</td>
</tr>
<tr>
<td>soup</td>
<td>10</td>
</tr>
<tr>
<td>vegetable curry</td>
<td>11</td>
</tr>
<tr>
<td>etc.</td>
<td></td>
</tr>
</tbody>
</table>

2. Definition of consistency.

Each of the different preparations will be coded according to consistency: liquid, liquid with solid pieces, semi-solid, solid.

Different preparations will be prepared and their observed consistency defined between the supervisor and PIs and standardized between the field workers.

3. Estimation of liquid content of the liquid-containing foods.

This will be done by measuring the liquid content of the different preparations by weighing each food and liquid ingredient during preparation and final prepared or cooked weight with a group of mothers in their homes. Approximately 5 of each of
the preparations will be measured depending on the degree of variation found. Ingredients will not be given to the mother as this may influence the consistency of the food she prepares. From this information factors for the liquid content of the different preparations will be calculated.

For preparations of the different consistencies the following criteria for calculating the proportion of liquid in the preparation, and from this developing factors to facilitate the extrapolation of liquid content for each of the preparations, will be applied:

a) **Liquid** preparations: considered as 100% liquid.

b) **Liquid with solid** preparations: after cooking the food preparation will be strained and the proportion of liquid to solid measured by weighing. From the range of liquid content measured the mean proportion of liquid will be calculated, giving a factor for the estimation of liquid for each type of preparation. If different consistencies are found for a specific type of preparation, these will be classified as "thick" or "thin", and respective factors developed.

c) **Semi-solid** preparations, such as rice powder-milk recipes: the different ingredients will be weighed as the mothers cook the preparation and the final cooked weight measured and the liquid content calculated. Means will be calculated to arrive at the factors for estimation of fluid content of each of the preparations.

d) **Solid** preparations: although solid food preparations contain liquid, this will not be considered for the purpose of this study which focuses on the increase in fluid intake during diarrhoea.

4. List of local utensils.

All local feeding utensils used for small children will be collected and will be listed and named.

For example:
- large cup
- small cup
- large glass
- small glass
- mollusk shell
- large spoon
- desert spoon
- teaspoon
- large dish
- small dish
etc.
The definition of the different sized utensils will be standardized between field workers.

5. Estimation of portion sizes.

Different portion sizes of liquid in the utensils will be measured through weighing. Repeated weighings will be made and means of the following portion sizes calculated. For the purposes of this study milli-litres = grammes.

For example:
large cup, full
large cup 1/2 full
large cup 1/4 full
desertspoonful
tea spoonful
mollusc shell
small dish full
small dish 1/2 full
small dish 1/4 full
etc.

ml/gm.

Familiarization of portion sizes and the estimation of their volumes/weights for liquids and foods preparations will be done through the observing and handling of different portion sizes of known weight. Subsequently, the estimation of portion sizes will be standardized between field workers through repeated observations and estimations with group and individual exercises.


For combinations of solid and liquid foods, such as rice and dal, amounts of the liquid-containing food in the mixture will be measured in different portion servings through weighing. Estimation of these portion sizes by the field workers will be standardized.

7. Estimation of "fingerful" size portions.

Although emphasis will be given to fluid intake it is necessary to measure finger servings as semi-liquid foods are frequently given this way from a shared receptacle. Semi-solid and liquid with solid preparations that are given to the child by fingerfuls will be measured by weight and averaged and a standard weight applied. "Fingerful" sizes of the child who feeds him/herself will be measured for the different preparations and standardized similarly.
8. Practice sessions.

To gain practice in estimating amounts of liquids and food offered and consumed by the child, and to understand some of the circumstances that may present, imitation feeding episodes and role-playing between field workers will be conducted, followed by practice sessions in the homes. In this way standardization between field workers can be refined.


Final standardization will be conducted on an individual basis. Correlations between estimated and actual weights for different portion sizes will be calculated for each field worker.
Child fluids during diarrhoea

Identification

1.1 Study number: ____________

1.2 Date of interview: (dd/mm/yy) ____________

1.3 Time of interview: (hh:mm) ____________ : ____________

1.4 Name and number of interviewer: ______________________

1.5 Child's name: ______________________

1.6 Child's CID number: ____________

1.7 Child's date of birth: (dd/mm/yy)

1.8 Child's age in months: ____________

1.9 Child's sex: ____________

1.10 Caretaker's name: ______________________

1.11 Caretaker's CID number: ____________

1.12 Caretaker's age in years: ____________

1.13 Caretaker's relationship to the child: biologic mother/other

Information on household

2.1 Number of persons in the household:

2.2 Number of children aged less than 5 years:

2.3 Age of youngest child:

2.4 Occupation of head of household:

2.5 Occupation of caretaker:

2.6 Education of caretaker:

2.7 How many surviving children does the caretaker have:

Diarrhoea episode

3.1 Has the child had diarrhoea at any time during the last two weeks?

3.2 When did the diarrhoea start?
3.3 When did the diarrhoea stop?

3.4 What is/was the name (in Bangla) of the diarrhoea?

3.5 What is/was the type of the child's stools?

3.6 Maximum no. (approx.) of stools on the worst day of diarrhoea:

3.7 What other signs/symptoms are/were associated with the diarrhoea?

**Standard WHO questions**

4.1 During (name's) diarrhoea did you give (name) much less, somewhat less, about the same, or more total fluids (including breastmilk and formula) than usual?

much less, somewhat less, about the same, more, don't know

4.2 During (name's) diarrhoea did (name) drink much less, somewhat less, about the same, or more total fluids (including breast milk and formula) than usual?

much less, somewhat less, about the same, more, don't know

4.3 Does (name) take solid or semi-solid food?

yes, no

4.4 During (name's) diarrhoea did (name) eat much less, somewhat less, about the same, or more food (including breast milk and formula) than usual?

much less, somewhat less, about the same, more, don't know

4.5 During the diarrhoea, how many times a day and night did you try to feed (name)?

4.6 During the diarrhoea did (name) drink:

plain water
lobon gur
sugar salt solution
ORS solution
breast milk
other milk
coconut water
sugar water
lotha
chirra
other fluids
4.7 If the child drank ORS,
Who advised you to give ORS to (name)?
Where did you obtain/purchase the ORS?
How did you prepare the ORS

4.8 If the caretaker has given a recommended home fluid, does she know how to prepare it correctly?

lobon gur yes, no
SSS yes, no

4.9 Was (name) given any drugs for diarrhoea?
yes, no

If yes, list drugs with source:

........................................
........................................
........................................
........................................
........................................
........................................
........................................

4.10 When should you take a child with diarrhoea to a health worker or health facility? Do not prompt, tick all signs mentioned.

many watery stools, repeated vomiting, marked thirst, not eating/drinking well, fever, blood in stool, not getting better/getting sicker, other, don't know

Other =

4.11 When a child has diarrhoea should the child be given much less, somewhat less, about the same, or more fluids?
much less, somewhat less, about the same, more, don't know

4.12 When a child has diarrhoea should the child be given much less, somewhat less, about the same, or more foods?
much less, somewhat less, about the same, more, don't know
4.13 Since this time yesterday, has (name) been breast fed?  
(diarhoea in last 24 hours)  
yes, no

4.14 Since this time yesterday, did (name) receive:  
(diarhoea in last 24 hours)  
vitamins, mineral supplements, medicine  
plain water  
sugar water  
fruit juice  
tea or infusion  
ORS solution  
infant formula  
tinned, powdered or fresh milk  
coconut milk  
lobon gur  
lotha  
chirra  
other solid or semi-solid foods ..........................  
other fluids

4.15 Since this time yesterday did (name) drink anything from a  
bottle with a nipple/teat  
(diarhoea in last 24 hours)  
yes, no
Observation form

Identification

1.1 Study number: 

1.2 Date of observation: (dd/mm/yy) 

1.3 Time at start: (hh:mm) 

1.4 Time at end: (hh:mm) 

1.5 Name and number of interviewer: 

1.6 Child's name: 

1.7 Child's CID number: 

1.8 Child's date of birth: (dd/mm/yy) 

1.9 Child's age in months: 

1.10 Child's sex: 

1.11 Caretaker's name: 

1.12 Caretaker's CID number: 

1.13 Caretaker's age in years: 

1.14 Caretaker's relationship to the child: biologic mother/other 

1.15 Is the child: diarrhoeal or healthy 

1.16 Day of diarrhoeal episode /__/ 

1.17 Does the child have fever, yes=1, No=0 /__/ 

2.1 Appetite of the child
(To ask mother at the end of the day)
Food 
Breast milk
(increased=1, decreased=2 unchanged=3, unknown=9) 
Liquids 

2.2 Child receives breast milk, yes=1, no=0 /__/
2.3 No. of breast milk episodes witnessed /__/
   (no. of pages)

2.4 No. of feeding episodes witnessed /__/
   No. of forms (intake) /__/
   No. of forms (behaviour) /__/

3. Number of occasions on which child was observed to defaecate:

4. Number of occasions on which child was observed to vomit:

5. Number of occasions on which child could not be observed:
<table>
<thead>
<tr>
<th>Reason</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td></td>
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</tr>
<tr>
<td>Mother's activity</td>
<td></td>
<td></td>
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<tr>
<td>Child fell asleep</td>
<td></td>
<td></td>
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<tr>
<td>Termination of breastfeeding</td>
<td></td>
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<td></td>
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</tbody>
</table>

**Yes = 1 NO = 0**

<table>
<thead>
<tr>
<th>Immediate only to breastfeeding</th>
<th>Was child crying or asking</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

**I or 2 breasts given**

**Total time breastfeeding**

**Minutes child not breastfeeding**

**Duration**

**Time of end hh:mm**

**Time of start hh:mm**

**D/F: episode**

**Observations**

**Child name**

**Date**

**Form no.**

**Page no.**

**Study no.**
### Feeding Episode: Behaviour

<table>
<thead>
<tr>
<th>Study no.</th>
<th>Child's name</th>
<th>CID</th>
<th>Caretaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form no.</td>
<td>Observer's name</td>
<td>No.</td>
<td></td>
</tr>
<tr>
<td>Page no.</td>
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<td></td>
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<tr>
<td>Date</td>
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</tbody>
</table>

**Feeding episode**
- Time of start **hh/mm**
- Time of end **hh/mm**
- Duration **hh/mm**

### Observations

<table>
<thead>
<tr>
<th>1. Liquid or food/preparation Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2. No.</td>
<td></td>
</tr>
<tr>
<td>3. Order of serving</td>
<td></td>
</tr>
<tr>
<td>4. Did child appear to be hungry/thirsty? 1=much/normal 2=sometimes 3=never</td>
<td></td>
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<tr>
<td>5. Did caretaker physically help the child to eat? 1=most of time 2=sometimes 3=never</td>
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<td>6. Did caretaker encourage verbally or by action? 1=most of the time 2=sometimes 3=never</td>
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<tr>
<td>7. Did caretaker pressure the child verbally or by action? 1=most of the time 2=sometimes 3=never</td>
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<tr>
<td>8. Did caretaker physically force child to drink/eat? 1=most of time 2=sometimes 3=never</td>
<td></td>
</tr>
</tbody>
</table>

9. Did child appear to prefer any liquids or foods?
   a. 1 = Yes 0 = No
   b. If so, which

10. Did child refuse any liquids or foods?
    a. 1 = Yes 0 = No
    b. If yes, which?
    c. Did caretaker insist in giving it? 1 = Yes 0 = No

11. Was feeding interrupted to give breast-milk? 1 = Yes 0 = No

12. No minor caretaker physically present with child during feeding episode

13. Location of child during feeding
    1 = Ground 2 = Seat 3 = Lap 4 = Other

14. Who terminated feeding episode?
    1 = Child 2 = Mother 3 = Other
    Reason: ____________________________

15. Child activity level during feeding
    1 = Active 2 = Irritable 3 = Sleepy

16. a. Other Family Members present during feeding?
    1 = Grandmother 2 = Father 3 = Sibling 4 = Other 5 = None

    b. Attitude of family members to child feeding:
    1 = Encourage 2 = Indifferent 3 = Interrupt
**FEEDING EPISODES: NIGHT RECALL**

<table>
<thead>
<tr>
<th>Feeding episode</th>
<th>Food/liquor Provision Name</th>
<th>Code</th>
<th>Consistency Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
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</table>
**CHILD'S DEFECATION**

<table>
<thead>
<tr>
<th>Episode</th>
<th>Time</th>
<th>Place</th>
<th>Consist</th>
<th>Blood</th>
<th>Nucus</th>
<th>Remarks</th>
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**CHILD'S VOMITING**

<table>
<thead>
<tr>
<th>No</th>
<th>Time</th>
<th>After fluid/food intake No=0, Y=1</th>
<th>Time after (min)</th>
<th>After which fluid/food</th>
<th>Remarks</th>
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UNOBSERVABLE

5.1 Child became unobservable at what time:

5.2 Why was child not observable: ........................................

5.3 Observation resumed at what time:

5.4 Were you able to ascertain whether the child had drunk/eaten anything during this period

no/yes .................................................................

5.5 Other remarks: ...........................................................

.................................................................
Re: K. Zaman proposal

This is a response to your request for comments on the revised proposal for the foods and fluids study in Matlab, Bangladesh.

Compared to the previous draft, I think the study is much stronger than it was before the consultancies of Simon Cousins and Hilary Creed.

The present proposal has two phases of a pilot study, which are labelled "Pilot study 1" and "Pilot study 2." These are actually a mixed bag, consisting of three distinctly different components, which are not yet clearly separated and conceptualized. The three components are:

1. An ethnographic study to describe distinctions on the part of the caretakers, between fluids and foods - for which no clear methodology is proposed.

2. Further developmental work on the instruments and "training and standardization of field workers"

3. A study to "Explore intra- and inter-child variability in types and amount of fluid intake, with small samples of 10 healthy children and 10 children with diarrhoea."

The first component is not actually a pilot study, but a linguistic anthropological (ethnographic) study. It is certainly an essential study for the interpretation of the study results, and, if properly structured, it also has the potential to be generalizable to other populations.

The second component is not strictly-speaking a pilot study, but a preparation phase for the study, particularly as it includes training a full staff of field workers.

The third component is the pilot study, in which the investigators conduct a small-scale version of the full study from recruitment of subjects through analysis. This is obviously an important component as it permits a review of areas of problems prior to the large-scale enterprise.

One feature of the pilot that I question is why it is necessary to conduct the observations for 3 days, which has been selected because it is the mean duration of an episode. On one hand, there is good reason to hypothesize that both food and fluid behaviour (giving and taking) and reporting about this behaviour are affected by when in the episode the observation or questioning occurs. But it is not clear how the pilot phase data will be used for decisions about the design of the larger study or the analysis of data. The sample is too small to support generalizations about how much behaviour changes over the course of the three days, and the pilot is not examining how reporting about behaviour is affected by day of episode in which the questioning takes place.

Given the strong likelihood that "day of episode" affects both behaviour and reporting, the best way to handle the behaviour part of the problem is by working hard to ensure that all cases in the observation group are really new episodes ("watery diarrhoea starting in the last 24 hours"). While this solution is vital to ensure comparability in the observations, it still does not address the problem of the effect of "day of episode" or "time since episode began" on validity.
of caretaker reports (see below).

The linguistic ethnography

All surveys that ask people to report on past behaviour have to cope with two types of problems: (1) Do the respondents understand the questions in the same way that the framers of the question intend? and (2) Do the respondents' answers correspond to the "reality" that they are reporting on.

The revised household survey questions add two more elements of complexity because the caretakers are requested not only to report about their own behaviour, but also about someone else's behaviour (i.e., the child's ingestion behaviour) and then to report on their perceptions of that specific recent behaviour compared to a perceived standard of "usual."

The respondent has to effectively process the following:

(1) What does the interviewer want to know?

(2) What did I do? (at some recent point in the past, varying from now to 2 weeks ago)

(3) What did the baby/child do? (at some recent point in the past, varying from now to 2 weeks ago)

(4) What did the baby do compared to what the baby usually does?

These are not simple questions. They require quite complicated cognitive assessments from the caretaker. Errors in any part of this sequence result in invalid data for that individual.

The first challenge, before assessing the validity of questions 2-4 (above) is to get item 1 "right." This requires careful linguistic work to get the denotative meanings of all the relevant nouns and verbs -- "receive," "give," "drink," "take," "fluids," etc. If these are correct, the caretaker presumably understands what the interviewer wants to know.

This is not a difficult task, nor one that takes a lot of time, provided that one knows the techniques and has the skills for collecting the data, (including proper verification techniques,) and analysing the results. The results then have to be used to frame the specific questions so that misunderstanding or misinterpretation is minimized.

This study is essential to the project. It does not require interviewing mothers of children with diarrhoea but it does require more than one informant, in order to verify the linguistic distinctions. Once the denotative meanings have been established for the Bangla dialect spoken in Matlab, the specific phrasing of the questions in the interview schedule will be established.

There are other issues concerning the interview schedule that need to be resolved before the pilot study, and which also need attention from an anthropologist:

In the present version of the interview schedule, the questions about what a caretaker "should do" are asked before the questions on what she actually did. This is not the correct
sequence. The specific problem of placement of questions can be easily corrected, but its occurrence reveals that the investigators are not experienced in questionnaire construction.

There are other problems in sequencing that need to be straightened out. The present format requires the mother to deal sequentially with following requests:

(1) "[child] has been breastfed" (This is a passive construction, linguistically, that focuses attention on the child but requests information on what the mother did), then;

(2) "did he/she receive" [specific list of liquids and solids] (This is an active construction that asks the mother to report on her own behaviour or that of another caregiver) then;

(3) "did he/she drink" [from bottle] (This is a a report on what the child did) then;

(4) "did you give him/her... fluids" (This introduces a new concept and asks mother first to recall her recent action, compare it to her usual past actions and then express this to the interviewer), then;

(5) "did he/she drink ... total fluids" (This asks the mother to report on the child's actions compared to her perceptions of child's past actions) then...

And so on, alternating actions and perceptions in a fashion that is likely to be quite confusing for the caretaker.

Given that the ultimate goal of the study is to provide answers to the question of how valid caretakers reports are, there is another design question that needs further attention. This is the issue of when the Group B sample are interviewed. The investigators acknowledge that the Group B sample is not comparable to the Group A sample in that the time lapse between the events being reported on varies from current (no time lapse) to 14 days in Group B, whereas the Group A sample are always interviewed 16 days after the episode and 24 hours after a day-long observation. This is a serious problem because there is a sizeable body of literature on the effects of time on recall. In the CDR household survey the assumption is that these differences are randomized out; that is, the approximately equal numbers are reporting on events that were 1, 2, 3, 4, ... up to 14 days ago. While that may be reasonably defensible in the survey, it casts real doubt on the validity of the Group A/Group B comparison because the two groups are so different on a variable (time since the event) that is known to affect reporting.

The problem isn't solved by using Group B responses to predict Group A behaviour unless the analysis is done separately for sub-samples, grouped into categories of "days since the start of the episode."

Alternatively, the size of the Group B sample could be substantially reduced and children with diarrhoea starting in the last 24 hours could be alternately assigned to "observation" and "control" and all caretaker "post episode" (PE) interviews be conducted at 16 days PE. The rationale for sample size calculation (p. 13) emphasizes the Group A versus Group B comparison, rather than "actual" versus "reported" behaviour (which is the central point of the study) and, more importantly, does not take into account the effect of time on reporting of behaviour.
"Children's fluid intake during diarrhoea: a comparison of questionnaire response with data from observation"

Thank you for sending me the revised version of this project. The protocol is excellently presented and I fully support the application. The additional preparation undertaken during the visit by Hilary Creed de Kanashiro has been very valuable in developing many of the key measurement and other fieldwork issues and it is good to see these so clearly laid out. I am happy that issues raised in previous reviews have been addressed. The study looks well set to provide answers to some important research issues for CDD.

A couple of minor comments. Firstly, as clearly stated in Hilary's trip report and in the proposal, the study will require quite substantial consultancy input (either local or external). Inputs from an anthropologist, nutritionist and data analyst are all necessary and it is important that appropriate personnel are identified and do not delay the initiation and conduct of the study. They have not been budgeted for, will WHO be providing these costs separately? Secondly, and I'm sure this will be resolved in instrument development, the draft questionnaire appears to ask questions of diarrhoea within the previous 24 hours whereas I thought it was meant to refer to the previous two weeks.

Please let me know if you have any queries. I look forward to the outcomes of this study.

Very best wishes
I am happy to see this proposal in its much improved form and I think the research is important for CDD programs. It is obvious that the consultant visit was extremely helpful to the investigators and her report was quite informative. I have a few comments and concerns and some suggestions:

1. I remain confused about the comparison groups. As I see it, the comparisons are these:

a) observational data during "health" (day 15, group A) with questionnaire data during "health" (day 16, group A)

b) questionnaire data during diarrhea (day 1, Group B) with observational data during diarrhea (day 2, Group A)

c) questionnaire data during diarrhea (day 1, group B) with questionnaire data during health (day 16, group A)

Unless I'm missing something (and this is definitely possible), there are no individual comparisons (comparing questionnaire data with observational data on the same children during diarrhea). I thought that this was the objective of the research. The only comparative data during diarrhea to assess differences in method (observation vs. questionnaire recall) are among different children on different days of a diarrhea episode. The present plan allows for a nice comparison of quantified intakes and behaviors among the same children during diarrhea episodes compared to "subsequent health", but this is not the main objective of the study -- and this work has been done elsewhere with published results, as noted by the investigators in their references. Although the sample size is relatively large, I am a bit concerned about extrapolating from group comparison data of different children (group a, day 2 and group b, day 1) as the test of the key research question. Perhaps this analytical strategy could be justified further?

I would prefer to see a comparison of questionnaire data and observational data on the same children for the same day, during diarrhea. Obviously, the fieldworkers would need to be different and the questionnaire data would need to be collected the following morning after the observational study. I would be quite interested to understand why the study was not designed this way. Is it because the investigators were worried that caretaker responses would be biased or untruthful due to the intensive observational day of study? If so, a way to check on this might be to randomize whether Group A receives a questionnaire on day 1 (enrollment) or day 3 (after the observational study) and to compare these against the observational data. This is just a suggestion and I really would be interested to understand in more detail the justification for the present design.

Another concern is the description of training and standardization of the fieldworkers for conducting the
Observational data collection. Having standardized similar instruments among 5-6 data collectors, I know that this is a real challenge and requires a systematic plan. For example, for each item observed, it is necessary to have inter-observer agreement of at least 80%. This means that paired observations must be done among the 10 data collectors (randomized pairs) and assessments made of problems with the operational definitions and codes of each item as well as difficulties of specific workers in reaching agreement. This step is absolutely critical and is further complicated by the need for the workers to be trained in quantified, observational measures of foods and fluids in addition to the infant and maternal behaviors. I suggest that the investigators review the manual on structured observations by Bentley et al that details these steps. I agree with the consultant that anthropological and nutritional technical assistance will be required during the training and for follow-up.

I agree that the results of this study may be limited because of the rather "mild" episodes of diarrhea that it is selecting for, due to ethical exclusion of more severe symptoms/episodes. Although understandable, it is likely that caretaker behaviors will not change to any great extent during diarrhea, compared to "health". This will limit the investigation of research objectives 1-4.

I enjoyed reviewing this proposal and support its funding. My comments are suggestions only and I believe that the research should go forward.
RESPONSE TO EXTERNAL REVIEWERS' COMMENTS

Response to external reviewer No. 1 (responses in order of the reviewers points):

We agree with the reviewers comments that all the preparatory works (training, standardization, small ethnographic study etc) before the actual phase of data collection are not regarded as the pilot phase. Accordingly, we have now divided it into preparatory and pilot phase. The objective of the pilot phase of the study is to explore the intra and inter-child variability in types and amounts of fluid intake among ten diarrhoeal and ten healthy children over three days.

As already mentioned the idea of the pilot study is to have an idea about the variability of fluid intake during diarrhoea and healthy periods. The data collected is not intended for decisions about the design of the larger study or making plan for the analysis. If the fluid intake varies substantially from one day to the next any comparison with a one day intake data may not be ideal. We considered this as a limitation of our study. However, we will ensure that those will be included in the observation group (group A) will have watery diarrhoea starting in the last 24 hours. Assistance from an anthropologist and nutritionist will be sought during training, standardization of the questionnaire and also in the pilot phase. Suitable techniques and skills for data collection will be developed.

As per suggestion of the reviewers the sequence of questions to be asked to caretakers has been modified in the questionnaire section.

We mentioned in the protocol that one subgroup analysis will be done to explore any effect of the differences in recall time. More sub groups analysis can also be made.

We have increased the sample size in group B since we thought that the administration of questionnaire (group B) to the mothers/caretakers can be performed easily. This increase also reduced the numbers of lengthy 12 hour observations in group A (in calculating sample size). WHO standard survey questionnaire also asks mothers/caretakers of their children with diarrhoea in the last two weeks.
RESPONSE TO EXTERNAL REVIEWERS' COMMENTS

Response to external reviewer No. 2 (responses in order of the reviewers points):

We have identified Drs. Sandra Laston and D.S. Alam from ICDDR,B as anthropologist and nutritionist respectively. They will assist during training, standardization of questionnaire and in piloting of the study. Some assistance from a Senior programmer level from ICDDR,B will be sought during analysis of the data.

The draft questionnaire contains questions about diarrhea occurring in the past 24 hours as well as in the last 2 weeks.
RESPONSE TO EXTERNAL REVIEWERS' COMMENTS

Response to external reviewer No. 3 (responses in order of the reviewers points):

The following comparisons will be made:

1. Individual level - A comparison of the observed with the reported changes in fluid intake (using data from Group A).

2. Population level - Observation data from group A will be compared with the questionnaire data from group B.

3. Proportions of caretakers reporting increased fluid intake will be compared between group A and group B. This will enable us an evaluation of the possible observation bias or "contamination" effect or effect due to differences in recall periods.

The study has been designed in such a way that there is no scope to see a comparison of questionnaire data and observational data on the same children for the same day. We thought that with this design (proposed design by the reviewer) there will be more chances of "contamination" effect of long 12 hours observation on the following day questionnaire. It may also have contamination effect of questionnaire on the following day observation (during diarrhoeal episode). Above all the design will be more complicated. We are also planning to have questionnaire by a separate group of workers.

We agree with the reviewers of the difficulties in standardizing our instruments. For this assistance would be sought from an experienced anthropologist and a nutritionist.
Dear Dr. Zaman,

We have now received from our external reviewers their comments and recommendations on your revised proposal for the study entitled:

"Children’s fluid intake during diarrhoea: A comparison of questionnaire response with data from observation"

We are pleased to inform you that the reviewers agreed to the importance of the proposed work and felt that significant improvements had been made in its design and specification of the procedures. The reviewers were, nonetheless, concerned about the complexity of the study and the need for additional technical support to the study team in order to ensure the successful achievement of the study's objectives. Of particular concern were that

(i) an anthropologist and a nutritionist be identified within ICDDR,B to participate actively in the implementation of the project, and

(ii) the results of the pilot studies 1 and 2 be reviewed by WHO and its advisers before agreement is confirmed to fund the remainder of the study.

We attach, for your use, extracts from the reviewers' comments and suggestions.

ENCLS.

cc: Director ICDDR,B
In addition, we recommend:

- a careful review and definition of the terms used in the protocol related to foods and fluids: offer and give, for example, are used as synonyms and the same appears to happen with receive/consume/drink (this is particularly noticeable in the sections entitled "research questions", "general objectives" and "specific objectives");

- the revision of the proposal's questionnaire ("Standard WHO Questions") to bring it into line with the most recent version of the Household Survey questionnaire, as the questions differ slightly from it (a copy of the current version of the Survey is attached);

- that information be collected on the number of liquid and watery stools when gathering data on diarrhoea, as this will allow an assessment of the severity of the episodes.

We look forward to receiving from you the following information:

(i) the study budget identifying separately the expenditures for the pilot studies 1 and 2 and the main study,

(ii) the assurance from the ICDDR,B of the active participation of an anthropologist and a nutritionist in the implementation of the study (and their identification) and

(iii) the national and institutional ethical clearances for the study.

The information will be reviewed as soon as it is received. If satisfactory, and provided that the required ethical and administrative clearances are received within WHO, a technical services agreement will be drawn for the implementation of pilot studies 1 and 2 and sent for your consideration and signature.

We look forward to hearing from you.

Yours sincerely,

[Handwritten Signature]

Dr J. Martines
Chairperson, Prevention Working Group
Division of Diarrhoeal and Acute Respiratory Disease Control