Attachment 1. 66

Date 25-1-87

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator FARUQUE AHMED

Application No. 87002

Title of Study PROSPECTIVE STUDY OF RISK FACTORS FOR THE OCCURRENCE AND CLINICAL SEQUELAE OF SHIGELLOSIS IN RURAL BANGLADESHI CHILDREN.

Trainee Investigator (if any) X

Supporting Agency (if Non-ICDDR,B) ① ICDDR,B SHIGELLA PROJECT ② W.H.O

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

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

1. Source of Population:
   (a) Ill subjects — (Yes) No
   (b) Non-ill subjects — (Yes) No
   (c) Minors or persons under guardianship — (Yes) No
2. Does the study involve:
   (a) Physical risks to the subjects — Yes (No)
   (b) Social Risks — Yes (No)
   (c) Psychological risks to subjects — Yes (No)
   (d) Discomfort to subjects — (Yes) No
   (e) Invasion of privacy — Yes (No)
   (f) Disclosure of information damaging to subject or others — Yes (No)
3. Does the study involve:
   (a) Use of records, (hospital, medical, death, birth or other) — (Yes) No
   (b) Use of fetal tissue or abortus — Yes (No)
   (c) Use of organs or body fluids — (Yes) No
4. Are subjects clearly informed about:
   (a) Nature and purposes of study — (Yes) No
   (b) Procedures to be followed including alternatives used — (Yes) No
   (c) Physical risks — (Yes) No
   (d) Sensitive questions — (Yes) No
   (e) Benefits to be derived — (Yes) No
   (f) Right to refuse to participate or to withdraw from study — (Yes) No
   (g) Confidential handling of data — (Yes) No
   (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure — N.A. Yes No
5. Will signed consent form be required:
   (a) From subjects — (Yes) No
   (b) From parent or guardian (if subjects are minors) — (Yes) No
6. Will precautions be taken to protect anonymity of subjects — (Yes) No
7. Check documents being submitted herewith to Committee:
   ___ Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).
   ✓ Protocol (Required)
   ✓ Abstract Summary (Required)
   ✓ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)
   ✓ Informed consent form for subjects
   ✓ Informed consent form for parent or guardian
   ✓ Procedure for maintaining confidentiality
   ✓ Questionnaire or interview schedule *

* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:
1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific questions to be asked in the sensitive areas.
3. An indication as to when the questionnaire will be presented to the Cttee. for review.

(PTO)

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

Faruque Ahmed
Principal Investigator

Trainee

87-002
23/11/87

SECTION - I : RESEARCH PROTOCOL

1. Title: Prospective study of risk factors for the occurrence and clinical sequelae of shigellosis in rural Bangladeshi children.

2. Principal Investigator: Faruque Ahmed

   Co-Investigators: J.D. Clemens, D.A. Sack, B.F. Stanton, M.R. Khan, M.N. Huda, M. Rahman.

3. Starting Date: March 1, 1987.

4. Completion Date: December 31, 1989.

5. Total Direct Cost : US $ 375,837 10 months Taka.
   (Prospective funding:
   i) ICDDR'B Shigella project funding from USAID
   ii) W.H.O.)

6. Scientific Programme Head:

   This protocol has been approved by the Epidemiology and Laboratory Science Division

   Signature of the Scientific Programme Head: Daniel A Sack

   Date: 15 Jan 1987

7. Abstract Summary

Children 0 - 4 years of age who are close contacts of cases of symptomatic shigellosis will be followed on alternate days for a period of 10 days. The purpose will be to identify risk factors for developing symptomatic shigellosis among the contacts. After the end of this 10 days follow up, these children will be given weekly visits upto day 35 and then another visit on day 84 so as to assess the factors affecting the frequency of persistent diarrhoea and nutritional decline after Shigella infections. The study will take place in Matlab, which is a rural area in Bangladesh.

8. Reviews:

   i) Ethical Review Committee : _____

   ii) Research Review Committee: _____

   iii) Director: _____

SECTION - II : RESEARCH PLAN

A. INTRODUCTION

1. Objective : To evaluate selected risk factors which may influence the risk of symptomatic Shigellae infections as well as factors affecting the frequency of sequelae of the infections (nutritional decline, persistent diarrhoea) so that interventions into the prevention and management of these infections can be devised.

2. Background: Dysentery has long been clinically recognized (1). As few as 10-200 viable Shigella dysenteriae 1 organisms ingested by mouth can cause infection (2). The tiny infective dose , in turn, permits effective contact spread from host to host without the need for enrichment growth in some vehicle such as food or water. Shigellosis is an important disease responsible for high rates of morbidity and mortality. In a cohort study by Mata (3) of young children in the village of Santa Maria Cauque, Guatemala, Shigella infections were common and were the most frequently identified enteric bacterial pathogen. Age specific prevalence rate in the 3rd year of life was about 20%. Incidence rates can also be calculated from the data, if the assumption is made that repeat isolation of a specific serotype following a culture-negative period of 2 weeks or more indicates a new infection; thus, the incidence rate was 1.9 episodes per child per year.

During the late 1960's, more than 8000 people died of shigellosis in Central American countries (4). In Guatemala, the fatatity due to shigellosis was 8.4% in villages and 10 to 15% in acute hospitalized cases (5).

In 1970, only 0.6% of the indoor patients yielded Shigella as a pathogen in the CRL (now ICDDR,B) hospital in Dhaka, Bangladesh; the rate increased to 9% in 1972 and 14% in 1973, and continued to increase at an extremely high rate, to reach a peak in 1974 when nearly 20% of the patients yielded positive diagnosis of shigellosis (6). A high rate of isolation of Shigellae was maintained thereafter, despite considerable fluctuation from one season to another (7). During 1979-1980, 12% of all patients attending the ICDDR,B Dhaka facilities were suffering from shigellosis (8). 82% of hospitalized shigellosis cases in Dhaka were aged less than 5 years, and 37% of all cases were infants less than one (9) Shigellae were most commonly isolated from children aged 1-4 years in the Matlab hospital of ICDDR,B (10).

Epidemiologic investigations carried out showed that children were the main victims of secondary infections after the disease was introduced into the family (11). The secondary infection rate due to S. Dysenteriae type 1 was found to be 29%, and in S. Flexneri it was 24%. Investigation in the St. Martin island epidemic showed an

overall attack rate of 33%, highest (53%) being in the age group 1-4 years (12). In a longitudinal study in rural Bangladesh, Shigellae were the second most frequent aetiologic agent in children with diarrhoea (13).

Mortality in hospitalized shigellosis was extremely high, despite the availability of antibiotics, intravenous fluids, and other supporting measures (14). Our experience in Dhaka hospital showed a case - fatality of 10%, in contrast to <0.5% in cholera. During the St. Martin epidemic, it was noted that in the absence of effective therapy, the overall case fatality was 7% ; the highest, 41%, occurred in infants (12). Treatment of shigellosis is becoming more difficult as the resistance to antibiotics appears to be increasing (10,12,15,16)

Risk Factors for Shigellosis

There has been a large number of studies suggesting that breast-fed children experience less diarrhoeal morbidity than non-breast-fed children. These studies have recently been summarized by Feachem (17) . The prevention of diarrhoea by breast feeding appears to be maintained for the first year of life, but little or no protection is evident for breast-fed children who are over one year of age. Although controlled studies have shown an impact of breast-feeding upon the severity of shigellosis (19), no rigorous studies have addressed the impact of breast-feeding upon the incidence of shigellosis.

There is a link between weaning practices and diarrhoea (20). It is recommended that complementary foods should not be introduced to exclusively breast-fed infants before 4 months, nor delayed beyond the age of 6 months (40). However, no studies have addressed whether age of introduction of complementary foods influences the risk of shigellosis.

There is conflicting information regarding malnutrition. In data from Indian children in Guatemala, Delgado et al (58) found that nutritional status was a predictor of the incidence of simple diarrhoea or of diarrhoea with mucus and blood. However, Black et al (33) observed that the incidence of all diarrhoea or diarrhoea associated with Enterotoxigenic E. Coli or Shigella did not differ according to nutritional status in Bangladesh.

Numerous studies of diarrhoeal disease epidemiology, and investigations of diarrhoea outbreaks, comment on behavioural factors that may affect the pattern of spread. However, these comments are speculative and do not firmly associate specific behaviours with specific levels of risk (60). One of the behaviours mentioned is the poor hygienic practices of young children and those who care for them. The specific behaviours that have received most attention are water handling, food-handling and hand-washing.

Hospital studies suggest that enteric infections can spread via contaminated hands and that hands can be decontaminated by washing with soap and water or water only (21,25,27). However, no studies have addressed whether naturally occurring hand washing behaviour in the home or use of other procedures such as rubbing the hands with soil influence the risk of shigellosis. The only information available regarding hand washing and shigellosis is from an intervention study by Khan in Bangladesh, where it is shown that the use of soap and water lowered the secondary case rate, among family contacts of shigellosis cases, by 84% (26).

There is an association between measles and diarrhoea. The aetiology of these measles-associated diarrhoeas is unknown, but some evidence points towards a frequently severe and dysenteric form of disease, with Shigella playing a major role (29). There is a need for further data on this possible relationship.

The role of vitamin A supplementation on diarrhoea control is uncertain and requires more research (29). No data is available covering the association between vitamin A deficiency and shigellosis.

Determinants of Clinical Sequelae of Shigellosis : Persistent Diarrhoea and Malnutrition

Data from Matlab show that 18.6 % of all under 5 deaths were due to diarrhoeal illnesses and 58% of all diarrhoeal deaths were attributable to chronic diarrhoea (50). The reported incidence rate of chronic diarrhoea shows wide variation. An incidence rate of 7 episodes per hundred child-years was found in Guatemala (28), while a rate of 83 episodes per hundred child-years was reported in Gambia (32). The incidence of prolonged diarrhoeal illnesses in rural Bangladesh was 38 episodes per hundred child-years, the highest incidence (47 per 100 child years) being in children between 36 to 60 months of age. 16% of the episodes of diarrhoea due to Shigellae were prolonged beyond 3 weeks (52). Post -Shigella persistent diarrhoea has also been noted to occur in other countries (3,18,22,23,24).

Only a few studies have been done to identify risk factors for persistent diarrhoea (53,54). Age, a history of previous diarrhoeal disease, duration of diarrhoea prior to admission, use of antibiotic or other anti-diarrhoeal agents and undernutrition have been implicated as predisposing factors. One study (53) demonstrated that bacterial aetiology (Salmonella) and severity of the acute attacks were positively correlated with the subsequent delayed recovery. Others found no positive correlation between delayed recovery from acute diarrhoea, on the one

hand, and severity and aetiology, on the other hand (54,55). Besides giving conflicting results, these studies suffered from selection biases due to assembly of cases while in the hospital. Studies to date have also failed to assess risk factors for persistent diarrhoeas among children infected with specific pathogens (e.g. Shigella).

Many studies have shown that diarrhoea leads to malnutrition (56, 57). An aetiology specific study of this relationship was performed in rural Bangladesh (30). This study reported that nutritional decline occurs after shigellosis in children of rural Bangladesh, but that the decline was restricted to faltering of linear growth rate rather than weight gain. However, the study appeared to have an inadequate sample size for detecting significant changes in weight gain after shigellosis, and it also failed to control for important confounding variables (e.g. socioeconomic status, dietary intake during diarrhoea) which can affect nutritional status (39, 59). An additional point to be noted is the absence of any published data describing the factors determining the nutritional decline among children with shigellosis.

3. Rationale: Shigellosis is an important disease responsible for high rates of morbidity and mortality in Bangladesh. Since there is no simple therapeutic measure for management of shigellosis such as the oral rehydration

available for watery diarrhoea, control of mortality due to shigellosis is going to be much more difficult than mortality due to the other causes of diarrhoea. Improvement of water supply and sanitary facilities, which should reduce the spread of shigellosis, will require large capital inputs and will be beyond the capacity of most of the governments of the developing countries for years to come. In the meantime, interim strategies will be required to reduce morbidity and mortality from shigellosis. Development of these strategies requires data clarifying the risk factors for shigellosis and its sequelae (31). Identification of the risk factors will also be needed for the evaluation of potential Shigella vaccines. Other data generated from this protocol, such as the secondary case rate among contacts of Shigella index cases will also be valuable for the planning of future Shigella vaccine trials.

B. SPECIFIC AIMS:

To evaluate, using a family study design (i.e. following family and neighbouring contacts of shigellosis patients), several risk factors for symptomatic Shigellae infections and several possible modulators of the risk of nutritional decline and persistent diarrhoea after Shigellae infections among intensively exposed children under 5 years of age in rural Bangladesh.

1. The risk factors under study will include:

   a) Low body stores of vitamin A.

   b) Breast-feeding as a component of the diet.

   c) Weaning practices.

   d) Overall nutritional status.

   e) Recent measles.

   f) Personal hygiene of the child and the mother.

   g) Water supply and storage of the family.

   h) Food handling practices of the family.

2. The potential prognostic factors for the clinical sequelae of Shigella infections to be studied will include, in addition to all of the aforementioned factors listed in "1", : (a) feeding practices during the course of the Shigellae infection (b) antibiotic therapy of the Shigellae infection.

C. METHOD OF PROCEDURE:

1. Location: The study will be conducted in the ICDDR,B Vaccine Trial Survey (V.T.S.) area in Matlab Upazilla, approximately 45 km southeast of Dhaka. The population of about 190,000 people has been under demographic surveillance since 1963; periodic censuses are carried out, and there is continuous registration of vital events (34). The population comprises Bengalis, 90% of whom are Muslims and 10% are Hindus (62). There are 149 villages in the area. The population is served by 3 treatment centers (Matlab Bazar,

Nayergaon and Kalirbazar), which are the only sources of care for diarrhoea.

2. Research design : overall plan

a) Short-term follow-up for shigellosis: The shigellosis cases diagnosed by culturing the faecal specimens or rectal swabs of the admitted patients of the treatment centres will be taken as index cases. The neighbourhood of each index case will be visited usually within 24 hours, but no later than 48 hours after the arrival of the index case at the treatment centre. All the families [defined as persons sharing the same cooking pot (35)] situated in the courtyard of the index case, and two adjacent courtyards, will be studied, since earlier research has demonstrated frequent spread of shigellosis among children of neighbouring families (36). On the average there are 4.5 families in a courtyard (unpublished observaton). Only children aged less than 60 months and present on the first or second day of the study will be included. There is about one child in this age group per family (unpublished observation, Matlab). All relevant baseline information, rectal swabs, finger tip blood samples and measurements will be obtained from all under 5 children on the first day of participation. These children will then be visited on alternate days upto 10 days so as to obtain histories about the occurrence of diarrhoea as well as rectal swabs from symptomatic children, which will be evaluated for the isolation of Shigellae.

To avoid any bias, the research workers acquiring baseline information on days 1 and 2 will be different from the workers obtaining data thereafter. Also, the baseline information will be recorded in a separate data form, and this data form will not be available to the persons doing subsequent follow ups.

b) Long-term follow-up for sequelae of shigellosis.

After the end of the 10 days of follow up, all study children will be visited once a week for a total of 4 weeks i.e. they will be visited on days 14, 21, 28 and 35. During these weekly visits 7-day diarrhoeal recall histories will be obtained to identify episodes of persistent diarrhoea and all such symptomatic episodes will be evaluated for Shigellae. Anthropometric measurements will be performed on day 28. Another visit will be given on day 84 so as to obtain anthropometric measurements for detecting nutritional decline.

[Note: All the data forms will be pre-coded and will be filled out by the interviewer or observer in the bari. The forms will be modifications of that used in the Urban Volunteer Project (47) and the Family Studies of the Oral Cholera Vaccine Trial Project. The laboratory results will also be recorded on pre-coded forms.]

3. Research design: detailed procedures and definitions

a) Treatment centre surveillance for index cases

All patients presenting with diarrhoea to the Matlab, Nayergaon and Kalirbazar treatment centres will be identified through computerized census lists as to whether they reside in the VTS area. An assistant will be on duty at all locations specifically for this purpose. All patients residing in the VTS will receive a stool culture. At Nayergaon and Kalirbazar treatment centres bacteriologic facilities are not available. Therefore, stool and rectal swab samples will be cultured on transport media (buffered glycerol saline) and transferred to Matlab treatment centre.

At Matlab microbiological evaluation will employ conventional techniques (see Annex 1),in addition to a co-agglutination test for the rapid diagnosis of Shigella, which gives results within 6 hours of specimen collection (developed by Dr. Mahbubur Rahman, Asst. Scientist, ICDDR,B). This rapid test will make it possible to initiate the family study the day after the index case is admitted to the hospital (conventional techniques require 48 hours for identification of Shigellae). The studies in which the positive results of the rapid tests have not been confirmed by the conventional techniques will be discarded. All V.T.S. patients presenting with diarrhoea (defined as an illness during which 3 or more non-bloody loose motions, or 1 or more loose motions with blood occurred in any 24 hour period) associated with isolation of Shigella species will constitute potential

index cases. If, on any particular day, there are more than one index cases, the cases will be randomly sampled to initiate the family study, but in any case no more than 1 case will be selected on any particular day.

b) Recruitment of participants:

After identification of an index case in the treatment centre, a research team will visit residents of the neighbourhood of the case, where they will explain the study in the local language (Bengali) to a responsible adult from each family and obtain written informed consent (see consent form) for participation of all children aged <60 months and residing in the neighbourhood.

c) Acquisition of baseline data:

i) Composition of team: The team that will collect the baseline data on days 1-2 of the family study will consist of one medical assistant, one senior health assistant (female), one health assistant, one female helper and a porter. The female senior health assistant (assigned randomly) and health assistant will arrive at 7.00 a.m. They will obtain written consent. The female S.H.A. will start collecting observational data. She will do so till 12.00 noon. The other members of the team will arrive at 9.00 a.m. The medical assistant and the health assistant will be responsible for taking histories, measurements and specimens. The medical assistant will have the additional responsibility of looking for the ocular symptoms and signs

of vitamin A deficiency. The female helper will help in motivation of the participants and also assist in taking measurements. The porter will carry the length board, height stick and salter scale.

ii) Activities of the team:

The team will take histories, observations, measurements and specimens.

Histories: The histories will include demographic features, socio-economic status, diet, recent morbidity and therapies. The histories of the study children will be obtained from their mothers or, in her absence, from a reliable family member.

Demographic features will include age and gender of all children in the family, child spacing, number of living siblings, earlier death of an under 5 year old child, age and parity of the mother, mother's current marital status, mother's presence, family size and religion.

Information regarding socio-economic status will comprise education of mother and head of household, household crowding (expressed as number of persons per sleeping room), family income, ownership of house and land, type of house construction, possession of luxury items, and latrine type.

Dietary history will include the breast feeding status of all children under 3 years of age e.g. breast milk only,

breast milk plus water, breast milk plus foods or only foods. If the child takes food only, then information will be obtained regarding the age at which breast milk was stopped. Weaning practices of all children under 12 months of age will also be noted. The particular practice that will be looked at is the age at which water and other foods were introduced. Early and late weaning will be defined as introduction of complementary foods to exclusively breast-fed infants before 4 months (i.e. 0-3 months) and after 6 months (i.e. 7 months and over) of age, respectively (40). Intake of vitamin A rich foods, and the use of potash alum in drinking water will also be noted.

Data about recent morbidity will include occurrence of measles within the previous 6 months. Measles will be defined as fever lasting 3 days or more with a generalized skin rash and coryza. History of diarrhoea in the previous 7 days will be noted. The medical assistant will examine all the children below 60 months of age and note the presence of the ocular symptoms and signs of vitamin A deficiency (38). Any child with symptoms or signs of vitamin A deficiency will be referred to the Matlab treatment centre for treatment. Occurrence of fever, respiratory illness and scabies will also be noted.

Information about therapies will include antibiotic ingestion during the previous 7 days, intake of high potency

vitamin A capsule in the previous 6 months, and measles vaccination anytime before. The information regarding measles vaccination will be confirmed from the MCH-FP records of the ICDDR,B.

Observations: The observations to be noted are water supply and storage of the family, food handling practices of the family, and personal and domestic hygiene. A study by Stanton and Clemens (47) has used observations to obtain data regarding water-sanitation behaviours. Stanton also demonstrated that in Bangladesh hygienic practice recalls and KAP assessments should not be used as a replacement for direct observations of hygienic practices (48). The observations will be done on day 1 only so as to document the behaviours before the occurrence of shigellosis in study subjects.

The source from which the family fetches its drinking and cooking water will be observed. It will be noted whether there is opportunity of drainage from latrines into any of the water sources. It will also be observed whether the drinking and cooking water are stored in narrow or wide necked containers, whether they are covered or not, whether stored inside or outside the house, and whether dipping of hands occurs while using the stored water.

When the female senior health assistant arrives in the morning, she will look for the presence of any stored

child's food and ask how long ago it was cooked. She will observe whether it is stored in a closed or an open container. She will note whether the food taken by the child is specially cooked for the child or part of the adult diet. She will also note whether it is served cold or hot.

Personal hygiene of the child, mother, or other persons who tend the child will be observed. Handwashing practices (use of soap, ash, soil, water or nothing) of the mother before preparing food, feeding child, defaecating, and after washing anal region of child and touching stool will be observed. If the child self-feeds then the handwashing practices of the child before eating and after defaecating will be noted. Disposal of faeces of children will be observed. When a crawling child defaecates then the time elapsing before it is cleaned will be noted. For an ambulatory child, the site of defaecation will be noted (inside or outside the compound). Whether the children place garbage or waste products inside their mouths will be observed.

The presence of exposed human faeces in proximity to the latrines will be observed. The presence of domestic animals (indicator of flies) or heaped garbage in the compound will be recorded.

Measurements: The weight will be taken by 25 kg salter scales (to the nearest 0.1 kg). Length boards (wooden

platform with a sliding foot board) will be used to take the length of under 2 year olds, and height sticks will be used to take the height of the over 2 year olds (to the nearest 0.1 cm). The children will be classified using weight for age, weight for height, and height for age compared to the NCHS standard (41). Mid-upper-arm circumferences will also be recorded.

Specimens: Rectal swabs and finger-tip blood samples will be taken from all under 5 children on day 1.

The rectal swabs taken will be transported in buffered glycerol saline media from the field as it gives higher yield of Shigella (42). On arrival at the Matlab laboratory plating will be done on MacConkey and Salmonella-Shigella (S.S.) media. Shigella will be grouped serologically using the slide agglutination test with antisera (43). Sensitivity will be done using the method of Bauer et al (44). (See Annex 2 for flow chart).

The blood samples will be centrifuged in the Matlab laboratory, and the resulting serum will be frozen for storage. It will subsequently be transported to the Dhaka laboratory for estimating vitamin A levels. Plasma vitamin A levels in the blood samples will be estimated by the high-pressure liquid chromatography (H.P.L.C.) method (38, 61).

d) Acquisition of post-baseline data during the intensive follow up (days 2 to 10):

i) Composition of team: The team will consist of 1 senior health assistant (S.H.A.), 1 health assistant (H.A.), 1 female helper and a porter. They will visit the families on alternate days up to day 10 (i.e. days 2, 4, 6, 8 and 10). The S.H.A. and the H.A. will be responsible for obtaining the data.

ii) Activities of the team: The team will take histories and specimens.

Histories: History of the number and character of loose motions occurring after the previous visit will be obtained. Children who are $\geq$ 4 years old will give their own histories. For younger children, the histories will be obtained from their mothers. If there is diarrhoea then the feeding practices during the diarrhoea will be noted i.e. change in the quantity of breast-milk or other foods after the onset of illness. Occurrence of fever, measles, respiratory illness and scabies will also be noted. Therapies received will also be recorded e.g. ORS, antibiotics, vitamin A capsules.

Specimens: Rectal swabs will be obtained from children complaining of diarrhoea since the last visit. A child not suffering from diarrhoea will not have any rectal swabs taken.

Procedure in case a child is absent: If a child is absent

on any of these days then up to 96 hours recall histories will be taken.

e) Acquisition of post-baseline data during prolonged follow up:

i) Composition and schedule of the team: The team will consist of a medical assistant, a female helper and a porter. Its first visit will be on day 14. The team will record relevant events occurring between day 10 and day 14. Thereafter, they will give weekly visits up to day 35 and will take 7-day recall histories. Another visit will be given on day 84.

ii) Activities of the team: Histories, measurements and specimens will be taken.

Histories: Occurrence of diarrhoea (with date of starting and stopping), fever, measles, respiratory illnesses and scabies will be noted. Ocular symptoms and signs of vitamin A deficiency will be recorded. Current breast feeding status will be noted. Therapy with antibiotics or high potency vitamin A capsules will also be noted.

Measurements: Height, weight and mid-upper-arm circumference will be taken on day 28 and day 84.

Specimens: Rectal swabs will be taken only from children who had Shigella isolated during the 10 days of follow up as

well as those complaining of diarrhoea in the interval since the last visit. It will be taken on the first 4 weekly visits i.e. days 14, 21, 28 and 35. No rectal swabs will be taken on day 84.

4. Definitions:

a) Definition of symptomatic shigellosis - A child having both a positive culture and diarrhoea on any of the 10 days (35).

b) Definition of persistent diarrhoea: An episode of diarrhoea lasting for more than 2 weeks will be defined as persistent diarrhoea (45,22).

c) Definition of episode of diarrhoea: An illness with at least one 24-hour period with $\geq$3 non-bloody loose motions or $\geq$ 1 bloody loose motion. The onset of an episode is the first day with diarrhoea (defined above) before which there were at least 7 consecutive diarrhoea-free days. The end of the episode is the last day of diarrhoea followed by $\geq$ 7 consecutive diarrhoea-free days (49).

d) Definition of nutritional decline: Nutritional decline will be defined as a decrease of 10% weight for age or 10% weight for height (using NCHS standards).

5. Treatment for illnesses of the study participants:

The contacts of the index cases will be treated for shigellosis if clinical diagnosis is made (i.e. febrile,

bloody dysentery with abdominal pain). They will be treated with nalidixic acid or ampicillin using conventional doses (46). Antibiotic sensitivities of Shigella isolates will be checked when the results are available and if needed the antibiotic will be changed. Severe cases of shigellosis will be referred to the Matlab treatment centre. Cases of vitamin A deficiency diagnosed clinically in the field will be referred to the treatment centre in Matlab. The participants will also receive treatment for minor ailments e.g. paracetamol, ORS packets, benzyl benzoate (for scabies), etc. These will be supervised by a physician.

Any other serious illnesses will be referred to the Matlab treatment centre for treatment.

6. Quality control:

The teams will be supervised by a field research officer and a senior field research officer. In addition, the treatment centre surveillance will be supervised by a senior medical officer and a senior field research officer. They will in turn be under the supervision of a manager. The principal investigator will also be extensively involved in field supervision.

7. Sample size:

a) For assessing risk factors for symptomatic shigellosis, the number of under 5 year old children required is about 1000. This has been calculated by standard sample size

calculation formulas and using correction factor for unequal exposed and non-exposed groups. Power was taken as 80% and a significance level of $p<0.05$ (2-tailed). Loss to follow up was assumed to be 20%. Of the total under 5 children, children under 3 years of age are estimated to be 64%, and children under 1 year of age are taken to be 22% (37). The assumed prevalence of the possible risk factors and the incidence of Shigella illness among the study children is shown in annex 3.

b) For assessing the risk factors for the clinical sequelae (persistent diarrhoea, nutritional decline) of shigellosis, the number of under 5 children required is about 1550. This has been based on the assumption that the number of cases of persistent diarrhoea and nutritional decline needed is 25 each. The secondary case rate of shigellosis among the contacts is assumed to be 15% (36,35,26,63). It is also assumed that 15% of the shigellosis cases will develop persistent diarrhoea (52), and 15% will develop nutritional decline (30). Loss to follow up is assumed to be 28%.

Assuming there are 8 children per family study, the number of family studies required is about 200. This will take about 1 year 3 months of field work. The family studies will commence after a period of 3 months required for planning and preparation. It may also be noted that the compilation of data results from laboratory studies will be completed within 6 months after the end of the family studies.

8. Data analysis:

To be eligible for analysis, a child must be present on days 1 or 2 and on any 2 other days during the intensive follow up.

i) For evaluating the risk factors for shigellosis, the incidence of shigellosis in groups exposed and non-exposed to the risk factor under study will be compared using relative risks. Only children lacking a history of recent diarrhoea and negative for Shigella on baseline will be analyzed. Statistical significance of these relative risks will be assessed with standard chi square tests (or Fisher exact tests) where applicable. Confounding variables will be taken into account using logistic regression (51).

ii) For identifying risk factors for persistent diarrhoea after shigellosis, the Shigella diarrhoea cases diagnosed during the 10 days of follow up will be the sample; the development of persistent diarrhoea in the exposed and non-exposed groups will be compared, again using logistic regression to control for confounding variables.

iii) For identifying risk factors for nutritional decline, the procedure will be similar to that of persistent diarrhoea.

9. Confidentiality:

To preserve confidentiality, all data forms will be kept in

locked filing cabinets at Matlab and at ICDDR,B. Subjects will not be identified by name, but only by study number; and no subject will be individually identified in any report of the findings.

D. SIGNIFICANCE

Identification of risk factors for shigellosis and its sequelae will be needed to plan intervention studies. This will lead to more effective control measures. Thus mortality and morbidity from shigellosis will be greatly reduced. The prevention of shigellosis will also reduce the expenditure of the National Health Systems of the developing countries.

E. FACILITIES REQUIRED

The facilities of the ICDDR,B will be sufficient to conduct this study.

F. COLLABORATIVE ARRANGEMENT

No external collaboration is required.

REFERENCES

1. Ackerknecht, E.H., History and Geography of the Most Important Diseases, Hafner, New York, 1965, 210 pp.

2. Levine, M.M. et al. Pathogenesis of shigella dysenteriae 1 (shiga) dysentery. J. Infect. Dis. 127:261-270 (1973).

3. Mata, L.J. The children of Santa Maria Cauque : A prospective field study of health and growth. MIT Press, Cambridge, 1978.

4. Gangarosa, E.J., Perera, D.R., Mata, L.J., Mandizabol - Morris, C., Guzman, G., Reller, L.B. Epidemic shiga bacillus dysentery in Central America. II. Epidemiologic studies in 1969. J. Infect. Dis. 1970; 122 : 181 - 90.

5. Mandizabol-Morris, C.A., Mata, L.J., Gangarosa, E.J., and Guzman, G. (1971). Epidemic shiga-bacillus dysentery in Central America, Derivation of the epidemic and its progression in Guatemala, 1968-69. Am.J. Trop. Med. Hyg., 20; 927-933.

6. Khan, M.U., Curlin, G.T. Shigellae dysentery : a new health hazard in Bangladesh. Bangladesh Med. J. 1974; 3:42-7.

7. Rahaman, M.M., Huq, I., Dey, C.R. Superiority of MacConkey's agar over Salmonella - Shigella agar for isolation of shigella dysenteriae type 1. J. Infect. Dis. 1975; 131 : 700-3.

8. Stoll, B.J., Glass, R.I., Huq, M.I., Khan, M.U., Holt, J.E., Banu, H. Surveillance of patients attending a diarrhoeal disease hospital in Bangladesh. Br. Med. J. 1982; 2:1185-8.

9. Khan, M., and Shahidullah, M. Shigellosis in Dhaka and its Epidemiological Pattern in Affected Families : 1980. In : Rahaman, M.M., Greenough, W.B., Novac, N., et al, eds. Shigellosis : a continuing global problem, Dhaka : International Centre for Diarrhoeal Disease Research, Bangladesh, 1983 (Special publication No.20 : Page No.75-82)

10. Hossain, K.M.B., Glass, R.I., Huq, M.I., Yunus, M., and Hossain, M.M. Surveillance of Shigellosis in Matlab : A Five Year Review. In : Rahaman, M.M., Greenough, W.B., Novac, N., et al, eds. Shigellosis : a continuing global problem, Dhaka : International Centre for Diarrhoeal Disease Research, Bangladesh, 1983 (Special Publication No.20 : Page No. 100-106).

11. Khan, M., Shahidullah, M. Contrasting epidemiology of shigella dysenteriae and shigella flexneri, Dacca. Trans.

R. Soc. Trop. Med. Hyg. 1980; 74 : 528-33.

12. Rahaman, M.M., Khan, M.U., Aziz, K.M.S., Islam, S. and Kibriya, A.K.M.G.(1975). An outbreak of dysentery caused by shigella dysenteriae type I on a coral island in the Bay of Bengal. J. Infect. Dis. 132, 15-19.

13. Black, R.E., Merson, M.H., Huq, I., Alim, A.R.M.A., and Yunus, M., 1981. Incidence and severity of rotavirus and Escherichia coli diarrhoea in rural Bangladesh : Implications for vaccine development, Lancet, 1:141-143.

14. Rahaman, M.M., Koster, F., Majid, A. Clinical characteristics, complications and treatment of shigellosis. In : Proceedings of the 10th meeting of the Scientific Review and Technical Advisory Committee of the Cholera Research Laboratory, 1975. Dacca : Cholera Research Laboratory, 1976 : 9-14.

15. Khan, M.U., Roy, N.C., Islam, M.R., Huq, M.I., Stoll, B. Fourteen years of shigellosis in Dhaka : an epidemiological analysis. Int. J. Epidemiol. 14 : 607 - 613, 1985.

16. Rahaman, M.M., Huq, I., Dey, C.R., Kibriya, A.K.M.G. and Curlin, G. (1974). Ampicillin resistant shiga bacillus in Bangladesh. Lancet, i, 406-407.

17. Feachem, R., Koblinsky, M. Interventions for the control of diarrhoeal diseases among young children : promotion of breast feeding. Bull WHO 1984; 62:271-91.

18. Gordon, J.E. Acute diarrhoeal disease. Am. J. Med. Sci. 248 : 345-365 (1964).

19. Clemens, J.D., Stanton, B., Stoll, B., et al. Breastfeeding as a determinant of severity in shigellosis. Am J Epidemiol 1986; 123:710-20.

20. Ashworth, A., and Feachem, R.G. Interventions for the control of diarrhoeal diseases among young children: weaning education. Bull WHO 1985; 63(6):1115-1127.

21. Samadi, A.R., et al. Detection of rotavirus in hand-washings of attendents of children with diarrhoea. Br Med J 1983; 286: 188.

22. Mata, L.J., Catalan, M.A., and Gordon, J.E. Studies of diarrhoeal disease in Central America. IX. Shigella carriers among young children of a heavily seeded Guatemalan Convalencent home, Am. J. Trop. Med. Hyg. 15:632-638(1966).

23. Gordon, J.E., Guzman, M.A., Ascoli, W., and Scrimshaw, N.S. Acute diarrhoeal disease in less developed countries. 2. Patterns of epidemiological behaviour in rural Guatemalan villages, Bull. WHO 31 : 9-20 (1964).

24. Higgins, A.R., Floyd, T.M., and Kader, M.A. Studies in shigellosis. II. Observations on incidence and etiology of diarrhoeal disease in Egyptian village children, Am.J.Trop.Med. Hyg. 4:271-280 (1955).

25. Hutchison, R.I. Some observations on the method of spread of Sonne dysentery. Monthly Bulletin of the Ministry of Health and the Public Health Laboratory Service 1956; 15:110-118.

26. Khan, M.U. Interruption of shigellosis by handwashing, Trans.R.Soc.Trop.Med.Hyg. 1982; 76:164-168.

27. Sprunt, K. et al. Antibacterial effectiveness of routine handwashing. Paediatrics 1973; 52:264-71.

28. Gordon, J.E. et al. Nutritional and infection field study in Guatemala villages 1959-64, VI. Acute diarrhoeal disease and nutrition disorders in general disease incidence. Arch Environ Health 1968; 16:424-437.

29. Feachem, R.G. Preventing diarrhoea : What are the policy options? Health Policy and Planning 1986; 1(2):109-117.

30. Black, R.E., Brown, K.H., Becker, S. Effects of diarrhoea associated with specific enteropathogens on the growth of children in rural Bangladesh. Paediatrics 1984 Jun; 73(6):799-805.

31. World Health Organization. Diarrhoeal Diseases Control Programme. Support of biomedical research projects in 1987. WHO/CDD/RES/86.9.

32. Rowland, M.G.M., Rowland S.G.J.G., and Dunn D.T. The relation between weaning practices and patterns of morbidity from diarrhoea: an urban Gambian case study. In: Diarrhoea and malnutrition in childhood, eds. Walker-Smith, J.A., McNeish, N.S. Butterworks 1986.

33. Black, R.E., et al. Malnutrition is a determining factor in diarrhoeal duration, but not incidence, among young children in a longitudinal study in rural Bangladesh. Am J. Clin.Nutr. 1984 Jan; 39(1) : 87-94.

34. Ruzicka, L.T., and Chowdhury, A.K.M.A. (1978). Demographic Surveillance System - Matlab, volume 3: vital events and migration - 1974. International Centre for Diarrhoeal Disease Research, Bangladesh, Dhaka, Scientific Report # 11.

35. Khan, M., Curlin, G.T., Huq, I. Epidemiology of shigella dysenteriae, type 1 infections, in Dacca urban area. Trop. Geogr. Med. 1979; 31:213-23.

36. Boyce, J.M., Hughes, J.M., Alim, A.R.M.A., Khan, M.U., Aziz, K.M.A., Wells, J.G., Curlin, G.T. Patterns of shigella infection in families in rural Bangladesh. Am J Trop Med Hyg 1982 Sep; 31 (5):1015-20.

37. Shaikh, K., Mostafa, G., Sarder A.M., Wojtyniak, B. (1984). Demographic Surveillance System - Matlab, Volume 12 : Vital events and migration-tables 1982. International Centre for Diarrhoeal Disease Research, Bangladesh, Dhaka, Scientific Report No. 62.

38. Control of vitamin A deficiency and xerophthalmia. WHO Tech Rep Ser 1982; 672: 1-70.

39 Mosley, W.H., Chen, L.C. Child survival, strategies for research. A supplement to Pupulation and Development Review, Vol. 10.

40. Underwood, B.A., and Hofvander, Y. Appropriate timing for complementary feeding of the breast-fed infant. A review. Acta Paediatrica Scandinavica, Supplement 1982; 294:1-32.

41. National Center for Health Services, Growth curves for chidren birth - 18 years, United States, Rockville, M.D: National Center for Health Statistics, 1977. [Vital and Health Statistics, Series 11, No. 165, DHEW publication No. (PHS) 78-1650].

42. Stypulkowska - Misiurewiez H. Problems in Bacteriological Diagnosis of Shigellosis. In : Rahaman, M.M., Greenough, W.B., Novac, N., et al, eds. Shigellosis a continuing global problem, Dhaka : International Centre for Diarrhoeal Disease Research, Bangladesh, 1983 (Special Publication No. 20 : Page No. 87 - 98).

43. Edwards, P.R., and Ewing, W.H. (1972). Identification of Enterobacteriaeceae (3rd Edition). Burgess Publishing Company.

44. Bauer, A.W., Kirby, W.M.M., Sherris, J.C. and Turk, M. (1966). Antibiotic susceptibility testing by a standardized simple disk method. Amer. J. of Clin. Path., 45, 493 - 496.

45. Valman, H.B. Chronic diarrhoea. Br. Med. J. 1981 Jun 27; 282 (6282):2120-2.

46. Nelson, W.E., Vaughan III, V.C., Behrman, R.E., eds. Nelson textbook of pediatrics, twelfth edition. Page No. 670-71. W.B. Saunders Company.

47. Stanton, B.F., and Clemens, J.D. An educational intervention for altering water-sanitation behaviours to reduce childhood diarrhoea in urban Bangladesh: II. A randomized trial to assess the impact of the intervention on hygienic behaviours and diarrhoea rates. Am J Epidemiol 1986 [In press].

48. Stanton, B.F., Clemens, J.D., et al. Comparability of responses to 24 hour recall and knowledge-attitude practice questionnaire and direct observations in water and sanitation studies. Bull WHO [In press].

49. Higgins, A.R., and Floyd, T.M. Studies in shigellosis. I. General considerations, locale of studies, and methods. Am J Trop Med Hyg 1955; 4:263-270.

50. Chowdhury, M.K., Razzaque, A., Mosfata, F., et al. Demographic Surveillance System - Matlab, Volume 10, International Centre for Diarrhoeal Disease Research, Bangladesh, Scientific Report No.58, November, 1982.

51. Kleinbaum, Kupper, Morgenstern, eds. Epidemiologic Research. Lifetime Learning Publications. Belmont, La. 1982.

52. Black, R.E., Brown, K.H., Becker, S., et al. Longitudinal studies of infectious diseases and physical growth of children in rural Bangladesh II. Incidence of diarrhoea and association with known pathogens. Am J. Epidemiol 1982; 115: 315-324.

53. Halliday, K., et al : Persistent post-entiritis diarrhoea in childhood. Med. J. Australia 1 : 18-20 1982 [illegible] Disease Research, Bangladesh, 1983 (Special Publication No. 20 : Page No. 87 - 98).

43. Edwards, P.R., and Ewing, W.H. (1972). Identification of Enterobacteriaeceae (3rd Edition). Burgess Publishing Company.

44. Bauer, A.W., Kirby, W.M.M., Sherris, J.C. and Turk, M. (1966). Antibiotic susceptibility testing by a standardized simple disk method. Amer. J. of Clin. Path., 45, 493 - 496.

45. Valman, H.B. Chronic diarrhoea. Br. Med. J. 1981 Jun 27; 282 (6282):2120-2.

58. Delgado, H.S., et al. Diarrhoeal diseases, nutritional status and health care: Analyses of their interrelationships. Ecology of Food and Nutrition 1983; 12:229-234.

59. Victora, C.G., Vaughan, J.P., Kirkwood, B.R., et al. Risk factors for malnutrition in Brazilian children: the role of social and envirionmental variables. Bull WHO 1986; 64(2):299-309.

60. Feachem, R.G. Interventions for the control of diarrhoeal diseases among young children: promotion of personal and domestic hygiene. Bull WHO 1984; 62(3):467-476.

61. Bieri, J.G., et al. Simultaneous determination of a-tocopherol and retinol in plasma or red cells by high pressure liquid chromatography. Am J Clin Nutr 1979; 32:2143-2149.

62. Comilla District Statistics 1983, Bangladesh Bureau of Statistics, Government of the People's Republic of Bangladesh.

63. Khan, M.U., et al. Changes in the trend of shigellosis in Dhaka : family study on secondary infection, clinical manifestation and sensitivity pattern : 1980. Trans Roy Soc Trop Med Hyg (1984) 78,151-156.

64. WHO Tech Rep Ser 1976; 590 : 1-88 (Vitamin A deficiency and xerophthalmia : a report of a joint WHO/USAID meeting).

65. Brown, K.H., Black, R.E., Becker,S. et al. Consumption of foods and nutrients by weanlings in rural Bangladesh. Am J Clin Nutr. 1982; 36(5) : 878-89.

66. Koster, F.T., Curlin, G.T., et al. Synergistic impact of measles and diarrhoea on nutrition and mortality in Bangladesh. Bull WHO 1981; 59(6):901-8.

67. Curlin, G.T., Aziz, K.M.A., Khan, M.R. The influence of drinking tube well water on diarrhoeal rates in Matlab Thana, Bangladesh. Dhaka: International Centre for Diarrhoeal Disease Research, Bangladesh, Jun 1977. 18p. (Working paper no.1).

68. Brown, K.H., Black, R.E., and Becker,S. Seasonal changes in nutritional status and the prevalence of malnutrition in a longitudinal study of young children in rural Bangladesh. Am J Clin Nutr 1982; 36 : 303-13.

ABSTRACT SUMMARY

(For Ethical Review Committee)

A study is proposed to be conducted in the Matlab field study area of the International Centre for Diarrhoeal Disease Research, Bangladesh, to identify the factors associated with the occurrence of (a) symptomatic shigellosis and (b) clinical sequelae (persistent diarrhoea, nutritional decline) of shigellosis, in children under 5 years of age. The participants will be followed on alternate days for a period of 10 days and after that weekly visits will be given upto day 35. Another visit will be given on day 84 (i.e. visits will be on days 1,2,4,6,8,10,14,21,28,35 and 84). Relevant histories will be taken, and some hygienic behaviours will be observed. Nutritional measurements like height, weight and mid-arm circumference will be recorded. Rectal swabs will be taken for the diagnosis of shigellosis. It will be taken from all children on the first day of the study so as to differentiate between the incidence and prevalence of shigellosis. On subsequent days, rectal swabs will be taken only from children having diarrhoea. Finger-tip blood samples will be obtained at baseline (day 1 or 2) only so as to detect sub-clinical vitamin A deficiencies.

1. Children 0 to 4 years of age who are contacts of cases of symptomatic shigellosis will be eligible for the study. Children of this age group will be studied as the mortality

and morbidity due to shigellosis is the highest in this group.

2. There are no potential risks.

3. Procedures for protecting against or minimizing potential risks : not applicable.

4. To safeguard confidentiality, all data forms will be kept in locked filing cabinets at Matlab and at ICDDR,B. Subjects will not be identified by name, but only by study number; and no subject will be individually identified in any report of the findings.

5. Signed informed consent statement (see consent form) will be obtained from the authorized legal guardian or parent of the subject. No information will be withheld from the participants. The consent form will be read to the parent/guardian of the children in their homes, and every effort will be made to ensure that they understand the tenets of informed consent.

6. The interview will take place in the homes of the participants. The mother or , in her absence, other reliable family members will be interviewed for information relating to the younger childern. Information relating to demographic features, socio-economic status, diet, recent illnesses and therapies will be obtained. About 20 minutes will be required for an interview on the first day of the study. On

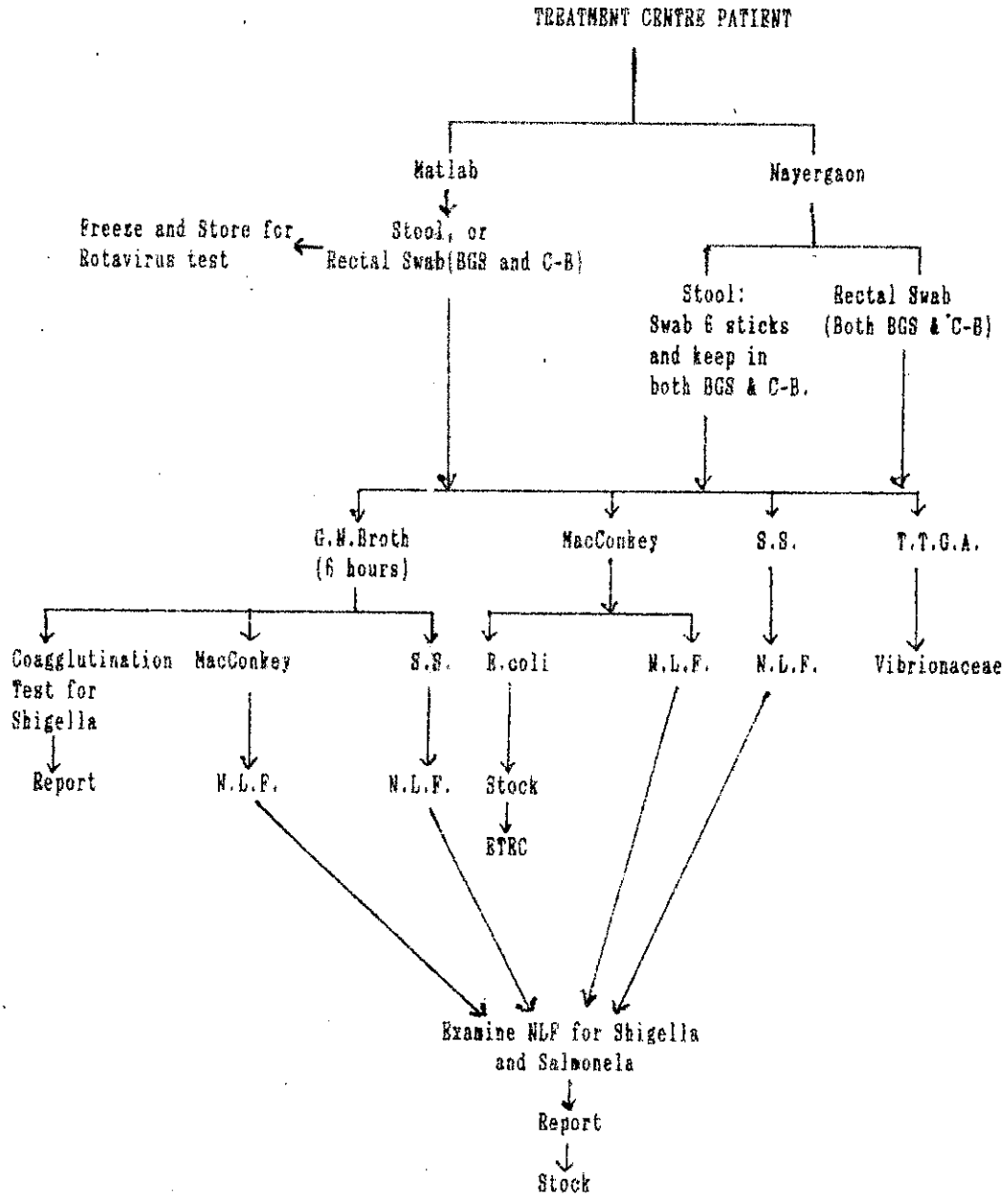
subsequent visits, a maximum of 5 minutes will be required.

7. The subjects will be treated for clinical shigellosis as well as for other minor illnesses found during the period of follow up. Severe cases of shigellosis, vitamin A deficiencies and other serious illnesses will be referred to the Matlab hospital.

The identification of the risk factors of shigellosis and its clinical sequelae will be required for planning intervention studies, thus leading to prevention of the disease. Prevention will lead to decreased suffering and death, as well as reduce the expenditure of the National Health Systems of the developing countries.

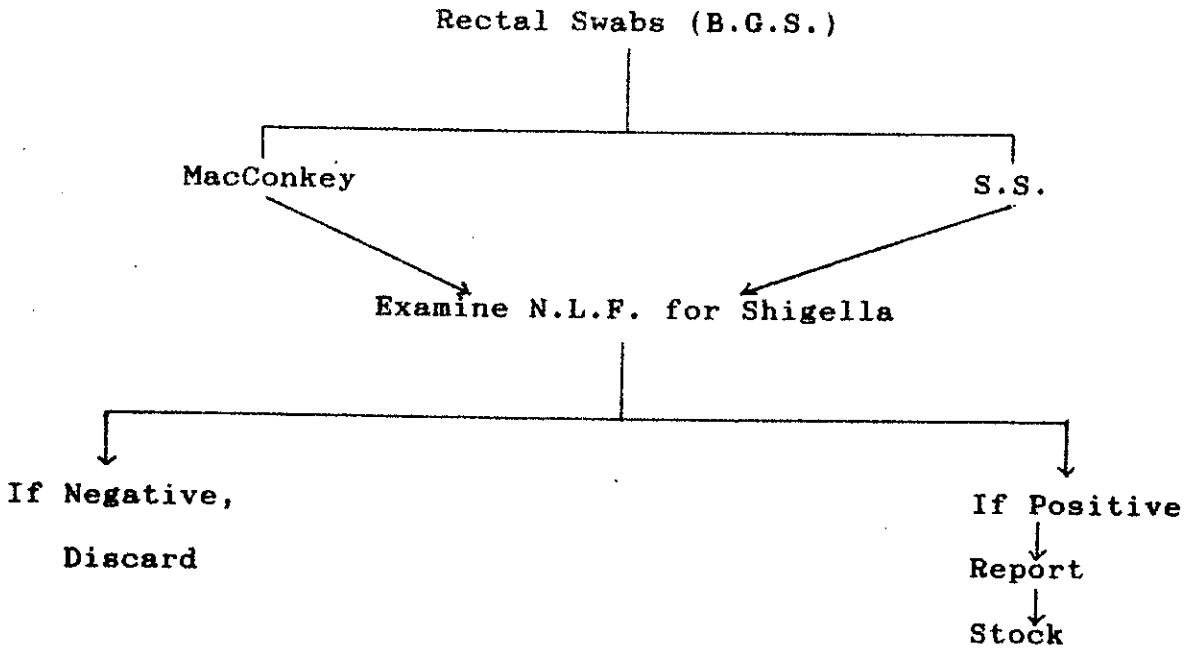
8. The study requires the collection of rectal swabs and finger-tip blood specimens of the subjects. The vital events recorded by the Demographic Surveillance System of the ICDDR,B will also be needed.

Annex. I


TREATMENT CENTRE PATIENT
Matlab
Mayergaon
Freeze and Store for Rotavirus test
Stool, or Rectal Swab(BGS and C-B)
Stool: Swab 6 sticks and keep in both BGS & C-B.
Rectal Swab (Both BGS & C-B)
G.N.Broth (6 hours)
MacConkey
S.S.
T.T.G.A.
Coagglutination Test for Shigella
MacConkey
S.S.
E.coli
N.L.F.
N.L.F.
Vibrionaceae
Report
N.L.F.
N.L.F.
Stock
ETEC
Examine NLF for Shigella and Salmonela
Report
Stock

Annex 2

INDEX CASE CONTACTS



Annex 3

Possible risk factors		Prevalence	Incidence of Shigella illness	Total number of under 5 year olds required
Vitamin A status	Poor	3%	0.36	982
	Adequate	97%	0.12	
Breast-feeding (under 3 year olds)	No	50%	0.16	996
	Yes	50%	0.08	
Weaning practices (under 1 year olds)	Poor	50%	0.15	969
	Adequate	50%	0.03	
Measles within last 6 months	Yes	5%	0.30	1005
	No	95%	0.12	
Personal hygiene	Poor	30%	0.20	583
	Adequate	70%	0.10	
Water Storage	Poor	20%	0.20	766
	Adequate	80%	0.10	
Water supply	Poor	60%	0.20	510
	Adequate	40%	0.10	
Malnutrition	Present	70%	0.16	758
	Absent	30%	0.08	
Food handling practices	Poor	80%	0.16	996
	Adequate	20%	0.08	

References used for assuming prevalence of the risk factors:

(a) Vitamin A status: In Bangladesh, clinical vitamin A deficiency was found in about 34% of 0-6 year old children (64). Since there is a vitamin A distribution program in Matlab, a prevalence of 3% is assumed
(b) Breast-feeding: Unpublished observation.
(c) Weaning practices: ref. 65.
(d) Measles : An attack rate of about 20% was found by koster in 1975-76(66 Since there is a measles immunization program in parts of Matlab now, a prevalence of 5% is assumed.
(e) Personal hygiene, water storage, food handling practices-Unpublished observations.
(f) Water supply - 40% drink tube well water (67).
(g) Malnutrition - ref. 68.

Annex 4

ACTIVITY CHART

ACTIVITIES	DAY OF STUDY																				
	1	2	3	4	5	6	7	8	9	10	14	21	28	35	42	49	56	63	70	77	84
HISTORIES																					
Demographic	✓																				
48 hour recall diarrhoeal history	✓	✓		✓		✓		✓		✓											
7 day recall diarrhoeal history	✓										✓	✓	✓	✓							
Feeding during diarrhoea		✓		✓		✓		✓		✓											
Diet	✓										✓	✓	✓	✓							✓
Socio-economic status	✓																				
Recent morbidity	✓	✓		✓		✓		✓		✓	✓	✓	✓	✓							✓
Recent therapy	✓	✓		✓		✓		✓		✓	✓	✓	✓	✓							✓
OBSERVATIONS:																					
Water supply and storage	✓																				
Food handling practices	✓																				
Personal hygiene	✓																				
Domestic hygiene	✓																				
MEASUREMENTS:																					
Height	✓												✓								✓
Weight	✓												✓								✓
Arm circumference	✓												✓								✓
RECTAL SWABS*	✓	✓		✓		✓		✓		✓	✓	✓	✓	✓							
FINGER - TIP BLOOD	✓																				

* On day 1, rectal swabs will be taken from all under 5 children.

On days 2 to 10, rectal swabs will be taken from children suffering from diarrhoea

On the weekly visits (days 14,21,28 and 35 only), rectal swabs will be only taken from children who had shigella isolated durings days 1 to 10.

[Note : The baseline information of a child absent on day 1 will be taken on day 2 (if present)]

SHIGELLOSIS: RISK FACTORS : 1987 - 1989

Program Name : LS & ED

Principle Investigator : DR FARUQUE AHMED

Budget Code:

Protocol No:

SUMMARY BUDGET	1987	1988	1989	TOTALS
3100 Local Salary	67110	48875	17100	133085
3200 International Salary	0	29238	0	29238
3300 Consultants	0	0	11000	11000
3500 Travel Local	600	600	0	1200
3600 Travel International	0	0	0	0
3700 Supplies	7059	5629	2340	15028
3800 Other costs	1000	1100	3100	5200
4800 Inter Departmental	70100	58200	8600	136900
Total Direct Operating	145869	143642	42140	331651
Capital Expenditure	9050	0	0	9050
TOTAL DIRECT COST	154919	143642	42140	340701
With expected increase (15% annually)	154919	165188	55730	375837

SHIGELLOSIS: RISK FACTORS, 1987

Program Name: LS & ED

Principle Investigator: DR FARUQUE AHMED

Budget Code:

Protocol No:

DETAILED BUDGET 1987

PERSONNEL REQUIREMENT (Local)

	No/Pos	Man mon	Amount
A Staff	0	0	0
B Recruitment	27	270	29150
C Allocate from	13	130	37960
Subtotals	40	400	67110
D Separations	0	0	0
E Allocate to	0	0	0
Subtotals	0	0	0
TOTAL	40	400	67110

NEW RECRUITS

Job	Level	No	Man mo	$/mo	Amount
Medical Officer	NOA	1	10	350	3500
Field Research Officer	GS5	1	10	200	2000
Senior Health Asst(female)	4	2	20	150	3000
Health Asst (Medical Asst)	3	5	50	120	6000
Female Helper		6	60	35	2100
Porter		6	60	35	2100
Boatman		1	10	45	450
Programmer Analyst	NOB	1	10	410	4100
Data Management Officer	GS5	1	10	200	2000
Data Processing Assistant	GS4	1	10	150	1500
Coding Assistant	GS3	2	20	120	2400
	TOTAL	27	270		29150

MANPOWER ALLOCATED FROM OTHER AREA-LOCAL

Job	Level	Bdg Cd	No/pos	Man mo	$/mo	Amount
Epidemiologist (PI)	NOB	19400	1	10	545	5450
Manager, Matab	NOB	17001	1	10	677	6770
Senior Field Res Off	GS6	17001	1	10	330	3300
Senior Health Asst	GS4	17001	4	40	272	10880
Health Asst	GS3	60201	4	40	229	9160
Clerk	GS3	17001	1	10	120	1200
Data Entry Tech	GS3	17001	1	10	120	1200
	TOTAL		13	130		37960

MANPOWER ALLOCATED FROM OTHER AREA--INTERNATIONAL

Person	Bdg no	Man mo	$/mo	Amount
J. CLEMENS	17001	N.C		0
D. SACK	19400	N.C.		0
TOTAL				0

TRAVEL PLAN -- LOCAL

TOTAL: 600

SUPPLIES AND MATERIALS

A/C	ITEMS	AMOUNT
3701	Drugs	2400
3702	Glassware	600
3703	Hospital Supplies	350
3704	Stationary	900
3705	Chemicals, Media	
3706	Uniforms	
3707	Fuel	
3708	Laboratory Supplies	100
3709	Housekeeping Supplies	50
3710	Janatorial Supplies	30
3711	Tools and Spares	
3712	Nonstock Items	1000
	SUBTOTAL	5430
3713	Freight (30%)	1629
	TOTAL	7059

OTHER COSTS

A/C	ITEMS	Amount
3800	Maintenance	100
3900	Rent, Communications, Utilties	50
4100	Finance Charges	
4200	Legal Charges	
4300	Printing and Publication	700
4400	Food and Overnight Lodging	50
4500	Service Charges	100
4600	Staff Development	
	TOTAL	1000

INTERDEPARTMENTAL SERVICES

A/C	ITEMS	Amount
4801	Computer Charges	5000
4802	Transport, Dhaka	800
4803	Transport, Matlab	900
4804	Water Transport, Matlab	39000
4805	Transport, Teknaf	
4806	Xerox	300
4807	Pathology	
4808	Microbiology	13900
4809	Biochemistry	9600
4810	X-ray	
4811	I.V. fluids	
4812	Media	
4813	Patient Hospitalization	
4814	Animal Services	
4815	Medical Illustration	
4817	Telex	500
4818	Outpatient Care	
4821	Library Services Charges	100
4830	Transport Subsidy	
	TOTAL	70100

CAPITAL EXPENSES

Item	Amount
XT Personal computer	7550
Office Furniture	1000
Filing Cabinets	500
TOTAL	9050

SHIGELLOSIS: RISK FACTORS, 1988

DETAILED BUDGET 1988

PERSONNEL REQUIREMENT (Local)

	No/Pos	Man mon	Amount
A Staff	40	293	48875
B Recruitment	0	0	0
C Allocate from	0	0	0
Subtotals	40	293	48875
D Separations	0	0	0
E Allocate to	0	0	0
Subtotals	0	0	0
TOTAL	40	293	48875

LOCAL STAFF

Job	Level	No	Man mo	$/mo	Amount
Managerial Staff					
Epidemiologist (PI)	NOB	1	12	545	6540
Manager, Matlab	NOB	1	5	677	3385
Medical Officer	NOA	1	5	350	1750
Field Staff					
Senior Field Res Officer	GS6	1	8	330	2640
Field Research Off	GS5	1	5	200	1000
Senior Health Asst (female)	4	2	10	150	1500
Senior Health Asst	GS4	4	20	272	5440
Health Asst (Medical Asst)	3	5	40	120	4800
Health Asst	GS3	4	20	213	4260
Female Helper		6	40	35	1400
Porter		6	40	35	1400
Boatman		1	8	45	360
Data Staff					
Data Management Officer	GS5	1	12	200	2400
Programmer Analyst	NOB	1	12	410	4920
Data Processing Assistant	GS4	1	12	150	1800
Data Entry Tech	GS4	1	12	120	1440
Coding Assistant	GS3	2	24	120	2880
Clerical					
Clerk	GS3	1	8	120	960
	TOTAL	40	293		48875

PERSONNEL - INTERNATIONAL

	No pos	Man mo	Amount
A Staff		0	0
B Recruitment		0	0
C Allocate from		6	29238
Subtotals		6	29238
D Separations		0	0
E Allocate to		0	0
Subtotals		0	0
TOTAL		6	29238

MANPOWER ALLOCATED FROM OTHER AREA--INTERNATIONAL

Person	Bdg no	Man mo	$/mo	Amount
J. CLEMENS	17001	6	4873	29238
D. SACK	19400	N.C.		0
TOTAL		6		29238

TRAVEL PLAN -- LOCAL

TOTAL: 600

SUPPLIES AND MATERIALS

A/C	ITEMS	AMOUNT
3701	Drugs	1600
3702	Glassware	400
3703	Hospital Supplies	250
3704	Stationary	900
3705	Chemicals, Media	
3706	Uniforms	
3707	Fuel	
3708	Laboratory Supplies	100
3709	Housekeeping Supplies	50
3710	Janatorial Supplies	30
3711	Tools and Spares	
3712	Nonstock Items	1000
	SUBTOTAL	4330
3713	Freight (30%)	1299
	TOTAL	5629

OTHER COSTS

A/C	ITEMS	Amount
3800	Maintenance	100
3900	Rent, Communications, Utilties	50
4100	Finance Charges	
4200	Legal Charges	
4300	Printing and Publication	800
4400	Food and Overnight Lodging	50
4500	Service Charges	100
4600	Staff Development	
	TOTAL	1100

INTERDEPARTMENTAL SERVICES

A/C	ITEMS	Amount
4801	Computer Charges	10000
4802	Transport, Dhaka	800
4803	Transport, Matlab	800
4804	Water Transport, Matlab	30000
4805	Transport, Teknaf	
4806	Xerox	300
4807	Pathology	
4808	Microbiology	9200
4809	Biochemistry	6400
4810	X-ray	
4811	I.V. fluids	
4812	Media	
4813	Patient Hospitalization	
4814	Animal Services	
4815	Medical Illustration	
4817	Telex	500
4818	Outpatient Care	
4821	Library Services Charges	200
4830	Transport Subsidy	
	TOTAL	58200

SHIGELLOSIS: RISK FACTORS, 1989

DETAILED BUDGET, 1989

PERSONNEL REQUIREMENT (Local)

	No/Pos	Man mon	Amount
A Staff	6	60	17100
B Recruitment	0	0	0
C Allocate from	0	0	0
Subtotals	6	60	17100
D Separations	0	0	0
E Allocate to	0	0	0
Subtotals	0	0	0
TOTAL	6	60	17100

LOCAL STAFF

Job	Level	No	Man mo	$/mo	Amount
Epidemiologist (PI)	NOB	1	12	545	6540
Programmer Analyst	NOB	1	12	410	4920
Data Management Officer	GS5	1	12	200	2400
Data Processing Asst	GS4	1	12	150	1800
Coding Asst	GS3	2	12	120	1440
	TOTAL	6	60		17100

MANPOWER ALLOCATED FROM OTHER AREA--INTERNATIONAL

Person	Bdg no	Man mo	$/mo	Amount
D. SACK	19400	N.C.		0

CONSULTANTS

Person	No of days	Perdiem and honararium	Travel cost
J. Clemens	60	7000	4000
	TOTAL	11000	

SUPPLIES AND MATERIALS

A/C	ITEMS	AMOUNT
3701	Drugs	
3702	Glassware	
3703	Hospital Supplies	
3704	Stationary	800
3705	Chemicals, Media	
3706	Uniforms	
3707	Fuel	
3708	Laboratory Supplies	
3709	Housekeeping Supplies	
3710	Janatorial Supplies	
3711	Tools and Spares	
3712	Nonstock Items	1000
	SUBTOTAL	1800
3713	Freight (30%)	540
	TOTAL	2340

OTHER COSTS

A/C	ITEMS	Amount
3800	Maintenance	
3900	Rent, Communications, Utilties	50
4100	Finance Charges	
4200	Legal Charges	
4300	Printing and Publication	3000
4400	Food and Overnight Lodging	
4500	Service Charges	50
4600	Staff Development	
	TOTAL	3100

INTERDEPARTMENTAL SERVICES

A/C	ITEMS	Amount
4801	Computer Charges	8000
4802	Transport, Dhaka	
4803	Transport, Matlab	
4804	Water Transport, Matlab	
4805	Transport, Teknaf	
4806	Xerox	500
4807	Pathology	
4808	Microbiology	
4809	Biochemistry	
4810	X-ray	
4811	I.V. fluids	
4812	Media	
4813	Patient Hospitalization	
4814	Animal Services	
4815	Medical Illustration	
4817	Telex	100
4818	Outpatient Care	
4821	Library Services Charges	
4830	Transport Subsidy	
	TOTAL	8600

WRITTEN CONSENT FORM FOR POTENTIAL PARTICIPANTS.

We are doing a study to identify the factors associated with the occurrence of (a) bloody dysentery and (b) malnutrition and persisting diarrhoea after bloody dysentery. We would like to examine all children below 5 years of age in your family. This will involve following these children on alternate days for 10 days and after that once a week for 4 weeks. Another visit will be given after 12 weeks. Histories regarding the children's food, recent illnesses and treatments, and your financial condition will be taken. Some of your day time activities will also be observed. Nutritional measurements (height, weight, arm size), stool and finger tip blood samples will be obtained. No risks are involved. Confidentiality will be preserved. The participants will be treated for bloody dysentery and other illnesses found during the period of follow up.

You have a right to refuse to participate or withdraw from the study. If you do so, the usual treatment provided to you from Matlab Hospital will not be affected in any way.

I fully understand the methods and purpose of this study and agree to participate.

Date: _____ Signature: _____

L.T.I. _____

সম্ভাব্য অংশ গ্রহণকারীদের নিকট থেকে লিখিত সম্মতি পত্র

আমরা রক্ত আমাশয় এবং রক্ত আমাশয়ের পরে দীর্ঘস্থায়ী উদরাময় এবং অপুষ্টির বিভিন্ন কারণ সমূহ নির্ণয় করার জন্য একটি সমীক্ষা করতে যাচ্ছি । এই জন্য আমরা আপনার পরিবারের পাঁচ বৎসরের নীচে প্রত্যেক শিশুদের পরীক্ষা করবো । এই পরীক্ষার জন্য আপনার শিশুদের এক দিন পর পর মোট দশ দিন পর্যবেক্ষণ করবো। এর পরে এক সপ্তাহ পর পর ৪ সপ্তাহ পর্যবেক্ষণ করবো। ১২ সপ্তাহ পর আবার পর্যবেক্ষণ করবো। সেই জন্য আপনার শিশুদের খাদ্য, সাম্প্রতিক অসুস্থতা ও চিকিৎসা এবং আপনার পরিবারের অর্থনৈতিক অবস্থার বিবরণ সংগ্রহ করা হবে। এ ছাড়া আপনাদের কিছু দৈনন্দিন কার্য্যাবলী পর্যবেক্ষণ করা হবে। সমীক্ষার জন্য ওজন, উচ্চতা, বাহুর পরিমাপ, পায়খানা ও রক্তের নমুনা সংগ্রহ করা হবে । এতে কোন প্রকার ঝুকির সম্ভবনা নেই এবং সম্পূর্ণ গোপনীয়তা রক্ষা করা হবে। তা'ছাড়া পর্যবেক্ষণ সময়ে অংশ গ্রহণকারীদের রক্ত আমাশয় ও অন্যান্য অসুখের চিকিৎসা করা হবে।

আপনি ইচ্ছা করলে এই সমীক্ষায় অংশ গ্রহণ থেকে বিরত থাকতে পারেন অথবা প্রত্যাহার করতে পারেন । আপনি যদি অংশ গ্রহণ নাও করেন তবুও মতলব হাসপাতালে আপনার স্বাভাবিক চিকিৎসার কোন এদটি হবে না ।

আমি উপরোক্ত বর্ণনা সঠিক অনুধাবন করে স্বেচ্ছায় অংশ গ্রহণ করতে সম্মত হইলাম ।

স্বাক্ষর ----------

তারিখ : ----------

বাম বৃদ্ধাংগুলের ছাপঃ ----------

CURRICULA VITAE

PRINCIPAL/CO-INVESTIGATOR

1. Surname/Family Name: AHMED

   First name/other names FARUQUE

2. Date of birth: 24th April, 1958

   Place of Birth: Bangladesh

   Nationality: Bangladeshi

3. Degrees

Degree	Year	Institution	Desciplines
M.B.B.S	1982	Dhaka Medical College	-

4. Academic Distinctions: Degree Year

5. Present post (Title, Institution, Dates)

   Title: Epidemiologist

   Institution: ICDDR,B

   Dates: From 22.09.1984

6. Previous posts (Title, Institution Dates)

   Title: Resident Medical Officer

   Institution: Children's Nutrition Unit
   Save the Children Fund (U.K.)

   Dates: 13.02.1984 - 20.09.1984

Contd.....P/2

CURRICULA VITAE

7. Academic & Research Awards, Consultant & other posts

8. Other University & Institutional Posts

9. a. Current Research Interests:

i) Evaluation of innovative field interventions for reducing childhood mortality.

ii) Diarrhoeal disease epidemiology.

iii) Nutritional epidemiology.

iv) Development of improved methods for observational epidemiologic studies.

b. On-going Research:

i) Evaluation of host factors influencing family transmission of ETEC.

ii) Development of improved standards for case-control studies assessing causal relationships between putative pathogens and clinical disease.

iii) Quantitative assessment of operational problems encountered in the administration of oral vaccines.

Publications & Communications:

Publications:

Clemens, J., Stanton, B., Chakraborty, J., Sack, D., Khan, M.R., Huda, S. Ahmed, F., Harris, J., Yunus, M., Khan, M.U., Svennerholm, AM., Jertborn, M., Holmgren, J. "B Subunit-Whole Cell and Whole Cell Only Killed Oral Vaccines Against Cholera : Studies on Reactogenicity and Immunogenicity" - Journal of Infectious Diseases (In Press).

FAMILY STUDY : FAMILY FORM

Card #: F___ Study #: ___ Fam CID : ___ ___
Vill Fam

Did you use fitcurry in drinking water today 0=No,1=Yes,9=DK	Religion 1=Muslim 2=Hindu 3=Other	Total # of family members	Total # of living children under 5	Earlier natural death of <5 child (0=No,1=Yes)	Months ago last death occurred (88=NA;99=DK)
___	___	___	___	___	___

FAMILY STUDY : INDIVIDUAL FORM

BASELINE DATA

LIST CHILDREN BORN ON OR AFTER 1.1.82

CID ___ ___ __ Name_____ Reg#___ ___ __ DOB:__ __ __ Sex __ (1=M 2=F) Months ago ___ elder child born ___ Months ago younger child born ___ Take BM ___ (0=No 1=BM only 2=BM+water 3=BM+food) Age (mo) ___ when water introduced ___ Age(mo) when other foods introduced ____ Months ago BM stopped ___ CID of mother ___

DOB of mother ___ Years of schooling of mother ___ Status of mother ___ (01=Married 02=Divorced 04=Widow 08=Away 16=Dead) Months ago child had measles ___ (8=NA;9=DK) Measles vaccine given before ____ (0=No,1=Yes,9=DK) Did child take vit A in last 6 months ___ Weight___ Height___ Arm circumference ____ Eye changes ____

times child took in last 7 days

Liver ____

Veg ____

Fruit ____

Dairy ____

Did child take antibiotics in last 7 days ____ (0=No;1=Yes;9=DK)

Did child have diarrhoea in last 7 days ____ (0=No;1=Yes;9=DK)

days ago diarr. started ___ (00=Today 88=No diarr. 99=DK)

KEY:

Measles: Fever lasting 3 days or more with generalized skin rash and coryza

Vegetables: Yellow, yellowish red and green leafy vegetables

Fruits: Yellow and yellowish red fruits-pumpkin, papaya, tomato, carrot, mango, sweet potatoes.

Dairy: Butter, egg yolk, whole milk.

Eye changes: 00=None; 01=Night blindness; 02=Conj. xerosis; 04=B.Spots; 08=C.xerosis; 16=Keratomalacia; 32=Corneal scar.

SHIGELLA STUDY

TEN DAY VISIT RECORD

Form: FU
Card #: F___ Study #: _____
CID: ___ ___ ___ Name: _____
Vill Fam Ind
Reg #: ___ ___ ___
Vill Fam Ind

For identification:
Head of household: _____
D.O.B. of child: _____
Sex of child: _____

Date of visit DD MM YY	Loose motion #	Sev	Char	If LM: then diet 0=No change 1=Increased 2=Reduced 3=Withdrawn 8=NA Breast milk	Other foods	Fever 0=No 1=Yes 9=DK	Morbidity 00=None 01=Measles 02=URTI 04=LRTI 08=Scabies	Anti-biotic 0=No 1=Yes 9=DK	Other Rx 0=none 1=vit A 2=ORS 4=Homeo pathy	Spec	Entered by	Shig. growth 0=No 1=Yes 9=Not done

KEY:

#=Number of loose motion (L.M) during last 24 hrs. (99=DK)

Sev=Severity of LM during last 24 hrs
0=No LM
1=LM, but no reduction of play
2=LM, reduced play, but not bedridden
3=LM, bedridden, but not hospitalized
4=LM, hospitalized, but did not die
5=LM, died
9=DK

Char=Character of LM during last 24 hours
0=No LM
1=Atleast 1 watery LM, never blood
2=All LM's non-watery, never blood
3=One or more LM with blood
9=DK

Measles: Fever lasting 3 days or more with a generalized skin rash + coryza

Spec=
Specimen taken:
0=None
1=R/S only
2=Blood only
3=R/S+Blood

WEEKLY VISITS

Form:FW
Study #:____

CID:___ ___ ___ Name:_____ Reg #:___ ___ __

Date of visit DD MM YY	Diarr.in last 7 days 0=No 1=Yes 3=DK	Days ago diarr. started 00=Today 88=NA 99=DK	Days ago diarr. stopped 00=Today 88=NA 99=DK 98=Still	Morbidity 00=None 01=Fever 02=Measles 04=URTI 08=LRTI 16=Scabies	Eye changes	Therapy 0=None 1=vit A 2=Anti-biotic	Take BM 0=No 1=BM only 2=BM+water 3=BM+food 9=DK	Height	Weight	Arm circum.	R/S taken 0=No 1=Yes

DAY 84 VISIT

Form FN
Study #

CID___ ___ __ Name_____ Reg#___ ___ __ Date of visit __ __ __

Diarr. since last visit	Morbidity	Eye changes	Therapy	Take BM	Height	Weight	Arm circum
0=No	00=None		0=None	0=No			
1=Yes	01=Fever		1=Vit A	1=BM only			
9=DK	02=Measles		2=Anti-	2=BM+water			
.	04=URTI		biotic	3=BM+food			
	08=LRTI		9=DK	9=DK			
	16=Scabies						

_____

_____

SOCIOECONOMIC DATA FORM

Form:SES Study #:____ Date of visit:_____

Family ID#	Head of House Yrs of schooling (99=DK)	Does family own House 0=No 1=Yes 9=DK	Does family own Land 0=No 1=Yes 9=DK	Possession of luxury items(Add) 00=None 01=Bed 02=C.boat 04=Hurricane 08=Quilt 16=W.watch 32=Transistor	Yearly income (999999 =DK)	Type walls 1=Jute 2=Bamboo 3=Tin 4=Wood 5=Concrete 6=Brick 8=Other 9=DK	Type roof 1=Straw 2=Tin 3=Wood 4=Concrete 8=Other 9=DK	# sleeping rooms	Tubewell in court yard 0=No 1=Yes, working 2=Yes,not working	Usual site for family defecation 0=No fixed site 1=Fixed site, no structure 2=Fixed site pit latrine 3=Fixed site, hang. lat. 4=Sanitary lat. 5=Fixed site, other struc. 9=DK	If own struc., type of walls 0=No struc owned 1=pucca 2=non-pucca 9=DK

Form:OBS Study # _____ Family:F____ Observer code:_____
Date of visit ____ ____ ____ Time of arrival ___ ___ Time of departure ___ ___

List children born on or after 1.1.82:
Continuation code:____
Child's C.I.D:____ ____ ___ Child's reg #:____ ____ ___ (Child's name:_____)
Mother's reg #:____ ____ ___ (Mother's name:_____)

Status of child (1=crawling;2=ambulatory;9=DK): ____

	EPISODE		
Defecation site (code A) :			
Time before feces removed (code B):	____	____	____
Occurrences before feces removed (code C):	____	____	____
Mechanism of feces removal (code D):	____	____	____
Time after defecation before hand washing of child (code E):	____	____	____
Solvent used (code F):	____	____	____
Time after defecation before anus washed (code E):	____	____	____
Activities after defecation before hand wash (code G):	____	____	____
Who washed child after defecation :	____	____	____
(0=not washed;1=child himself;2=mother;3=other;9=DK)	____	____	____
Handwashing of child before eating (code H):	____	____	____
Solvent used (code F):	____	____	____
Who fed child (1=child himself;2=mother;3=other;9=DK):	____	____	____
# times child placed garbage from ground into mouth (stop at 8)		____	
# times child put objects from ground into mouth (stop at 8)		____	

HOUSEHOLD OBSERVATION

Was cooked food left over from the day before to be eaten by child today (0=no;1=yes;9=DK) ____

Duration of storage of left over food (HH) (88=N.A;99=D.K) ____

Left over food covered (0=No;1=Yes;8=N.A;9=D.K) ____

Preparation of child's food (1=specially cooked for child; 2=part of adult diet;9=D.K) ____

Some cooked child's food left uncovered before eating(0=No;1=Yes;9=DK) ____

How child's food served (1=served hot; 2=served cold;9=DK): ____

	DRINKING	COOKING
Source of water (1=tubewell;2=river;3=canal;4=ditch;5=pond 6=surface water;9=DK)	_____	_____
Oppurtunity of drainage from latrines into water sources: (0=No;1=Yes;9=DK)	_____	_____
Neck of container for storing water : (1=narrow;2=wide;9=DK)	_____	_____
Water container covered : (0=No;1=Yes;9=DK)	_____	_____
Site of container : (1=inside house;2=outside house;9=DK)	_____	_____
Did anyone dip hand into container to obtain water : (0=No;1=Yes;9=DK)	_____	_____

Domestic animals observed in compound : (0=No;1=Yes;9=DK) ____

Heaped uncovered garbage observed in compound : (0=No;1=Yes;9=DK) ____

Presence of exposed human feces in proximity to latrines : (0=No;1=Yes;9=DK) ____

Form OBM

Date of visit: ___ ___ ___
DD MM YY

LIST MOTHER'S OF CHILDREN BORN ON OR AFTER 1.1.82:

Continuation code:____
Mother's CID:____ ____ ___ Mother's reg #:____ ____ ___ (Mother's name_____)
Vill Fam Ind Vill Fam Ind

Time after defecating before hand washing (code E): ___ ___ ___
Activities before hand washing (code G): ___ ___ ___
Solvent used (code F): ___ ___ ___

Time before hand washing after cleaning anus of child (code E): ___ ___ ___
Activities before hand washing after anus cleaned (code G) ___ ___ ___
Solvent used (code F): ___ ___ ___

Time before hand washing after removing stool from ground(code E) ___ ___ ___
Activities before hand washing after removing stool from ground: ___ ___ ___
(code G)
Solvent used (code F):
___ ___ ___

Handwashing before preparing food (code H): ___ ___ ___
Solvent used (code F): ___ ___ ___

Hand washing before serving food (code H): ___ ___ ___
Solvent used (code F): ___ ___ ___

Hand washing before feeding child (code H): ___ ___ ___
Solvent used (code F): ___ ___ ___

KEY

Defecation site code :

CODE A
1=floor of house
2=kitchen floor
3=compound ground
4=outside compound
5=latrine
8=other
9=don't know

Removal of feces

CODE B
0=not removed - left
1=removed immediately (<10 minutes)
2=removed 10 mins. to 30 mins.
3=removed 30 mins. to 60 mins.
4=removed after 1 hour
8=not applicable - feces in latrine or outside compound
9=don't know

Occurrences before removal :

CODE C
0=untouched
1=stepped in by human feet
2=rubbed in by feet
3=stepped in by animals
4=played in by children
5=eaten by dogs
6=spread in other ways
7=covered with ash or soil
8=N.A - feces in latrine or outside compd.
9=D.K

Stool removed from ground by :

CODE D
0=not removed
1=hand removed
2=hand, covered with leaves, etc.

3=scooper
4=broom
5=dog called specifically
6=other
8=N.A -feces in latrine or outside compd.
9=D.K

Time before hand wash :
Time before anus wash :

CODE E

0=not washed
1=immediately, < 1 minute
2=1-5 mins.
3=5-10 mins.
4=10-20 mins.
5=>20 mins.
9=D.K

Solvent :

CODE F

1=water only
2=soap
3=ash
4=soil
5=soap and ash or soil
6=other
8=N.A
9=D.K

Activities before wash hand :

CODE G

0=nothing
1=prepare food before cook
2=eat with hands, suck or lick fingers
3=eat with utensils or drink from cup
4=feed under 5 child
5=drink
6=other play, work

7=serve food already cooked
9=D.K

Wash hands before eating :

CODE H

0=never washed hands
1=washed hands immediately before eating
(<10 mins. and no other activity)
2=washed hands immediately, but then soiled
3=wash 10-20 mins. - no soil
4=wash 10-20 mins. - soiled
5=20-60 mins. - no soil
6=20-60 mins. - soil
9=D.K