

Attachment 1.
(FACE SHEET)

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Date 9/3/92

31/3/92

Principal Investigator Dr Hasan Ashraf

Trainee Investigator (if any) 22

Application No. 92-009

Supporting Agency (if Non-ICDDR,B) _____

Title of Study "Effect of Folic Acid
in acute diarrhoea in children"

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 ☒

Does the study involve:

- (a) Use of records, (hospital, medical, death, birth or other) Yes ☒ No ☐
(b) Use of fetal tissue or abortus Yes ☐ No ☒
(c) Use of organs or body fluids Yes ☒ No ☐

Are subjects clearly informed about:

- (a) Nature and purposes of study Yes ☒ No ☐
(b) Procedures to be followed including alternatives used Yes ☒ No ☐
(c) Physical risks Yes ☒ No ☐
(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 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.

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

Hasan Ashraf
Principal Investigator

SECTION I - RESEARCH PROTOCOL

1. TITLE : EFFECT OF FOLIC ACID IN ACUTE
DIARRHOEA IN CHILDREN
2. PRINCIPAL INVESTIGATOR : Dr Hasan Ashraf
CO-INVESTIGATOR : To be named.
PROJECT CO-ORDINATOR : Dr D Mahalanabis
3. STARTING DATE : April 1, 1992
4. COMPLETION DATE : September 30, 1993
5. TOTAL DIRECT COST : US\$ 27,375.
6. SCIENTIFIC DIVISION : This programme has been approved
by the Clinical Science Division.

D Mahalanabis

Signature of the Associate Director,
Clinical Science Division.

Date: _____

7. ABSTRACT SUMMARY:

Rotavirus and other non-cholera diarrhoea are important cause of severe diarrhoea in infants and children, often requiring hospitalization. As oral rehydration therapy does not reduce the severity and duration of diarrhoea, demand for useful drug is very high. Some limited study suggests that administration of oral folate during acute phase of infantile and early childhood (1-44 months) diarrhoea shortens the duration of diarrhoea, irrespective of whether the illness is caused by rotavirus. Folic acid have been shown to have no appreciable adverse effect in children. The addition of oral folate therapy to standard rehydration therapy is cheap, non-allergenic and readily available and it may reduce the duration of both rotaviral and non-rotaviral diarrhoea in infants and children. This may have important implication in shortening hospital stay, thus cutting costs and probably in reducing mortality. Folic acid therapy also improves clinical state readily in tropical sprue, which is a type of chronic diarrhoea.

In a double blind randomized study a total of 160 male patients aged 6-36 months with a history of watery diarrhoea less than 72 hours duration will receive either oral folate at a dose of 5 mg 8 hourly for 5 days or placebo for 5 days.

The study will be carried out in the study ward. Patients will be thoroughly screened before being entered into the study. Patients will remain under constant supervision of the experienced nurses. Investigators will be looking after the patients during the working hours on daily basis and will be available in any need for the patient. Appropriate measures will be taken whenever any complication arises.

On admission, stool microscopy, ELISA for rotavirus, culture for Salmonella, Shigella, Vibrios and Campylobacter will be done. E. coli colonies will be picked up and tested for toxins. Blood for total count of W.B.C., differential count, haematocrit, electrolytes, total protein, albumin will be taken on admission and repeated after 48 hours (2 ml). Serum folate level will be measured on admission and will be repeated during discharge. Six hourly intake and output measurements will be done by trained nurses using urine bags and cholera cots. All the patients will be admitted into the study after voluntarily signing a consent form by parents or legal guardian and will be kept under strict medical supervision by the investigators. All medical records will be kept confidential and remain with the investigator.

8. REVIEWS:

- a) Chairman, Research Review Committee: _____
- b) Chairman, Ethical Review Committee: _____
- c) Director, ICDDR,B : _____

SECTION II - RESEARCH PLAN

OBJECTIVES:

To determine the efficacy of folic acid in acute watery diarrhoea in children in:

- a) Reducing stool output(g/kg),and in
- b) Reducing duration of diarrhoea(hrs).

BACKGROUND:

Diarrhoea continued to be a leading cause of morbidity and mortality among children less than 5 years old in many parts of the world. Of the 15 million deaths occurring each year in children under 5 years in developing world approximately 4 million are associated with diarrhoea. Treatment of acute diarrhoea in children focuses on oral rehydration. In rotavirus gastroenteritis, the absorptive cells on the tips of the small intestinal villi are badly damaged and are replaced by upwardly migrating epithelial cells lining the crypts of lieberkuhn. Since folic acid has a key role in celluler DNA synthesis, we have decided to evaluate the effect of folic acid on severity and duration of diarrhoea among children admitted to the Clinical Reasearch Centre, ICDDR,B, many of whom have rotaviral gastroenteritis.

The results from previous study in South Africa(1) showed that the administration of oral folate during acute phase of childhood diarrhoea significantly shortens the duration of diarrhoea, irrespective of whether the illness is caused by rotavirus. The administration of folate was not designed to correct any deficiency. Folate has a role in renewal of epithelial cells of small bowel mucosa. Therefore, the most likely mechanism of folate's action would be an acceleration of the normal regeneration of the damaged epithelial cells in the intestinal brush border. So, a randomised and double blind clinical trial is necessary to evaluate the efficacy of folate in acute diarrhoea in children.

RATIONALE:

1. Rotavirus and other non-cholera diarrhoea are important causes of severe diarrhoea in children, often requiring hospitalization.
2. Existing treatment of diarrhoea due to rotavirus, enterotoxigenic E.coli and other non-cholera diarrhoeas includes a) replacement of fluid and electrolyte loss due to diarrhoea and vomiting, mainly with oral rehydration therapy (ORT) and b) appropriate feeding during and after diarrhoea to minimise nutritional consequences.

3. ORT does not reduce the severity and duration of diarrhoea and therefore, demand for useless and often harmful drug is very high.
4. Results of clinical trials with various antidiarrhoea drugs have been dissappointing; it is therefore important to evaluate new approaches to develop antidiarrhoea medicines.
5. Some limited study suggests that administration of oral folate during acute phase of infantile and childhood (1-44 months) diarrhoea may shorten the duration of diarrhoea, irrespective of whether the illness is caused by rotavirus.
6. Folate deficiency, which may lead to impairment of both cell mediated and humoral immunity, caused not only more severe rotaviral diarrhoeal disease in mice but also result in inhibition of weight gain during recovery.
7. Folic acid has little or no side effects in children.
8. The addition of oral folate therapy to standard rehydration therapy is cheap, non-allergenic and readily available and it may reduce the duration of both rotaviral and non-rotaviral diarrhoea in infants and children. This may have important implication in shortening hospital-stay, thus cutting costs.
9. Folic acid therapy improves the clinical state readily in tropical sprue which is a type of chronic diarrhoea commonly seen in older children and adults in this subcontinent.
10. We know that there is intestinal cell damage due to rotavirus. These damaged cells regeneration may be assisted by folate.
11. The major attraction of this protocol is the possibility of a simple additive to ORS which could significantly shorten diarrhoea. If it is not true, this would also be important in view of the Lancet paper(1).

OUTCOME VARIABLES:

1. Duration of diarrhoea(hours).
2. Stool output : The weight of stool in g/kg of admission body weight from admission to 24 hours and for the entire duration of diarrhoea.

MATERIALS AND METHODS:

The study will be conducted in the clinical research centre of ICDDR,B. Every year about 70,000 patients are treated in this centre, 60% of whom are below the age of 3 years. The study will be conducted for a period of 18 months from the date of starting the study.

INCLUSION CRITERIA:

1. Males aged 6 months to 3 years.
2. History of acute watery diarrhoea of <72 hours duration and had 4 or more liquid stools over 24 hours prior to admission.
3. The child has some signs of dehydration.
4. Nutritional status: Wt. for height > 70% of N.C.H.S. median.

EXCLUSION CRITERIA:

1. Systemic infection requiring prompt antibiotic treatment e.g. pneumonia, meningitis, septicaemia.
2. History of bloody diarrhoea (gross blood in stool).
3. Clinically apparent marasmus or kwashiorkor or marasmic kwashiorkor.
4. Patients suffering from cholera.
6. Any rehydration therapy (intravenous), antibiotics or antidiarrhoeal drugs given during the week before admission.)

SAMPLE SIZE CALCULATION:

From the data of Haffeejee (1) we assume that there will be a 20% reduction of duration of diarrhoea in the folic acid group compared to control group. Taking power as 80% and significance level as 0.05 (Mean duration = 92 hours, S.D.= 39).

$$n = \frac{2(S.D.)^2}{(W.D.)^2} \times 8 = \frac{2 \times (39)^2}{(18.4)^2} \times 8 = \frac{2 \times 1521}{338} \times 8$$

$$= \frac{3042}{338} \times 8 = 9 \times 8 = 72 \text{ in each group.}$$

Assuming a 10% dropout, the total sample size should be 80 in each group.

(S.D. = Standard Deviation; W.D. = Worthwhile difference between means of diarrhoea duration in hours).

From the data of FC Patra et al(17), we assume that there will be a 25% reduction of total stool output (ml/kg) in the folic acid group compared to control group. Taking power as 80% and significance level as 0.05 (Total stool output 253 ml/kg; S.E. 39.0)

$$S.D. = S.E. \sqrt{n}$$

$$(S.D.)^2 = (S.E.)^2 \times n = 39 \times 39 \times 24$$

$$n = \frac{(S.D.)^2}{(W.D.)^2} \times 8 = \frac{39 \times 39 \times 24 \times 8}{63 \times 63} = \frac{292032}{3969} = 73.$$

Assuming a 10% dropout, the total sample size should be 80 in each group.

(S.D.= Standard Deviation; W.D. = Worthwhile difference between means of total stool output in ml/kg; S.E. = Standard Error).

STANDARD MANAGEMENT AND EXPERIMENTAL TREATMENT:

PATIENT RECRUITMENT:

Children presenting at the CRC, ICDDR,B with a history of watery diarrhoea of 3 days or less and 4 or more liquid stools during 24 hours will be evaluated and if they fulfil the remaining inclusion and exclusion criteria will be admitted to the study.

INFORMED CONSENT:

If the patient is found suitable for inclusion into the study an informed consent will be obtained (English and Bangla consent form attached). The consent form will be administered by one of the investigators and then will be witnessed by another staff member.

CASE MANAGEMENT:

Patient will receive routine care which includes a) replacement of fluid and electrolytes mainly with ORT supported by I.V. treatment for those who need it; b) unrestricted breast feeding of those still breastfed during rehydration and maintenance therapy, and c) formula milk for non-breastfed children starting after initial rehydration period and d) semisolid and solid food appropriate for age during maintenance fluid therapy.

Oral folate will be administered to half of the patients at a dose of 5 mg 8 hourly for 5 days. In the control group placebo will be given identical in appearance to folate for 5 days.

CRITERIA FOR INTRAVENOUS FLUID:

1. Severe dehydration.
2. In patients whose hydration status cannot be maintained adequately orally or patients with intractable vomiting.
3. Patients with gross electrolyte imbalance requiring correction by appropriate intravenous fluid.
4. Patients developing paralytic ileus.

DEFINITION OF TREATMENT FAILURE:

1. Appearance or reappearance of signs of dehydration anytime after initial hydration.
2. Increase of stool volume to more than 200g/kg/day during any 24 hour period or to more than 2000 ml in any 24 hour period.
3. Stool volume greater than 60g/kg/day on day-5 of the treatment protocol.

SUMMARY OF PROCEDURE (BASELINE EXAMINATION):

A standard history and a thorough physical examination will be carried out after admitting the patient into the study by one of the investigators. Patient will be weighed and the following investigations will be done.

- a) Fresh stool for microscopy.
- b) Fresh stool for culture for Shigella, Salmonella, Vibrios and E.coli.
- c) Stool will be tested for rotavirus antigen.
- d) Blood for T.C., D.C., Hct., serum glucose (random), serum folate.
- e) Blood for electrolytes (Na⁺,K⁺,Cl⁻,TCO₂),serum sp.gr.,pr.(2ml of blood will be required for the test mentioned).
- f) Intake and output measurements will be instituted using urine bags and cholera cots.

During the course of illness-

- i) Patients will be evaluated every 8 hours and intake/output measurements will be summarised from tally sheets.
- ii) Patients will be weighed and physical examination findings will be recorded and time of cession of diarrhoea noted.
- iii) A second blood sample will be taken after 48 hours for Hct., plasma total solids and electrolytes(2ml).
- iv) A third blood sample will be taken for serum folate on Day-5.

RANDOMIZATION:

The patients in the study group will receive rehydration and maintenance fluid along with folic acid. While those in the control will receive rehydration and maintenance fluid with placebo. The medicine and placebo will be identical in appearance and packaged in identical containers. The containers will be arranged in a sequence of drug and placebo that corresponds to the randomization code then numbered sequentially. Containers of medicine with serial number will contain drug or placebo tablets according to master randomization chart.

DATA ANALYSIS:

The study groups will be compared for all the variables prior to intervention. Major outcome variables will be compared after evaluating their descriptive statistics for distribution etc. The quantitative outcome measures will be compared using students 't' test on primary data or after appropriate transformation when indicated and also by an equivalent nonparametric test e.g. Mann Whitney U test. Dichotomous outcome measures will be compared by (x)² test or Fisher's exact test as appropriate.

IMPORTANT DEFINITIONS:

1. Duration of diarrhoea after admission: The time in hours from initiation of study treatment until passage of the last liquid or semi-liquid stool prior to two formed stools or prior to 12 hours during which no stool is passed.
2. Stool output: The weight of stool in g/kg of admission body weight expressed per time period (from admission to 24 hours or for entire duration of diarrhoea).
3. ORS and plain water intake: The volume of ORS or plain water taken in ml/kg of admission body weight expressed per time period (e.g. from admission to 24 hours, or for the entire duration of diarrhoea).

ANNEX:

Diet

Age group: 1-3 years:-

Median body weight - 12 kg
 Energy requirement - 1300 kcal/d
 Protein ' ' - 15 g/d
 Folic acid ' ' 75 ug/d

Daily food allocation:

* * Breast feeding

		Ene/kcal	Pr./g	Folic(f) (ug)	Total f.acid (ug)
Milk cereal	1000 ml	670	10.4	1.6	3.2
Khichuri	200 g	200	-	5.9	10.0
Bread	2 slice(50g)	100	-	3.0	9.0
Egg boiled	one	90	7.0	40.0	40.0
Cooked rice	200 g	240	-	5.3	6.6
Chicken/ fish	100 g	150	10.0	3.2	6.8
Cooked mixed veg.	200 g	50	-	4.5	11.8
Cooked lentil	100 g	50	-	1.5	3.6
		1550	27.4	65.0	91.0

Distribution of food:

Milk cereal - 80 ml/ feed - 2 hourly (12 feeds/d)

Breakfast :

Bread - 2 slices

Boiled egg - one

Snacks at 10 a.m : Khichuri - 100 g

Lunch at 12 Mid-day:

Cooked rice - 100 g

Cooked chicken/fish - 50 g

Mixed veg. - 100 g

Cooked lentil - 50 g

Snacks at 4 p.m : Khichuri - 100 g

Supper at 6 p.m : Same as lunch

* In terms of egg and milk

** Not accounted

* In terms of egg and milk

** Not accounted

Age group: 6- 12 months

Median body weight : 9 kg

Energy requirement : 1000 kcal/d

Protein '' : 12 g/d

Folic acid '' : 25 ug/d

Daily food allocation:

		Ene/kcal	Pr/g	Folic(f)	Total f.acid
Breast Milk	500ml	340	6.0	6.5	-
Milk cereal	800ml	535	8.3	1.3	2.56
Khichuri	200g	200	5.0	5.96	10.63
		1075	19.3	13.76	12.63

Food distribution :

Breast Milk - On demand

Milk cereal - 70 ml 2 hourly

Mixed diet(Khichuri) - 50 gms at 6 a.m, 10 a.m, 2 p.m, 8 p.m.

REFERENCES:

1. Haffejee.I.E. Effect of oral folate on duration of acute infantile diarrhoea. The Lancet, Aug.6,1988.
2. Jacobo Ghitis et al. Tropical Sprue versus Primary Protein Malnutrition: Vit.B12 and Folic Acid Studies. The American Journal of Clinical Nutrition.20:1206-11,1967.
3. S.L.Gorbach et al. Tropical Sprue and Malnutrition in West Bengal. The American Journal of Clinical Nutrition.23:1545-1558,1970.
4. John Lindenbaum. Malabsorption during and after recovery from acute intestinal infection. British Medical Journal.2:326-329,1965.
5. N.D.Gallager. Importance of Vit.B12 and Folate Metabolism in Malabsorption. Clinics in Gastroenterology.12:437-441,1983.
6. Charles H. Halsted. Intestinal absorption and malabsorption of Folates. Ann. Rev.Med.31:79-87,1980.
7. Yehuda Matoth et al. Folic and Folinic Acid blood levels in diarrhoea, malnutrition and infection. Paediatrics, May,1964.
8. Thomas W. Sheehy et al. A study of the effect of folic acid on the intestinal aspects of acute and chronic sprue. Ann. of the Int. Med. 57:892-908,1962.
9. Richard Hunter et al. Toxicity of folic Acid given in pharmacological doses to healthy volunteers. The Lancet, Jan,10,1970.
10. Frederick A. Klipstein. Absorption of physiologic doses of Folic Acid in subjects with tropical sprue responding to tetracycline therapy. Blood.34:191-203,1969.
11. Weinstein W M. Epithelial cell renewal of the small intestinal mucosa. Med Clin North Am. 58:1375-86, 1974.
12. Rodriguez MS. A conceptus of research on folicin requirements of man. F. Nutr. 108:1983-2103,1978.
13. Morrey JD et al. Effects of Folic Acid malnutrition on rotaviral infection in mice. Proc Soc Exp Bio Med.176:77-83,1984.
14. Davidson GP et al. Structural and functional abnormalities of the small intestine in infants and young children with rotavirus enteritis. Acta Paediatr Scand. 68:181-186,1979.

15. Tomkins. Tropical malabsorption: recent concepts in pathogenesis and nutritional significance. Clinical Science.60:131-137,1981.
16. Haffejee.I.E. Folate for diarrhoea ? Dialogue on Diarrhoea, issue 43. Dec.1980.
17. FC Patra, D Mahalanabis, KN Jalan, A Sen and P Banerjee. Is oral rice electrolyte solution superior to glucose electrolyte solution in infantile diarrhoea ? Archives of Disease in childhood. 57:910-912,1982.

SECTION-III-BUDGET

A.PERSONNEL SERVICES:

	Rate	% of effort	US\$
Medical Officer	749	50x18m	6741
Research Trainee(Doctor)	188	100x18m	3384
Trainee Health Assistant	110	100x18m	1980
Volunteer (4)	50	100x18m	3600
			15705

B. Supplies and Materials			700
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C. Other costs			300
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D. Interdepartmental Service costs			10670
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27375

CONSENT FORM

(Statement read and clearly explained to the parents of the patients when consent is obtained.)

International Centre for Diarrhoeal Disease Research, Bangladesh is carrying out research to find out simple, effective and inexpensive treatment for diarrhoeal diseases. Your child is suffering from rotavirus or other non-cholera watery diarrhoea. Present treatment of rotavirus and other non-cholera watery diarrhoea includes replacement of fluid and electrolyte loss due to diarrhoea and vomiting mainly with oral rehydration therapy and appropriate feeding during and after diarrhoea. But as ORT does not reduce the severity and duration of diarrhoea, demand for useless and harmful drugs are very high. For the above reason, we are introducing a new drug (folate) that are being tested for their ability to treat rotavirus and other non-cholera diarrhoea. If you agree to participate into the study, your child will get either folate or identical tablets in addition to the usual conventional treatment i.e. appropriate replacement of fluid and electrolyte loss either by ORT or I.V. fluid and proper feeding. Your child has to stay in our hospital for about 5 days for full treatment. 2 ml of blood will be taken on admission, after 48 hours to determine electrolyte, complete blood counts and serum folate levels. Serum folate levels will be repeated during discharge. Stool, urine, and vomitus will be collected, measured and examined. The results of the investigations will be used to evaluate the effect of treatment. Your child will be discharged after diarrhoea has stopped and other necessary treatment completed.

Taking part in the study totally depends upon your own decision. You may withdraw your child from the study anytime and proper care will not be altered by that. If you are willing voluntarily to join in this study, then please sign your name or put left thumb impression on this consent form.

Signature of Investigator

Signature or L.T.I. of parent

Witness _____

Date: _____

(ਅਭੂਤਿਕਤਾ ਨਿਸ਼ਾਨ ਪ੍ਰਾਕਟਮ ਪਰ ਬਿਵਰਿਤ ਪਾਛੇ (ਆਨਾਨਾ) ਸ਼ਾਂਤਿ ਲਾਭ
ਪ੍ਰਾਪਤਿ ਪ੍ਰਾਪਤਿ, ਪ੍ਰੀਤਮ (ਦੇਸ਼) ਸ਼ਾਂਤਿ।)

[illegible]

এই গাছগুলো অংশগ্রহণ করা সম্ভূত হলে আপনার নিজস্ব ইচ্ছা অনুযায়ী
করা। এই গাছগুলো অংশ না নিলেও আপনার শিশু এই
প্রকল্পের মাধ্যমে শিক্ষণীয় চিকিৎসা গাছ এবং ইচ্ছা করলে (যা
আপনাকে নাম প্রত্যয় করা বাধ্যতামূলক। আপনি যদি উল্লিখিত গাছ
আপনার শিশুর শিশুর (এই গাছগুলো অংশগ্রহণ করা
গাছ, গাছ নীচের (বা উপর) দিন।

ମାଧବୀକର ସ୍ବାମୀ

ਅਭਿਯੋਗਕ

— ५२५ —

ਅਰਿਖ

CURRICULUM VITAE

1. Name: DR.HASAN ASHRAF.
2. Father's Name: Mr.Mir Ashraf Ali.
3. Date of Birth: 26th.Sept.,1955.
4. Nationality: Bangladeshi by birth.
5. Religion: Islam.
6. Marital Status: Married.
7. Educational Qualification:a) M.B.B.S. from Dhaka Medical College under Dhaka University, 1980. b) M.C.P.S.(Paediatrics) from the Bangladesh College Of Physicians and Surgeons, July, 1991.
8. Date of Joining at I.C.D.D.R,B.: 14-3-1985.
9. Present Position: Medical Officer, Clinical Research Centre, I.C.D.D.R,B.

ACADEMIC QUALIFICATIONS:

Degree	Institution	Board/Univ.	Div./Class	Year
Secondary School Certificate(SSC)	Mohammadpur Govt. High School,Dhaka.	Dhaka	First(80.6%)	1971
Higher Secondary Certificate(HSC)	Notre Dame College,Dhaka.	Dhaka	First(72.1%)	1973
M.B.B.S.	Dhaka Medical College,Dhaka.	Dhaka University	Passed (Regular)	1980
M.C.P.S. (Paediatrics)	Bangladesh College of Physicians and Surgeons		Passed	1991 (July)

EXPERIENCES:

- (a) In-Service Trainee Doctor: In Dhaka Medical College Hospital from 11-3-81 to 10-3-82.
- (b) Medical Officer, Mohammadpur Thana Health Complex, Jessore from 11-3-82 to 18-12-82.
- (c) Assistant Surgeon, Bangladesh Railway Hospital, Chittagong from 19-12-82 to 31-8-84.
- (d) Resident Medical Officer, Dhaka Shishu (Paediatric) Hospital from 1-9-84 to 13-3-85.
- (e) Medical Officer, Clinical Research Centre, I.C.D.D.R, B. from 14-3-85 till now.

Total duration of experience: 11 years.

TRAINING ACTIVITIES:

- (a) Participated as a faculty Member in several International and National training courses on diarrhoeal diseases at I.C.D.D.R, B.
- (b) Participated in the International Workshop on Clinical Research Methods in Diarrhoeal Diseases at I.C.D.D.R, B, 1989.
- (c) Participated in the WHO/ADDR Workshop on Algorithm for the management of Persistent Diarrhoea held in New Delhi, 1991.
- (d) Participated in the Research Methodology Workshop at I.C.D.D.R, B., 1991.

CURRENT RESEARCH ACTIVITIES:

- (a) Working as a Co-Investigator in the study " Evaluation of hyperimmune bovine colostrum in the treatment of shigella in children."

ABSTRACTS PUBLISHED:

- (a) S.K.Roy, M.Shahrier,H.Ashraf, M.Akramuzzaman, A.N.Alam, S.A.Sarker, R.Haider, H.Rahman and N.Majid. " Characteristics of persistent diarrhoea patients and their response to dietary management. 5th. Asian Conference on Diarrhoeal Diseases,Sept. 1989, Kathmandu, Nepal.
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- (c) Mitra AK, Mahalanabis D, Ashraf H, Tzipori S, Unicomb L, Eeckles R. Hyperimmune bovine colostrum reduces diarrhoea due to rotavirus: a double-blind, controlled clinical trial (Abstract). In: Programme & abstracts; proceedings of the Annual Scintific Conference of ICDDR,B, Dhaka, 26-28 October 1991. Dhaka: International Centre for Diarrhoeal Disease Research, Bangladesh, 1991:53-54
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NEW PROTOCOL:

1."Effect of Folic Acid in acute watery diarrhoea in children" Will work as a Principal Investigator of this study which will start very soon.

2."Algorithm for the management of persistent diarrhoea in hospitalized children in Bangladesh."

Will also work as a Principal Investigator of the study which will start in March, 92.