

REVIEW BOARD ON THE USE OF HUMAN VOLUNTEERS
CRL

Date 12.5.79

26

Principal Investigator Dr.H.Rabbani Trainee investigator(if any) _____

Application No 79-006 Supporting Agency(if Non-CRL) _____

Title of study Studies on the incidence of Project status:
Diarrhea in Bangladeshi rural children & its association with
diarrhea and malnutrition. (✓) 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 possibly damaging to subject or others NA 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 NA Yes No
 - c) Physical risks Yes No
 - d) Sensitive questions Yes No
 - e) Benefits to be derived NA Yes No
 - f) Right to refuse to participate or to withdraw from study Yes No
 - g) Confidential handling of data 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 Board for review.

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

H. Rabbani

Principal Investigator

Trainee

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

79-006

Received on
21/5/79.

SECTION I - RESEARCH PROTOCOL

1. Title: STUDIES ON THE INCIDENCE OF MEASLES IN BANGLADESHI RURAL CHILDREN AND ITS ASSOCIATION WITH DIARRHOEA AND MALNUTRITION.
2. Principal Investigator: Dr.Hassan Rabbani.
3. Co investigators: Drs. Asma, Muntaj, Gilman and M.U.Khan.
4. Starting Date: 1 June 1979
5. Completion Date: 30 April 1981
6. Total Direct Cost: \$ 26,185 (Tk.393,361)
7. Abstract Summary: A cohort of 500 children (age 0-6 years) from the village Nandipara will be studied for 2 years (1 year at the initial phase and then for another year) to determine the incidence and prevalence of measles and the age specific attack rate in Bangladeshi rural children specifically examining the relationship between diarrhea and measles and wasting and measles. This will be done by maintaining a diarrhea surveillance program by twice weekly visit to every child included in the study. By a case control method nutritional intervention will be made in measles cases and the control children to see the effect of supplemental food on the recovery of growth rate in children with measles. Nutritional status will be determined by taking monthly anthropometric measurements. Rectal swabs from every child with diarrhea will be taken and looked for V.Cholerae, E.Coli(ST <), Shigella, Salmonella and Rota Virus. Data will be collected to determine the protective effects of socio-economic factors on the development of measles complications. Attempts will also be made to identify the seasonal and the climatic determinants of measles in Bangladesh.
8. Reviews:
 - a). Research involving human subjects _____
 - b). Research Committee _____
 - c). BMRC _____
 - d). Director _____
 - e). Controller/Administrator _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION:

1. Objectives;
 - a). To define the morbidity statistics of measles (age specific attack rate) in Bangladeshi peri urban children.
 - b). To determine the interrelationship of diarrhea and malnutrition with measles and to identify the etiologic agents of diarrhea associated with measles.
 - c). To evaluate the effects of nutritional intervention on the recovery of growth rate in children with measles.
 - d). To determine the protective effects of socio-economic factors on the development of measles complications.
 - e). To identify the seasonal and climatic determinants of measles in Bangladesh.

2. Background:

Measles appears to be a killing disease affecting the young children in the tropical and other less developed parts of the world (Morley et al 1963, Scrimshaw et al 1966). Newborn infants are protected for about 6 months by transplacentally acquired antibody. Most of the data on measles has been recorded from Africa and South and Central America. The behaviour of measles varies in different parts of the world according to conditions it has to face. In developed countries like the United States and Europe, where the standard of living is high and where measles has for

long been endemic, the disease tends to occur in cycles of 2-3 years, the greatest incidence in children in the 3 to 5 years age group and to be a relatively mild disease. In less developed countries like Nigeria, though still an endemic disease, measles has its major incidence in the children under 2 years of age and is a severe disease with unusual clinical features like hemorrhagic skin rash and severe epithelial desquamation and has a high mortality rate (Morley et al. 1963). In more isolated parts of the world, the virgin soil countries, the disease takes yet another pattern, sweeping through the whole population from youngest to oldest with great rapidity and causing high mortality at all ages (Panum. 1847, Rosen. 1962, Christensen. 1952, Simmons et al. 1944,45,51, & 54, Bech. 1962, Gear. 1962 and Peart et al. 1954).

Measles has been shown to be associated with high mortality rate. Mortality in some epidemics has varied from 20 to 50 percent (Senecal et al. 1962, Editorial, Lancet. 1968). Death rates in developed countries of Europe and North America in 1962 ranged between 0.1 and 0.5 per 100,000 population (UN,1963). In the same year the rates were 85 times greater in Mexico than in the United States, 268 times in Guatemala and 274 times in Ecuador (Pan American Health Organization and WHO,1964). Although no data exists from Bangladesh and only a few is available from India, it is difficult to believe that measles in this subcontinent is mild and of little consequence as it was once thought to be. Ghose and Dutt reported from India in 1960 (Ghose et al, 1961) that one in every four patients with respiratory infections

admitted to 3 major fever hospitals in Delhi had measles as the initiating cause. Obviously from the available figures any index of its prevalence is at best a striking under estimate. Most peoples in this country will consider measles as a benign disease. It is not well appreciated that measles causes prolonged morbidity not only among those with bacterial complications but also in non complicated disease.

Measles and Diarrhea:

Clinically diarrhea is common and severe necrotizing gastroenteritis has been described at autopsy (Williams and Osotimehin, 1970). This happens probably due to invasion of the lymphoid tissues of the gut by the rapidly multiplying viruses. Morley reported from Nigeria that out of a total 179 attacks of diarrhea in 259 children with different infections observed for a period of 3 years, 109 attacks occurred in children with measles (Morley et al 1963). From India Silhar reported in 1958 (Silhar and Maru, 1958), 21.2% cases and Ghose reported in 1961 (Ghose and Dutt, 1961), 29.9% cases are associated with measles diarrhea. The high incidence of measles at 1 to 3 years of age coincides with the age distribution of acute diarrheal diseases and with that of malnutrition, the later being well established as due to inadequate supplementation of breastmilk and consequent protein deficient diet during and after the weaning. Both diseases bear strongly

on the nature and frequency of complications and death from measles. In none of the African and Indian study the etiologies of diarrhea associated with measles have been established. Correct etiological diagnosis of diarrheas associated with measles may bring out important existing interrelationship amongst the different pathogens involved. Recently work from the Teknaf project of this laboratory has indirectly shown that measles often produces increased susceptibility to symptomatic shigella infection.

Measles and Malnutrition:

The status of nutrition of the children seems to affect the epidemiological pattern of the disease. Protein deficiency appears to be associated with much higher incidence of complications, specially enteritis and the attack of measles accentuates the effect of malnutrition on the child (Morley et al, 1963). This has been reported frequently in such countries as Nigeria and India, though it is often difficult to separate the exact factors concerned (Morley, 1962, Taneja, 1962). Many investigators have emphasized that measles has the capacity to precipitate serious nutritional disease in children already suffering from borderline deficiency (as commonly seen in Bangladesh). Under natural condition a net deteriorating effect of measles on nutritional status is evident in many ways. Loss of body weight occurs during the acute attack. Several weeks are needed

for the weight to return to preceding level and still longer to regain the expected rate of growth. Recently it has been suggested that it is during the period of recovery from measles that we should concentrate on feeding supplements, since at this time the child both needs and wants to take more foods and therefore the calories. While the child is sick, the total food intake is often markedly reduced because of anorexia and because protein intake is less by a change in diet to liquids and starchy foods. Food supplement in a still sick child will not be utilized properly.

Socioeconomic status of population at risk and effects of seasonality:

There appears little doubt that the economic and the social conditions and changes in the environment affect the epidemiological behaviour of measles much more than any possible change in the biological characteristics of the virus itself. In cities it spreads more rapidly than in rural areas and country children have more chance of reaching adult life without catching measles than the city children (Bloomfield, 1958). Seasonal variation in incidence probably depends more on social factors than on any effects of climate on the virus. The high incidence usually observed during the winter season is probably due to indoor social gathering of peoples, giving the virus a good chance to disseminate.

Summary: Most of the data on measles has been recorded from Africa and South and Central Americas. Comparable studies from Bangladesh would be useful. Incidence of measles is not known for this country. Different ethnic group seem to react to measles in different patterns. Simple problems such as age of onset, the seasonal incidence, the nutritional effects and the diarrhea rates are unknown in regard to measles. Also unknown are the protective effects of family income on recovery of growth rates in these children. Finally the role that food supplementation may play in reducing nutritional complications and in achieving rapid growth rate has not been studied.

3. Rationale of the study:

Measles is a disease which affects all mucus membranes. Secondary infections by bacterial agents have been previously documented. There is evidence that measles also affects the digestive tract by disrupting the epithelial continuity and also perhaps by decreasing T cell responsiveness. This may explain why children with measles also have an increased number of symptomatic shigella infections.

In this studies two approaches will be followed. Diarrhea sueveillance will be used to provide age specific rates of diarrhea. Etiologies of the diarrhea will be confirmed by appropriate culture of rectal swabs. This will provide the pattern of diarrhea present in each child. Similarly growth curves will establish the pattern of growth for each child.

This will be done by performing monthly anthropometric measurements. Two times a week all mothers in the census area will be asked wheather any children has measles. If an affermative answer is obtained the diagnosis will be confirmed and a case control study instituted. By using the case control method we should be able to separate the effect of measles from what is only background infection. This will be done by matching each measles child with two control children, closely matched for location, income and social status. This data is already existing with the previously done census data.

These matched children will then be studied intensively for 7 weeks period for the following characteristics- anthropometrics, diarrhea verified by stool samples, weekly rectal swabs and dietary intake. It is assumed that most of these children will have weight loss or increase in weight. These will be documented by weekly anthropometric measurements and weight velocity curves will be compared with the control children. Stool frequency will be documented both historically and by stool sampling. Rectal swabs will be taken weekly for evaluation of the frequency of enteropathogen carriage. Agents looked for will include rota virus, toxigenic E.Coli, V.Cholerae, shigella and salmonella. This will allow us to analyze the rates of specific infection associated with measles infection compared to the controls. The effects of measles on diet intake will be determined. Diet supplementation will be given to one half of the measles cases and their controls. Differences in weight over the two week period will be determined and analyzed. Diet

will be checked so that it is known what supplementation is taken, since disease is associated with anorexia. Finally respiratory infections will be treated with erythromycin when determined necessary. It is recognized that this may affect the infection rates, but this is not certain and will be established by comparing the etiology rates of those given erythromycin versus those not given antibiotics

B. SPECIFIC AIMS:

- a). To obtain age and attack rate data on measles over a two year period at Nandipara.
- b). To document by a prospective study the measles morbidity, specifically examining the relationship between diarrhea and measles and wasting and measles.
- c). To establish whether supplemental feeding during recovery period (after the rash disappears) is useful in preventing and reversing the weight loss.
- d). In the measles placebo group relating the protective effect of income on nutritional wasting.

C. METHODS OF PROCEDURES:

1. Location of the village: Nandipara stands at a distance of 2 miles from Rasabo (Madartak) on the eastern outskirts of Dacca city with a

total population of 2000 . It takes 30 minutes by a motor vehicle from ICDDRDB to arrive at the village. Majority of the population are the Moslem immigrants from the state of Assam in India who arrived in the village in early 1962. A large portion of the adult population work in the surrounding agricultural land, but some people also work as day laborer in the Dacca city.

2. Subjects of study: 500 children of age 0-6 years without a previous history of measles will be selected for the proposed study. Subjects will be chosen selectively so as to form a closely matched homogenous group. Both male and female children will be included.

3. Study Period: The study will be carried over a period of two years, comencing 1 May 1979 and ending 30 April, 1981.

4. DIARRHEA SURVEILLANCE:

Every child admitted into the study will be visited by a field worker twice every week. Every child in the study will have a height and weight taken and nutritional anthropometrics measured at the time of admission into the study. Every mother will be asked whether any child has developed any form of skin rash on the day of visit or during the preceding days. If any skin rash is reported the child will be seen by the field worker to establish the diagnosis of measles. The field workers will be assisted by the investigators (Drs. Rabbani & Asma) by their weekly visit in doubtful cases of diagnosis. Other informations on the study children will include presence or absence of diarrhea (4 or more loose stools in the previous 24 hours), dysentery (mucoid and bloody stool) , fever, cough, ano-

rexia, draining ears and vomiting. For each measles case, two closely matched control cases will be selected (case control study) from the non measles cases and will be similarly followed by diarrhea surveillance and anthropometric measurements.

Rectal Swabs: When a child has diarrhea (measles case or from the control group) 2 rectal swabs will be taken. One will be placed in Cary-Blair transport media and the other in phosphate buffer saline (PBS-pH 7.4). All swabs collected in the village will be brought to the ICDDRB laboratory in the same evening for plating. Swabs will be plated on Mansoor's agar (SP), SS and Mac Conkey's agar and the plates incubated for 18-24 hours. The plates will be looked for *V.Cholerae*, *Shigella* and *Salmonella*. From the Mac Conkey's plate 5 lactose positive colonies will be picked that are typical of *E.Coli* and will be stored in blood agar slant for testing of LT by using either Chinese hamster ovary cell assay or Y_1 Adrenal cell assay. Two of the colonies will be tested for ST by infant mouse assay. Swabs in the PBS will be preserved frozen until they can be tested for rota virus antigen by the Elisa assay. Another stool sample will be taken to ICDDRB in MIF (merthiolate-iodine-formalin) and will be microscopically examined for the presence of ova and parasites.

General Medical Care:

Study subjects will not be given any special attention except for the clinical service presently being offered to the whole village by the

weekly medical service program organized by Dr. B. Seaton and Dr. Rabbani. But the physician may provide simple treatment with aspirin, iron & multi-vitamin, spirit or dettol for wounds and skin ointment. Confirmed shigella cases will be treated with a single dose of ampicillin (RH Gilman & H. Rabbani, 1977, CRL data, unpublished). Respiratory infections like pneumonia will be treated with erythromycin. Children having diarrhea will be treated with oral fluid electrolyte solution in their village homes. Only those cases who have moderate to severe dehydration will be brought to CRL hospital and treatment with I.V. fluid and antibiotics will be given where needed. Hospitalization of the cases will be done following a definite clinical criteria. These may include:

- a). Moderate to severe degree of dehydration.
- b). Uncontrolled diarrhea of more than 15 days duration.
- c). Severe cases of dysentery with prolapse of rectum.
- d). Post measles pneumonia with sufficient clinical indication of antibiotics and resuscitation therapy.
- e). CNS complications following measles.

NUTRITIONAL INTERVENTIONS:

Nutritional interventions will be made in measles children and control cases by giving daily feeds with Soya protein milk and biscuits and bananas. Each new measles case will be alternately assigned to one of the two groups. In one group food supplementation is given and in other

no food is supplemented. Similarly using a chart of randomized numbers, the non measles cases will be divided into two groups- one is supplemented and the other not. If any child in the supplemented control group develops measles he will be totally excluded from the study. The non supplemented children may be given some sort of nutritionally inert candy or placebo feeds. The total caloric value and the type of food given will be pre determined. Feeding programmes will be well organized, since this is the area of much irregularity and has been the subject of much criticism in many earlier studies. Feeding centers will be directly supervised by the field workers daily and also by the investigators themselves from time to time. Each child will be observed to make sure that the food has been eaten by the child during each feeding session. The parents may help the children to swallow the food. But no children or their parents will be given foods to take to their homes for later consumption.

Anthropometrics: Anthropometric measurements will be performed on all children with measles and in the control group. These measurements will be made at monthly intervals in their village homes. All nutritional data will be compared to appropriate international standard. Weights of unclothed children will be determined using spring scales in kilograms. All subjects below 3 years will have their lengths measured in centimeters in recumbent position by a portable measuring board and for subjects more than 3 years old, heights will be directly read from a vertical scale with child in erect position. Upper arm circumference will be measured in centimeters

and triceps skin fold will be measured in millimeters by a hand calipers according to the technique suggested by Jelliffe (Dr.Black's on going diarrhea - growth study at Matlab).

Data Analysis:

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

- 1). Determination of age specific attack rate of measles in Bangladeshi children below 6 year's of age.
- 2). Diagnosis of the etiological agent of diarrhea and dysentery associated with measles.
- 3). Incidence of re-infection by specific diarrheal agents in measles associated diarrhea and diarrhea without measles.
- 4). Number of diarrheal attack per child per year will be compared in children with measles and those without measles.
- 5). Whether supplemental feeding during early convalescent period in measles associated diarrhea can achieve the normal catch up growth for the average children . For this growth curves of different groups will be compared.

- 6) Whether supplemental feeding can prevent development of post measles complications.
- 7) What is the role of income in the prevention of post measles complications.
- 8) Is there any effect of climate on the relative incidence of measles and its associated complications.

Statistical Principles:

The informations collected through the questionnaires and examinations (enclosed with the protocol) will be transferred directly on to the IBM cards without any intermediate coding and analysis will be performed by using the computer. The parameters of this study will mainly be the rates, such as measles attack rate, diarrhea attack rate etc. The comparison of measles and diarrhea rates among various demographic (age, sex), nutritional socio-economic group will be done through statistical tests such as χ^2 , t tests and analysis of variance (ANOVA) technique will be applied for the significance test.

D. SIGNIFICANCE: (See Rationale)

E. FACILITIES REQUIRED:

1. Office space for Drs. Rabbani, Asma & Montaz: The present office will be utilized with a little modifications of furnitures like desk, table, file cabinet etc.
2. Laboratory Space: CRL existing lab will be used.

3. Hospital Resources: None.
4. Animal Resources: 10,000 suckling mice for ST assay.
5. Logistical Support: Data processing and computer support from the statistical branch.
6. Major items of equipment:
 - Weighing scales - 2
 - Measuring board - 2
 - Vertical Scale - 2
 - Hand Callipers - 3
7. Others: None.
8. Transport: Transport will be supported by the existing transport facilities.

(F). COLLABORATIVE ARRANGEMENTS:

- a). Collaborative arrangements may have to be sought for ELISA assay for the detection of Rota virus, depending upon the existence of CRL lab facilities.
- b). Food materials may be obtained from World Food Program/FAO or other aid giving agencies.

: 1 :

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Abstract Summary: Cohort study of measles, diarrhea and nutrition and the effect of supplemental feeding on measles associated malnutrition.

1. This study will be conducted on a cohort of 500 children of both sexes from 0-6 year's age at Nandipara over a period of 2 years. This age group has been selected because measles appears to be most common in this age group and in which both complications and mortality is relatively high. History regarding the onset of measles or diarrhea will usually be gathered from the parents or any other responsible adult member of the family, in addition the sick child will be seen both by the field workers and the physicians. All new births that will occur during this period will be included in the study.

2. As this study will mostly collect descriptive epidemiological data on measles, diarrhea and nutrition, there involves no risk as related to the physical, psychological, social, legal or other aspects of the subject. Procedures to be performed are - collection of rectal swabs and stool samples and monthly measurements of height, weight and arm circumference. When a child has measles, simple treatment with aspirin, cough syrup etc may be given and when complicated by diarrhea or dysentery they will be appropriately treated at their homes or be brought to CRL hospital in severe cases.

3. Does not apply.

4. Data collected will be computerised and confidentiality will be maintained by locking the files in the cabinet until completion of the study. All data will be abbreviated and will be published without reference to subject's name and identity.

5. As the subjects are children under 5 years age, informed consent

(signed or thumb print) will be obtained from the parents or the guardians of the child at the time of admitting the child into the study.

6. Parents or responsible adult family members will be interviewed at their village homes by the visiting field workers about the history of measles or diarrhea on the day of visit or during the preceeding days. Visits by the field workers will be made two times a week for 2 consecutive years. Informations about monthly income with occupation will also be obtained.

7. The direct benefit to the subject will be a general medical care available to every child at home when they are sick with measles or diarrhea. Regular visiting by the health personnel will make them aware of their health condition which may have long term effect on the community's health in general. Children getting supplemental feeding will directly gain on health from regular high calorie intake. Knowledge of the observational data will help understanding the natural course of the disease in a particular setting which is essential in formulating hypothesis and for the development of projected control programmes.

8. Records of the informations will be kept preserved after collection from the field by the field workers. No pre-existing hospital records will be utilized.

SECTION III

A. DETAILED BUDGET

1. PERSONNEL SERVICES

<u>Names</u>	<u>Position</u>	<u>% Effort</u>	<u>Annual</u>	<u>Project Requirements</u>	
			<u>Salary</u>	<u>Taka</u>	<u>Dollars</u>
Dr Hassan Rabbani	Clinical Res Physician	50	30,504	15,252	1,016
Dr Asma Islam	Study Physician	60	26,400	15,840	1056
Dr RH Gilman	JHU (consultant)	NO	cost to ICDDR,B		
Dr Mumtaz	Study Physician	40	24,000	9,600	640
Dr. Mahmood	Head, Animal Resource	10	45,470	4,547	303
Dr. MU. Khan	Head, community studies	10	48,000	4,800	320
Mr I. Huq.	Head, Microbiology	10	30,100	3010	200
Mr. Maksood	Field Assistant	100	13,200	13,200	880
Mr. Abdul Bari.	Field Assistant	100	13,200	13,200	880
Mrs. Hazra (female)	Field Assistant	10	13,200	13,200	880
Mr. Henry Ghose	Study Clerk	20	8,520	1,704	113
Statistician	(To be named)	10	35,000	3,500	233
Key punch operator	To be named	40	14,000	5,600	373
			<hr/>		
			Sub Total :	103,453	6894

2. SUPPLIES

<u>Items</u>	<u>Unit Cost</u>	<u>Amount required</u>	<u>Project Requirement</u>	
			<u>Taka.</u>	<u>Dollars</u>
Rectal Swab for <u>V.Cholerae.</u>	Tk. 3.28	6000	19,680	1,312
Rectal Swab for Sal/Shig.	Tk. 2.50	6000	15,000	1,000
Biochem test for <u>V.Cholerae.</u>	Tk. 1.02	6000	6,120	408
Biochem test for sal/shig.	Tk. 0.80	6000	4,800	320
Culture for <u>E.Coli.</u>	TK. 2.00	6000	12,000	800
Stock culture vials.	TK. 0.50	15000	7,500	500
ST assay supplies.	\$ 0.11	6000	9,900	660
ST assay .(Mice).	Tk. 3.00	600	18,000	1200
Rota virus (ELISA).	Tk. 1.50	6000	9,000	600
Stool M.E.	Tk. 2.00	500	1,000	66
Tab Aspirin.	Tk. 90/1000	2000	180	12
Benzyl benzoate lotion.	Tk. 30/1b	10 lb	300	20
Skin ointment	Tk. 5/tube	100	500	33
Eye ointment.	Tk. 3/tube	100	300	20
Ampicillin syrup.	\$ 15.80/L	10	2,370	158
Tab multivitamins.	Tk. 90/100	10,000	900	60
Syrup multivitamin.	Tk. 20.80/1b.	30	624	41
Tab Fersolate.	Tk. 120/1000	5000	600	40
Cough syrup.	Tk. 8.50/Bot.	500	4,250	283
Erythromycin tabs.	Tk. 2000/1000	1000	2,000	133
Cotton.	Tk. 20/1b	5 lb	100	6
Spirit.	Tk. 4/1b	5 lb	20	1
Towel.	Tk. 16.00	10	160	10
Soaps.	Tk. 2.70	100	270	18
Candy.	Tk. 150/1000	5000	750	50
Balloons.	Tk. 24.00	5 gross.	120	8
Thermometer (Oral).	Tk. 5.00	20	100	6
Thermometer (Rectal).	\$ 0.55	20	165	11

IBM cards.	\$ 48/10,000	90,000	6,480	432
IBM Tapes.	\$ 8.19/tape	12	1,474	98
Pens/Papers etc.	Total :	1,500	1,500	100
Feeding shed construction.	Total:		5,000	333
Salter scales.	\$ 25.00	3	1,125	75
Skin fold callipers.	\$ 125.00	2	3,750	250
Length Board.	\$ 20.00	2	6,00	40
Recording papers.	\$ 8/roll	10	1,200	80
Boxes for scales.	Tk. 500.00	2	1,000	66

Sub Total: 139,108. 9241.

3. EQUIPMENTS:

Calculators.	6	\$ 80 Each	Tk. 4,800	\$ 320
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Sub Total: Tk.4,800 \$ 320

4. PATIENTS HOSPITALIZATION:

Number of patients days @ Tk.150.00/day:	Tk. 40,000	\$ 2666
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Sub Total: Tk. 40,000 \$ 2666

5. OUT PATIENTS CARE: None.

6. CRL TRANSPORT: @ Tk.100.00/day for 2 years: Tk. 48,000. \$ 3200

Sub Total: Tk. 48,000 \$ 3200

7. TRAVEL AND TRANSPORTATION OF PERSONS:

Local Travel: To different foreign organs offices; Tk. 3000. \$ 200
 International Travel: Attendance at meetings; Tk. 15,000 \$ 1000

Sub Total: Tk. 18,000. \$ 1200

8. TRANSPORTATION OF THINGS:

Import: None.

9. RENT, COMMUNICATION & UTILITIES:

Postage (Foreign) ;	Tk. 1,000	\$ 66
Telephone (Local) :	None	None
Telephone (US)	Tk. 2,000.	\$ 133
Talex to Baltimore.	Tk. 2,000.	\$ 133
Rent	None	None

Sub Total: Tk. 5,000. \$ 332

10. PRINTING AND REPRODUCTION:

Forms and record sheet.	Tk. 4,000	\$ 266
Publication Cost.	Tk. 3,000	\$ 200
Reprint purchase.	Tk. 3,000	\$ 200

Sub Total: Tk. 10,000. \$ 666

11. CONTRACTUAL SERVICES:

Computer time @ Tk. 800/hour:	Tk. 25,000	\$ 1666
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Sub Total: Tk. 25,000 \$ 1666

B. BUDGET SUMMARY

	<u>Taka.</u>	<u>Dallars</u>
1. Personnel Services.	103,453	6,894
2. Supplies	139,108	9,241
3. Equipments.	4,800	320
4. Patients Hospitalization.	40,000	2666
5. Out patients care.	none	none
6. CRL Transport.	48,000	3200
7. Travel of Persons.	18,000	1200
8. Transportation of things.	none	none
9. Rent/Communications.	5,000	332
10. Printing & Reproduction.	10,000	666
11. Contractual Services.	25,000	1,666
12. Measles Vaccine.	To be added	

 Grand Total: Tk. 393,361

\$ 26,185

Conversion Rate: (Tk. 15.00 equals \$ 1.00)

INTERNATIONAL CENTER FOR DIARRHEAL DISEASE RESEARCH
BANGLADESH

(Consent Form)

I understand that International Center for Diarrheal Diseases Research, Bangladesh is running a research project at Nandipara to study the interrelationship between measles (lunti), diarrhea and malnutrition. From this study it will be possible to know what is the causal agent of diarrhea associated with measles and the value of dietary intake in preventing the development of post measles complications such as weight loss, respiratory infections, diarrhea etc. I also understand that my child if less than 6 years can participate in this study. If I consent to take part in this study with my child, I can expect the following:

- a). A field worker will regularly visit the child at home and will take height, weight and other body measurement which will not cause any pain or injury to the child.
- b) If the child develops measles during any time, the type and duration of illness will be recorded. Stool samples and rectal swabs will be taken when the child has diarrhea or dysentery. As there is no specific treatment for measles, cases with dysentery or other complications will be appropriately treated with medicine. Cases which require IV fluid will be taken to CRL hospital and treated accordingly.
- c). Monthly measurements will be performed on the child to determine the height, weight and arm circumference.
- d). If the child falls in the test group, he/she will be given some daily food for some period. But if the child falls on the control group by a lottery basis, he will not be given any foods. Though some candy or similar food may be considered.
- e). You have complete liberty to take your child off the study at any time and no penalty will be offered in such cases.
- f). All the records will be kept confidential.

If you want to participate, then sign your name below.

Signature _____
Date _____

আন্তর্জাতিক ডায়োরিয়া গবেষণা কেন্দ্র ভাঙ্গা বাংলাদেশ

সম্মতিপত্র

হায়, ডায়োরিয়া ও প্লুর্সিহীনতা এ তিনটি ব্যাধির মধ্য পারস্পরিক সম্পর্ক নির্ণয়ের জন্য আন্তর্জাতিক ডায়োরিয়া গবেষণা কেন্দ্র একটা গবেষণা চালাচ্ছে। হাঙ্গের সঙ্গে বা পরে, ডায়োরিয়ার কি কারণ এবং প্লুর্সি নিয়ন্ত্রণের মাধ্যমে হাঙ্গের জটিলতা কতটুকু হ্রাস কিম্বা নিবারণ করা যায় এ গবেষণায় তা ধরা পড়বে। নিম্নের শর্তাবলী গািলন করলে আমরা ৬ বছর কিম্বা তার চেয়ে ছোট ছেলে/মেয়ে এ গবেষণায় অংশ গ্রহন করবে।

- (১) কোন ব্যথা বা আঘাত না দিয়ে গবেষণা কর্মী প্রতিদিন ছেলে/মেয়ের ওজন উচ্চতা এবং দেহের অন্যান্য পরিমাপ সংগ্রহ করবে।
- (২) পরিদর্শন চলা কালে কারও হাম দেখা ^{দিলে} রেকর্ড করা হবে। ডায়োরিয়া চলাকালে গায়খানা এবং রেকটাল মোয়াব সংগ্রহ করা হবে।
- (৩) পরীক্ষার্থী কিছু ছেলে/মেয়েকে কিছুদিন কিছু খাবার দেয়া হবে।
- (৪) ইচ্ছা করলে ছেলে/মেয়েকে যে কোন সময় গবেষণা থেকে প্রত্যাহার করা যাবে। শুধুমাত্র কোন ক্ষতিগূরন দিতে হবে না।

গবেষকের স্বাক্ষর
৩১৫

স্বাক্ষর/টিপসহি
৩১৫

MEASLES-DIARRHEA STUDY

(Study subject selection at Nandipara)

<u>Census No</u>	<u>Name</u>	<u>age</u>	<u>sex</u>
	Date of birth _____		
	Weight (Kg) _____		
	Length (mm) _____		
	Arm circumference (mm) _____		
	Skin fold thickness (mm) a) _____ b) _____ c) _____	Mean _____	
	Previous history of measles:	YES	NO

ISOLATION RATES OF
SHIGELLA, SALMONELLA E.COLI, V.CHOLERAЕ & ROTA VIRUS FROM DIARRHEA STOOLS OF
CHILDREN WITH & WITHOUT MEASLES

Age	Children with Measles						Children without Measles					
	Tot.No.of cases	No.with Shigella	No.with E.H.	No.with E.coli	No.with cholera	No.with rotavirus	Tot.no.of cases	No.with Shigella	No.with E.H.	No.with E.coli	No.with Cholera	No.with rotavirus
0-6 mnths												
1 yr.												
2 yrs.												
3 yrs.												
4 yrs.												
5 yrs.												
6 yrs.												
All ages	Tot.Nos.of cases	____%	____%	____%	____%	____%	Tot.Nos. of cases	____%	____%	____%	____%	____%

TABLE -

MEASLES, DIARRHEA AND DEATH (OVER 2 YEARS OBSERVATION)

Age	Total Children	Children with Measles			Children without Measles		
		No. of Children	cases developed diarrhea	Death Occured	No of child	cases developed diarrhea	Death Occured
0-6 m							
-1yr							
-2yrs							
--3yrs							
-4yrs							
5yrs							
6yrs							

MONTHLY INCOME
and DEVELOPMENT OF COMPLICATIONS OF MEASLES

Monthly Income Per family in Taka	Complications of Measles			
	Diarrhea	Dysentery	Resp. Inf.	Others
> 300				
300-500				
500-700				
700-1000				
1000-1500				
> 1500				

Nos Positive Over Total (%)

Average Monthly Income throughout the year.

EFFECTS OF SEASONALITY

Distribution of Measles Cases Throughout the Year
(Observations of 2 years)

Age Groups of measles children	Spring	Summer	Monsoon	Winter
	March-May	June-July	Aug-Oct	Nov-Feb
0-6m				
1yr				
2yrs				
3yrs				
4yrs				
5yrs				
6yrs				