

Library (2)

Attachment 1.

Principal Investigator Dr Asma Islam

Trainee Investigator (if any) 22

Application No. 87-017

Supporting Agency (if Non-ICDDR,B) _____

Title of Study A case control study

Project status:

of risk factors for dehydrating diarrhoea
in children.

- New Study
- Continuation with change
- No change (do not fill out rest of form)

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

- Source of Population:**
- (a) Ill subjects Yes No
 - (b) Non-ill subjects Yes No
 - (c) Minors or persons under guardianship Yes No
- 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 N.A Yes No
 - (d) Sensitive questions N.A 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 NA 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.

(PTO)

Asma Islam
Principal Investigator

A-034087

JUN 23 1987

Trainee

87-017

22.06.87

SECTION I : RESEARCH PROTOCOL

1. Title : A case control study of risk factors for dehydrating diarrhoea in children.
2. Principal investigator : Dr Asma Islam
Co-investigators : Dr J.D. Clemens
Physicians (to be named)
3. Starting date : As soon as fund is available.
4. Completion date : One year after the date of start
5. Source of fund : Request made to WHO
6. Total direct cost : US \$34,475.00
7. Scientific programme: This protocol has been approved by the Clinical Sciences Division



Signature of Division Head

Date 22.6.87

8. Abstract summary

To determine the risk factors for development of dehydration, a case-control study will be conducted at ICDDR,B, Dhaka Hospital. Five hundred and four children aged 0-35 months with acute diarrhoea attending the Dhaka Hospital will be studied. Patients will be randomly assigned to either a case or control group as per definition. Cases will be patients with moderate and severe degree of dehydration. Patients with none or mild degree of dehydration will serve as controls. Cases and controls will receive the usual treatment practised at ICDDR,B.

On admission a physician will take a detailed history of illness and immunization status and perform physical examination to assess degree of dehydration and other signs of illness. Stool will be examined microscopically and cultered for enteric pathogen. The care taker or mother of the children will be interviewed by an interviewer on management of diarrhoea at home, feeding practices before onset of diarrhoea, during diarrhoea and hygienic practices. The interviewer will not be informed about the association of risk factors to the outcome. The interviewer will also weigh the child on admission and at 8 hours (after rehydration). The length/height and mid-arm circumference will be measured after rehydration. Information on socio-demographic aspects will also be collected by the interviewer. Each subject will be followed at their home within 1 week of discharge by an interviewer to observe mothers' feeding practices and hygienic behaviours.

Reviews:

- (i) Ethical Review Committee: _____
- (ii) Research Review Committee: _____
- (iii) Director, ICDDR,B : _____

SECTION II : RESEARCH PLAN

A. INTRODUCTION

1. Objective

To identify risk factors for developing severe or moderate dehydration in children less than 3 years of age suffering from acute watery diarrhoea.

2. Background

Diarrhoeal disease continues to be one of the leading causes of childhood morbidity and mortality in developing countries. In Matlab, Chen LC et al. reported diarrhoea to be a significant cause of death among children in rural Matlab (1). The majority of these diarrhoeal deaths are due to dehydration (2). Studies have shown that duration of diarrhoea is prolonged in malnourished children (3,4). There are differences in hygienic practice in families between high and low diarrhoea rates (5). Handwashing and breast feeding practices reduce the spread and severity of shigellosis (6,7). But relatively very little is known about the difference in risk factors leading to death in some diarrhoeal episodes while self-limiting in others.

3. Rationale

Although oral rehydration therapy has been a major achievement in treating dehydration due to diarrhoea but it has certain limitations for the treatment of severe dehydration and its effectiveness in unspecialised use in the community remains uncertain. Death in acute diarrhoea is most often due to severe dehydration which results from loss of body water and salts. Factors which contribute to the development of severe dehydration in some while not in others have not been investigated. Such investigation would result in better understanding and identifying the risk factors (demographic, socio-economic, hygienic, etiologic, nutritional and dietary). This would allow the development of appropriate interventions to prevent severe dehydration and thereby reduce diarrhoeal deaths. This research would also be helpful in developing more effective ways of implementing

control strategies for diarrhoeal diseases according to the geo-cultural needs of the country.

B. SPECIFIC AIMS

(a) To determine whether early home therapy with home fluids and oral rehydration salt solution prevents development of dehydration during an episode of diarrhoea.

(b) To evaluate the role of breast-feeding and weaning practices in reducing the risk of developing dehydration.

(c) To evaluate the role of hygiene practices with regard to water use, disposal of excreta and handwashing after defecation and its effect on the development of dehydration.

C. EXPERIMENTAL DESIGN AND METHODOLOGY

A clinic-based case-control study is being proposed in order to resolve the unethical, practical and logistical drawbacks of closely following a child suffering from diarrhoea to observe development of severe dehydration.

STUDY AREA

The study will be conducted in Dhaka Hospital, ICDDR,B because of logistical and technical feasibility. During 1985, 57350 patients received care free of charge at the Treatment Centre. The treatment centre provides care to the impoverished urban dwellers. Patients are received from a distance of $1/2$ mile to 20 miles of the treatment centre. The hospital is supported by a pathology and microbiology and a biochemistry laboratory. Since 1979, 4 percent of all patients presenting for care of diarrhoea at this hospital have been systematically sampled and evaluated for epidemiologic clinical characteristics as well as for diarrhoeal pathogens. Distribution of patients by month, age and dehydration are presented in Tables 1 (a,b), 2 and 3.

STUDY POPULATION

Children aged 0-35 months, attending the Treatment Centre, Dhaka Hospital with a history of acute watery diarrhoea will be selected for the study by the following definition of cases and controls:

Definition of cases: Cases are those children with moderate or severe dehydration assessed by clinical symptoms and signs.

Definition of controls: Controls are those children with mild or no dehydration as per clinical symptoms and signs.

Definition of acute watery diarrhoea:

Diarrhoea which is watery or liquid in nature and without blood and of duration of less than 7 days. Infants and children aged < years: an increase in the frequency plus a change in the consistency of stool which is of concern to the mother.

Selection procedure for cases and controls

Criteria	Cases	Controls
1. Age	0-35 months	0-35 months
2. Reason for attendance	Watery diarrhoea	Watery diarrhoea
Duration	<7 days	<7 days
Dehydration	Severe/moderate	Mild/none
3. Dehydration signs:		
(a) Loss of skin elasticity	Yes	No
(b) Sunken eyes		
(c) No urine in last 12 h		
(d) Sunken fontanelle	At least one of b-e	None
(e) Pulse rapid, feeble pulses		
4. Interviewee: Person generally responsible for child care.		
5. Exclusion criterion: Child accompanied by someone who is not generally responsible for child.		
Sampling method	All eligible	One control/case chosen to give similar age distribution to cases (systematic sampling)

SAMPLING PROCEDURES

Source: Cases and controls will be selected according to the criteria set above from the attendances at the Dhaka Treatment Centre of ICDDR,B round the clock in order to include all cases which might arrive at night and also to meet a representative selection from the same population.

DETERMINATION OF SAMPLE SIZE

The number of cases and controls is calculated by assuming a power of 90% to detect risk factors at 5% significant level and the associated relative risk levels of the order of ≥ 2 . The following table presents the sample size required by each risk factor to detect a relative risk of ≥ 2 . Estimates have been made of the prevalence of exposure among the controls for each of the different risk factors according to Schiesselman JJ (8).

Risk factor	Prevalence	Relative risk to be detected	No. of children required (<3 years)
Breast feeding	50%	> 2	182
Home therapy	50%	> 2	182
Bad hygiene practice	20%	> 2	229
Sample size for both groups		= 229 x 2 groups	= 458
Added for refusals		10%	= 46
Total number of study population			504

Both cases and controls will be selected from 4% systematic sample of all patients presenting to triage area of Dhaka Hospital by a paramedic. An attendance register will be maintained by the paramedics at the triage for those selected in 4% sample (Surveillance patients). The register will include age of the child, sex, address, date and time of attendance, type and duration of diarrhoea, signs of dehydration, reasons for refusal etc. The register will provide selection of cases

and controls. As mentioned earlier all children qualifying as cases and controls will be enrolled around the clock. The nurse on duty at the triage will be instructed by the P.I. to refer the cases and controls. Approximately one control per case will be selected. Based on the surveillance data (Table 3) the number of cases and controls less than 3 years are 197 and 710 respectively. Therefore, it is expected that all cases and every other control will be selected by systematic numbering of hospital identification number so as to meet the requirement of one control per case. The number of children required to detect risk factor of hygienic practices is slightly low according to surveillance data but calculations made accordingly are reasonable to detect the relative risk with a power of 90%.

ETHICAL ISSUES

An informed consent from the mother or the caretaker of the child will be obtained before the study is undertaken after explaining to them the nature and purpose of the study.

COLLECTION OF DATA

After enrollment in the study a detailed history of illness and immunization will be recorded and physical examinations performed by a physician with particular attention to degree of dehydration. Since the etiology of diarrhoea is an important variable responsible for the development of dehydration, stool for microscopic examination and culture for rotavirus, C. jejuni, EPEC, ETEC, and shigella will be performed at ICDOR, B on enrollment in the study. Each subject will also be interviewed by a trained field research officer who will not be informed about the association of risk factors to the outcome nor about case/control status and will collect information on demographic and socio-economic characteristics, breast-feeding history, weaning practices, diarrhoea management at home with home fluids and drugs,

dietary history before and during diarrhoea. Anthropometry will also be taken by the interviewer - weight/height/length and mid-arm circumference on admission, weight repeated at 8 hours of hydration and at discharge. Appendix I, II, III, IV and V show the questionnaire. The address will be taken in detail so that the home of each patient can be located subsequently. After discharge from the treatment centre each subject will be followed within 1 week at their home to observe mothers' feeding practices and hygienic behaviours. The field research officer will not be informed of the basic hypothesis of the observation and will not make any comment on behaviour of the mother.

Visits will be for periods of 4 hour at same, fixed time of the day (6 a.m. - 12 noon) for all patients (cases and controls). The field research officer will observe the behaviours of the mother according to the observational form developed for hygienic practices and feeding practices. The field research officer will also write the description of events noted in the observation form in Bengali. It is anticipated from ongoing studies at ICDDR,B that 90% of the cases could be followed. So attempts will be made to follow-up all patients with an understanding of 10-15% of drop outs.

DATA ANALYSIS

Cases and controls will be compared to each risk factor of interest with adjustment for confounding variables which include age of the child, sex, nutritional status, pathogens, distance of home from clinic and socio-economic status and other risk factors as necessary. Means of duration of diarrhoea and vomiting prior to hospitalization between the cases and controls will be compared. Median frequency of diarrhoea and vomiting prior to hospitalization will be compared. Basic statistical tests will be done at ICDDR,B. The project will require assistance of a consultant for performing sophisticated statistical analysis like multivariate analysis using a

conditional or unconditional logistic regression, for several risk factors after adjustment for confounding variables. Request for assisting sophisticated statistical data analysis is being made to Betty Kirkwood working at the LSHTM. She has kindly expressed her willingness to do so.

DURATION OF STUDY - One year six months.

One year from the start to cover seasonal variations.

Six months for data analysis.

D. SIGNIFICANCE

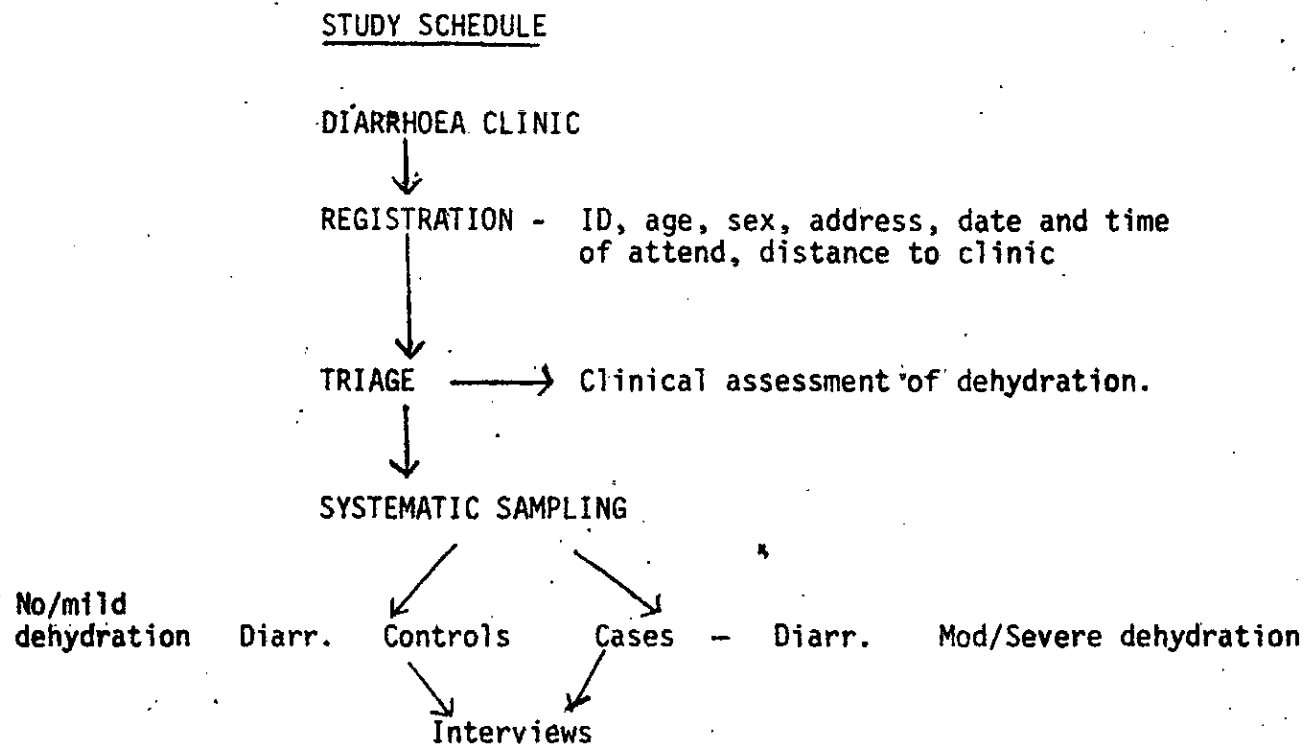
To identify simple and inexpensive risk factors which could be effectively implemented for preventing dehydration and death.

E. FACILITIES REQUIRED

1. No new space is required.
2. ICDDR,B laboratory facilities for stool microscopy and culture are adequate.
3. Hospital resources: The study will utilize patients selected from the treatment centre. No extra space will be required.
4. Animal resources will not be necessary.
5. Data analysis: Help of computer branch will be required.

F. COLLABORATIVE ARRANGEMENTS: Nil.

A schematic presentation of the study schedule is presented below:



Questionnaire on:

- | | | |
|--------------------|----|--|
| <u>Doctor</u> | 1. | Clinical and immunization history (Appendix II). |
| <u>Doctor</u> | 2. | Physical examinations and stool sample and other investigations as necessary. (Appendix II) |
| <u>Interviewer</u> | 3. | Management of diarrhoea - drugs/fluids at home (Appendix III). |
| " | 4. | Breast feeding and weaning history (Appendix IV) |
| " | 5. | Hygiene practices (observation at home to verify results of interview) - Appendix V. |
| " | 6. | Anthropometrics - age, weight on admission and after rehydration; height/length and arm circ. on admission. - Appendix II. |
| | 7. | SES - Appendix I. |

A detailed questionnaire is presented in Appendix I, II, III, IV & V.

REFERENCES

1. Chen LC, Rahman M, and Sarder AM. Epidemiology and causes of death among children in a rural area of Bangladesh. *International Journal of Epidemiology* 1980;9(1):
2. The management of diarrhoea and use of oral rehydration therapy: a joint report WHO/UNICEF Statement, 2nd edition, WHO, Geneva 1985.
3. Palmer KL, Koster FT, Alam AKMJ, Islam MR. Nutritional status: a determinant of severity of diarrhoea in patients with cholera. *J Infect Dis* 1976;134:8-14.
4. Tomkins A. Nutritional status and severity of diarrhoea among pre-school children in rural Nigeria. *Lancet* 1981; 860
5. Stanton B, Clemens J. An educational intervention for altering water sanitation behaviours to reduce childhood diarrhoea in Bangladesh. I. Application of the case-control method for development of an intervention. II. A randomized trial to assess the impact of the intervention of hygienic behaviours and diarrhoea rates. *American Journal of Epidemiology* (in press).
6. Clemens J, Stanton B, et al. Breast feeding as a determinant of severity of shigellosis: evidence for protection throughout the first three years of life in Bangladeshi children. *American Journal of Epidemiology* 1986;123:710-720
7. Khan MU. Interruption of shigellosis by handwashing. *Trans Roy Soc Trop Med Hyg* 1981;76(2):164
8. Schlesselman JJ. Case-control studies: Design, conduct, analysis. Oxford University Press 1981, New York.

Table - 1(a)

Month of attendances of watery diarrhoea

Cases*													
Age (yrs)	J	F	M	A	M	J	J	A	S	O	N	D	Total
<1	10	13	17	26	8	12	4	5	9	9	6	6	125
1-2	8	1	7	7	8	10	6	6	3	3	5	13	77
3-4	3	3	4	10	7	1	4	1	4	5	8	6	56

* Diarrhoeal patients with moderate/severe degree of dehydration

Table - 1(b)

Month of attendances of watery diarrhoea

Controls *													
Age (yrs)	J	F	M	A	M	J	J	A	S	O	N	D	Total
<1	24	25	55	42	36	37	22	18	19	19	37	44	378
1-2	27	22	36	39	21	23	21	27	26	16	20	42	320
3-4	2	4	3	5	11	6	7	8	10	7	8	6	77

* Diarrhoeal patients with none and mild degree of dehydration

Source: 1985. Surveillance data of Dhaka Hospital, ICDDR,B

Table - 2

Degree of dehydration in children less than 3 years and 5 years

	< 3	< 5	Total
None	169	196	365
Mild	535	582	1117
Moderate	176	218	394
Severe	21	35	56
Total	901	1031	1932

Table - 3

ATTENDANCES OF DHAKA TREATMENT CENTRE, 1985

Degrees of Dehydration

Age (years)	None	Mild	Moderate	Severe
<1	87	297	107	11
1-2	82	244	69	10
3-4	27	47	42	14
>5	160	283	266	121

SECTION III : BUDGET

A. Detailed Budget

Personnel

<u>Name/Position</u>	<u>Grade</u>	<u>% of effort</u>	<u>One year's project requirement (US \$)</u>
Dr Asma Islam, Principal Investigator.	NOB	60	3585
Dr J. Clemens, Co-investigator		10	-
Physicians - 3 (to be named)	NOA	20 each	2880
Interviewer - 8 (to be recruited)	GS3	100	11520
Data entry technician	GS3	25	420
Secretary	GS5	25	615
Study clerk	GS3	25	420
Sub-total:			19440

Supplies & materials

500

Equipments

350

Interdepartmental services

Xerox & mimeography	250
Patient hospitalization @\$4.00 per day x 504 =	2016
Stool culture & M/E	4969
Travel to and from field area (home visits)	1950
Data analysis	5000
Sub-total:	14185

14185
34475

B. BUDGET SUMMARY

1. Personnel	US \$ 19,440
2. Supplies & material	500
3. Equipments	350
4. Interdepartmental services	14,185
Total :	\$ 34,475

TOTAL PROJECT REQUIREMENT \$34,475

ABSTRACT SUMMARY FOR ETHICAL REVIEW COMMITTEE

1. Five hundred and four children aged 0-35 months suffering from acute watery diarrhoea will be selected from the ICDDR,B triage area and randomly assigned to either a case or a control as per definition. Detailed questionnaire on history of illness, home management of diarrhoea, feeding practices, hygienic practices will be administered by a doctor and or interviewer to identify risk factors responsible for development of dehydration.
2. There is no significant risk. Patients with acute watery diarrhoea presenting at ICDDR,B triage area will be selected.
3. Patients will be enrolled in this study from surveillance patients and will follow the routine treatment provided by the treatment centre and/or general ward.
4. All the records will be kept confidentially by the investigators. Only identification number of the patient will be used during data analysis.
5. Informed consent (signed or thumb impression) will be obtained from the patient's guardian or parent after full explanation of the procedure in Bengali.
6. Interviews will be obtained with regard to history of diarrhoea and its management at home feeding practice and hygienic practices.
7. The patient will benefit from the treatment of diarrhoeal illness.
8. The study will require stool for microscopic examination and culture on admission to determine the cause of diarrhoea and appropriate management.

CONSENT FORM

A case control study of risk factors for dehydrating diarrhoea.

The International Centre for Diarrhoeal Disease Research is conducting a study to understand why in some children diarrhoea is self-limiting and in others it leads to severe dehydration. We would examine your child and provide treatment for diarrhoea. During this time, we would also like to ask you some questions related to diarrhoea and its management at home, feeding practice before and after diarrhoea and hygienic practices. We would also weigh and measure the height/length of your child on admission and at 8 hours of admission to assess the dehydration status. Stool will be examined to determine the cause of diarrhoea on admission. An interviewer will visit your home within 1 week of discharge to enquire about your child's welfare. Your child will receive treatment for diarrhoea even if you are not willing to participate in this study.

If you agree to participate in this study then please sign below.

Signature of Investigator

Signature/Thumb print of guardian

Date _____

অম্মতি-সম্বন্ধ

(জামরিয়ায় সান্নি-স্বন্যতাৰ সন্মত অম্মতি-সম্বন্ধ স্থাপিতমূহ
নিকাশনেৰ উল্লিখিত প্ৰকাৰে কৰা-বন্দোবস্ত সৰ্বাধিক ।)

আনুষ্ঠানিক উদ্বোধনৰ কাৰ্য্যকৰণৰ ক্ষেত্ৰত সৰ্বাধিক কাৰ্য্যকৰণ
সাধ্যতঃ জানিতৈ চাওঁ যে, যেন কিছু অৱস্থাত নিশ্চয়-
জামরিয়া-আপনাৰ সন্মতত গোলা হলে যাম আৰু কিছু অৱস্থাত
নিশ্চয়-জামরিয়া-জনিত-অতিবিক্ৰম সান্নি-স্বন্যতাৰ গোলা ।
আমরা আপনাৰ নিশ্চয়কে পৰীক্ষা কৰে জামরিয়াৰ চিহ্নিত
দেবো । যি-সময়ে আমরা আপনাকে আপনাৰ নিশ্চয়-
জামরিয়া সন্মতত আপনি যি-বি-ব্যক্তি নিযেছেন যে
বিশয়ে, তাৰ জামরিয়া-স্বত্বৰ আৰু ও পৰে যাবাৰে-
অভ্যাস কৰেন ছিহ্নিত পৰে তাৰ দ্বাৰা সন্মতীয় কিছু প্ৰশ্ন
কিছুপাতা পৰে । আমরা তাৰ-উক্তি পৰ ওজন নেবা পৰে
লক্ষ্য/উক্তি পৰে পৰে আৰু যি-পৰ আৰু ও তাৰ-
ওজন নেবা সান্নি-স্বন্যতাৰ অৱস্থা দেখাৰ জন্য । উক্তি পৰ
জামরিয়াৰ পৰন জনাৰ জন্য-আপনাৰ নিশ্চয়-সামান্য
পৰীক্ষা কৰা হলে । আপনাৰ নিশ্চয়কে সন্মতত সন্মত
ছিহ্নিত-দেবাৰ পৰ-একসময়ৰে মৰ্য্যে পৰজন সন্মতীয়
আপনাৰ বাসায় গিয়াে নিশ্চয়-দ্বাৰা-যাবা-যাবা সন্মত
কিছুপাতা পৰে । আপনি যদি পৰ কাৰ্য্যকৰণ বান্ধী নাও
যাৰে তবুও আপনাৰ নিশ্চয়-সন্মতত সন্মত-
চিহ্নিত পৰে ।

যদি আপনি পৰ কাৰ্য্যকৰণ অংশ গ্ৰহণে বান্ধী যাৰে
তবে নিচে দ্বাৰা-পৰ-চিহ্নিত-দিহ্ন ।

কাৰ্য্যকৰণৰ দ্বাৰা

সম্বন্ধ :

দ্বাৰা/বন্দোবস্ত-দ্বাৰা
অতিবিক্ৰম-।

APPENDIX I

SOCIO-ECONOMIC AND DEMOGRAPHIC DATA

1. Patient's name _____
2. Father's name _____
3. Address _____
4. Study No. _____/_____/_____/_____/_____
5. Patient Hospital I.D. No. _____/_____/_____/_____/_____/_____
6. Date of interview. _____/_____/_____/_____/_____/_____/_____/_____/_____

Y Y M M D D
7. Date of attendance _____/_____/_____/_____/_____/_____/_____/_____/_____

Y Y M M D D
8. Time of attendance _____/_____/_____/_____/_____
9. Time taken to reach ICDDR,B from home (h/min) _____/_____/_____/_____/_____
10. Mode of transport _____/_____

Bus=1, Rickshaw=2, Scooter=3, Car=4, Boat=5, Boat+Rickshaw=6
Boat+Scooter=7, Others (specify)=8
11. Distance (kilometer) to ICDDR,B Treatment Centre from home _____/_____/_____/_____/_____
12. Who is primarily taking care of the child? _____/_____

Mother=1, Father=2, Grandmother=3, Older sibling=4, Others (specify)=5
13. How old is your child? (months) _____/_____/_____
14. Tell the sex of your child. [Male=1, Female=2] _____/_____
15. Other than this sick child, how many children (living) do you have? _____/_____
16. What is the birth order of the sick child? _____/_____

First=1, Second=2, Third=3, Fourth=4, Fifth=5, Sixth=6, Seventh=7
Eighth=8, Ninth=9
17. What is the age of your youngest child? (months) _____/_____/_____
18. Is the youngest child a girl or a boy? [Girl=1, Boy=2] _____/_____
19. Did you ever attend school? (mother) [Yes=1, No=2] _____/_____
20. If yes, what class did you reach? _____/_____

Class 1-5=1, Class 6-10=2, Class 11-12=3, Class > 12=4
Others (specify)=5

21. What type of institute was it? ___/
 Religious=1, School/College=2, Others (specify)=3
22. Did your husband ever attend school? [Yes=1, No=2] ___/
23. If yes, what class did he reach? ___/
 Class 1-5=1, Class 6-10=2, Class 11-12=3, Class > 12=4
 Others (specify)=5
24. What type of institute was it? ___/
 Religious=1, School/College=2, Others (specify)=3
25. What is the primary occupation of your husband? ___/___/
 Farmer=1, Day labourer=2, Rickshawpuller=3, Taxi or bus driver=4
 Mill worker=5, Non-executive=6, Office executive=7, Business=8
 Others (specify)=9, Unknown=99
26. Does your husband perform any other work (for cash or kind) besides primary occupation? [Yes=1, No=2] ___/
27. How much does he earn on an average per month? ___/___/___/___/___/___/
28. Do you have a paid job or any work? [Yes=1, No=2] ___/
29. If yes, how much do you earn on an average (per month) Taka ___/___/___/___/___/___/
30. How many hours do you have to work per day? ___/___/
31. Do you own or rent the house? [Yes=1, No=2] ___/
32. How many people live in this house? ___/___/
33. What is the construction of the house?
 a. Roof: Straw=1, Tin=2, Wood=3, Concrete=4, Others=5 ___/
 b. Walls: Bricks=1, Tin=2, Bamboo=3, Others=4 ___/
 c. Floor: Pucca (brick/concrete)=1, Kancha(mud)=2 ___/
 d. Electricity: (Yes=1, No=2) ___/
 e. Number of sleeping rooms ___/
34. What assets do you possess? ___/___/___/___/
 Radio=1, Transistor=2, T.V.=4, Freeze=8, Electric fan=16
 Domestic animal=32, Boat=64, Alairah=128, Bicycle=256.
 Cot=512, Others=1024

APPENDIX 2

MEDICAL HISTORY FORM

1. Study No. _____
2. Patient I.D. No. _____ Time: _____
3. Date of interview _____
Y Y M M D D
4. At what time of the day did you first notice your child's diarrhoea? _____
 Morning=1, Afternoon=2, Evening=3, Night=4
5. What was the date/day of the week you have observed your child having watery diarrhoea? _____
Y Y M M D D
6. For how many days/hours the child has been suffering from diarrhoea prior to attendance at ICDDR,B?
 Days: _____
 Hours: _____
7. What was the maximum no. of stool in any 24 h prior to attendance? _____
8. What was the minimum no. of stool in any last 24 h prior to attendance? _____
9. What was the maximum no. of stool in last 24 h prior to attendance? _____
10. What was the maximum no. of stool on the day of onset of diarrhoea? _____
11. What was the condition of the child at the onset of diarrhoea (within 24 hours)?
 - a. Lethargic [Yes=1, No=2] _____
 - b. Thirsty [Yes=1, No=2] _____
 - c. Vomiting [Yes=1, No=2] _____
 - d. Diarrhoea [Yes=1, No=2] _____
 - e. Sunken eyes [Yes=1, No=2] _____
 - f. Tongue - [Moist=1, Dry=2] _____
 - g. Urine flow [Normal=1, Reduced=2, Absent=3] _____
12. What was the nature of stool at the onset of diarrhoea?
 Watery=1, Non-watery=2, Mucoid=3, Bloody=4

13. What is the nature of stool now? ___/
- Watery=1, Non-watery=2, Mucoid=3, Bloody=4
14. Did the child vomit prior to admission? [Yes=1, No=2] ___/
15. If yes, for how many days/hours the child had been vomiting prior to attendance? Days: ___/___/
- Hours: ___/___/.
16. What was the maximum no. of vomiting in any 24 h prior to attendance? ___/
17. What was the minimum no. of vomiting in any 24 h prior to attendance? ___/
18. What was the maximum no. of vomiting in last 24 h prior to attendance? ___/
19. Have your child had any sickness in the last two months (before onset of diarrhoea)? ___/___/
- None=0, RTI=1, Fever=2, Measles=4, Diarrhoea=8, Ear discharge=16
Do not know=99, Others (specify)=17
20. Where did you go for treatment when your child had first attack of diarrhoea? ___/
- ICDDR,B Hospital=1, Hospital/clinic=2, MBBS doctor=3 Local dispensary=4
Homeopath=8, Kabiraj=16, Religious leader=32, Others (specify)=64
21. If yes, duration of illness (days). ___/___/
22. Did the child receive any vitamin A capsule/injection in last 3-6 months? [Yes=1, No=2] ___/
23. How was your child's appetite before the onset of diarrhoea? [Good=1, Poor=2] ___/
24. How was your child's appetite during diarrhoea? [Good=1, Poor=2] ___/
25. If poor, for how many days? ___/___/
26. Did your child receive immunization against the following:
- | | | | |
|---------|-------|------|------|
| DPT | Yes=1 | No=2 | ___/ |
| POLIO | Yes=1 | No=2 | ___/ |
| Measles | Yes=1 | No=2 | ___/ |
| BCG | Yes=1 | No=2 | ___/ |
| TT | Yes=1 | No=2 | ___/ |

APPENDIX III

HOME MANAGEMENT OF DIARRHOEA

1. Study No. _____/_____/_____/_____/_____
2. Patient I.D. No. _____/_____/_____/_____/_____/_____
3. Date of interview _____/_____/_____/_____/_____/_____/_____/_____

Time: _____/_____/_____/_____/_____
4. When was diarrhoea first noticed? _____/_____/_____/_____/_____/_____/_____/_____

(Date of onset)
5. What did you do for the treatment of this episode of diarrhoea prior to attendance at ICDDR,B? _____/_____/_____/_____

Did not do anything=1, Visited the MBBS doctor=2
 Visited ICDDR,B hospital=3, Visited homeopath's clinic=4
 Visited other private clinics=5, Visited kabiraj/herbal=6
 Visited religious leader=7, Quack=8

Indicate the order of contact in 3 respective columns.
6. How many hours prior to attendance at ICDDR,B the child received treatment? _____/_____/_____
7. What type of treatment did the child receive within 24 hours of onset of diarrhoea? _____/_____/_____/_____/_____

Drugs (tablet, syrup)=1, Antibiotics (Syrup, capsules, tablets)=2
 Injections=4, Vitamins=8, ORS (packets)=16
 Intravenous saline (IV) bags=32

Indicate the treatment order in 3 respective columns.
8. If I.V. fluid was infused, how many bags were infused before attending ICDDR,B? _____/_____/_____
9. If ORS packet was received, how many packets did the child consume? _____/_____/_____
10. What was the quantity of water (in seer) used for dissolving each packet of ORS? _____/_____

1/2 seer=1 1 seer=2
11. How many hours did you continue feeding ORS? _____/_____/_____

[Date of initiating and stopping ORS]

12. Did you feed your child with home-made oral rehydration solution? Yes=1 No=2 ___/
13. If yes, what were the ingredients used? ___/
- Sugar+salf=1 Molasses+salt=2 Rice+salt=3
 Traditional fluid (cooked rice water)=4
 Others (specify)=5
14. How many spoon/scoop/handful of sugar/molasses/rice? ___/
15. How many spoons/pinch of salt? ___/
16. How did you measure water? ___/
- 1=Mug 2=Pot 3=Glass 4=Bottle
17. How many mugs/pots/glasses/bottles did you use? ___/
18. What was the amount of water by mug/pot/glass/bottle in seers? ___/
19. From where did you acquire the knowledge of preparation of ORS? ___/
- 1=Quack 2=Pharmacist 3=Health assistant 4=Radio 5=T.V. 6=Doctor
 7=Clinic 8=Hospital

APPENDIX IV
FEEDING PRACTICE

1. Study No. _____/_____/_____/_____/_____/_____/
2. Patient No. _____/_____/_____/_____/_____/_____/
3. Date of interview _____/_____/_____/_____/_____/_____/

Time: _____/_____/_____/_____/

A. DISTANT PAST

4. Did your child receive breast milk after birth? _____/

Yes=1 No=2 (If no skip to 8)

5. What did you do with the first milk of the breast (colostrum)? _____/

Thrown away=1 Given to the child=2

6. How long did you exclusively breast feed the child? (months) _____/_____/

7. After what age did you stop breastfeeding your child? (months) _____/_____/

8. At what age of the child did you start supplementation? (months) _____/_____/

9. Why supplemented? _____/

Inadequate breastmilk=1 Mother was suffering from illness =2

Child ill=3 Child malnourished=4

10. What type of food was used for supplementation?

a. Cow's milk (Yes=1 No=2) _____/

b. Goat milk (Yes=1 No=2) _____/

c. Formula milk (Yes=1 No=2) _____/

d. Barley (Yes=1 No=2) _____/

e. Rice gruel (Yes=1 No=2) _____/

f. Others (specify) _____/

11. What type of utensils did you use for supplementary feeding? _____/

Feeding bottle=1 Cup/spoon=2 Others (specify)=3

12. At what age of the child did you stop supplementation? (months) ___/___/
12. At what age did you introduce solid food? (months) ___/___/
13. What type of food did you introduce?
- a. Rice only [Yes=1 No=2] ___/
 - b. Rice + dal [Yes=1 No=2] ___/
 - c. Potato only [Yes=1 No=2] ___/
 - d. Rice + potato [Yes=1 No=2] ___/
 - e. Rice + dal + potato [Yes=1 No=2] ___/
 - f. Kichuri [Yes=1 No=2] ___/
 - g. Bread only [Yes=1 No=2] ___/
 - h. Rice + curry (chicken, beef, mutton, fish) [Yes=1 No=2] ___/
 - i. Others (specify) ___/
14. How often did you offer the solid food? No. of times/day ___/___/

B. Immediately prior to diarrhoeal illness:

1. What food did you offer the child just before the onset of diarrhoea?
- a. Breastfeed [Yes=1 No=2] ___/
 - b. Formula milk [Yes=1 No=2] ___/
 - c. Cow's milk [Yes=1 No=2] ___/
 - d. Goat's milk [Yes=1 No=2] ___/
 - e. Rice gruel/wheat [Yes=1 No=2] ___/
 - f. Cow's milk + suji (rice/wheat) [Yes=1 No=2] ___/
 - g. Goat's milk + suji (rice/wheat) [Yes=1 No=2] ___/
 - h. Barley [Yes=1 No=2] ___/
 - i. Rice [Yes=1 No=2] ___/
 - j. Dal [Yes=1 No=2] ___/
 - k. Curry (fish, meat, chicken) [Yes=1 No=2] ___/

1. Chapati/bread [Yes=1 No=2] ___/
- m. Khichuri [Yes=1 No=2] ___/
- n. Egg [Yes=1 No=2] ___/
- o. Leafy vegetables [Yes=1 No=2] ___/
- p. Non-leafy vegetables [Yes=1 No=2] ___/
- q. Muri [Yes=1 No=2] ___/
- r. Biscuit [Yes=1 No=2] ___/
- s. Others (specify) [Yes=1 No=2] ___/
2. How often did you breast feed your child during the day? ___/
- [6 a.m. - 6 p.m.]
- 2-4 times/day=1 4-6 times/day=2 6-12 times/day=3
- Adlibitum=4 NA=5
3. How many times a day do you food other than breastmilk? ___/
- [No. of times day]
- C. During illness
1. What did you feed your child after onset of diarrhoea?
- a. Breastfeed [Yes=1 No=2] ___/
- b. Formula milk [Yes=1 No=2] ___/
- c. Cow's milk [Yes=1 No=2] ___/
- d. Goat's milk [Yes=1 No=2] ___/
- e. Rice gruel/wheat [Yes=1 No=2] ___/
- f. Cow's milk + suji (rice/wheat) [Yes=1 No=2] ___/
- g. Goat's milk + suji (rice/wheat) [Yes=1 No=2] ___/
- h. Barley [Yes=1 No=2] ___/
- i. Rice [Yes=1 No=2] ___/
- j. Dal [Yes=1 No=2] ___/
- k. Curry (fish, meat, chicken) [Yes=1 No=2] ___/

- l. Chapati/bread [Yes=1 No=2] ___/
- m. Khichuri [Yes=1 No=2] ___/
- n. Egg [Yes=1 No=2] ___/
- o. Leafy vegetables [Yes=1 No=2] ___/
- p. Non-leafy vegetables [Yes=1 No=2] ___/
- q. Muri [Yes=1 No=2] ___/
- r. Biscuit [Yes=1 No=2] ___/
- s. Others (specify) [Yes=1 No=2] ___/

5. What was the breastfeeding practice during diarrhoea? ___/

- Continue breastfeeding as before diarrhoea=1
- Decreased breastfeeding=2
- Increased breastfeeding=3
- Stopped breastfeeding=4

APPENDIX V

HYGIENE PRACTICE

1. What is the source of water used for cooking? ___/
Piped water supply=1 Tubewell=2 Well=3 Pond=4
Canal=5 River=6 Others(specify)=7
2. What is the source of water for washing your utensils? ___/
Piped water supply=1 Tubewell=2 Well=3 Pond=4
Canal=5 River=6 Others(specify)=7
3. What is the source of water you use for bathing? ___/
Piped water supply=1 Tubewell=2 Well=3 Pond=4
Canal=5 River=6 Others(specify)=7
4. a. What is the source of drinking water for the family? ___/
Piped water supply=1 Tubewell=2 Well=3 Pond=4
Canal=5 River=6 Others(specify)=7
b. What is the source of drinking water for 0-35 months children? ___/
Piped water supply=1 Tubewell=2 Well=3 Pond=4
Canal=5 River=6 Others(specify)=7
5. Do you boil water for drinking for 0-35 months children? ___/
(Yes=1 No=2)
6. What type of container do you use for storing drinking water? ___/
Pitcher=1 Bucket=2 Drum=3
7. Do you cover the drinking water container? ___/
Never=1 Often=2 Always=3
8. If water is stored in a big container (bucket/drum) how do you get water from it? ___/
Always by sinking jug=1 Always by decanning=2
No definite pattern=3
9. Do you have your own latrine? (Yes=1 No=2) ___/
10. Do you share a latrine? (Yes=1 No=2) ___/
11. What type of a latrine do you own/share? ___/
Sanitary latrine=1 Pit latrine=2 Hanging latrine=3
Others (specify)=4 ___/

12. If your child defecates either inside the dwellings or in the courtyard where do you dispose them? ---/

Always in the latrine=1
Most of the times in the canal/ditch/drain=2
No definite pattern=3
Others (specify)=4

13. How do you wash your hand after cleaning your child following defecation? ---/

Always with water only=1 Sometimes with soil/ashes=2
Always with soil/ashes=3 Sometimes with soap=4
Always with soap=5 Others (specify)=6

14. How do you clean your hand after defecation? ---/

Always with water only=1 Sometimes with soil/ashes=2
Always with soil/ashes=3 Sometimes with soap=4
Always with soap=5 Others (specify)=6

15. Did you wash your hand before serving food to the family? ---/
[Yes=1 No=2]

16. Did you wash your hand before feeding the child with supplementary foods for each feed? [Yes=1 No=2] ---/

OBSERVATION OF CHILD

Date of observation _____ Patient's name _____
Name of observer _____ Pt. ID # _____ Study # _____
Time of arrival _____ Time of departure _____

1. Feeding pattern of the child: /___/

Exclusively breast fed = 1, Partially breast fed = 2,
Supplementary feed = 3,

2. Utensils used for feeding: /___/

Feeding bottle = 1, cup-spoon = 2, plate = 3,
other (specify) = 4.

3. Utensils washed immediately before feeding: /___/

Washed = 1, not washed = 2

4. If washed, washed with: /___/

only water = 1, boiled water = 2, water + soap = 3,
water + ash = 4

5. Who fed the child: /___/

child himself = 1, mother = 2, grand mother = 3,
others = 4

6. Water drank after feed: /___/

Did not = 1, boiled water = 2, supply water = 3,
tube-well = 4, well = 5, pond = 6

OBSERVATION OF CHILD (CONTINUED PAGE 2)

7. Defecation site of child: /___/

Floor of house = 1, kitchen floor = 2, court yard = 3,
drain = 4, latrine = 5, other (specify) = 6, N.A. = 8

8. Removal of faeces by: /___/

not removed = 1, mother = 2, grand mother = 3,
Other = 4, N.A. (faeces in latrine) = 8

9. Who washed child after defecation: /___/

Not washed = 1, child himself = 2, mother = 3,
grand mother = 4, others = 5

10. Time lapsed between defecation and hand washing (min) /___/___/

11. Activities performed before handwashing yes=1, no=2 /___/

(If yes, specify activities)

12. After defecation, hand washed with: /___/

water only = 1, soil = 2, soap = 3

OBSERVATION OF MOTHER

Name of the mother ----- Child ID # -----

1. Defecation site: /___/

Sanitary latrine = 1, pit latrine = 2, hanging latrine = 3,
others (specify) = 4

2. After defecation hand washed with: /___/

Only water = 1, soil = 2, soap = 3

3. Time lapsed between defecation and hand washing (min) /___/___/

4. Hand washing before preparation of food: /___/

Did not wash = 1, washed with water only = 2,
washed with water and soap = 3, washed with water
then soiled = 4, washed with water + soap then soiled = 5

5. Hand washing before serving food: /___/

Did not wash = 1, washed with water only = 2,
washed with water + soap = 3, washed with water then
soiled = 4, washed with water + soap then soiled = 5

6. Hand washing before feeding child: /___/

Did not wash = 1, washed with water only = 2,
washed with water + soap = 3, washed with water then
soiled = 4, washed with water + soap then soiled = 5

OBSERVATION OF HOUSEHOLD

Child ID: _____

1. Source of water for drinking:

/___/

Piped water supply = 1, tubewell = 2, pond = 3,
canal = 4, river = 6, other (specify) = 7

2. Source of water for cooking:

/___/

Piped water supply = 1, tubewell = 2, pond = 3,
canal = 4, river = 6, other (specify) = 7

3. Source of water for washing utensils:

/___/

Piped water supply = 1, tubewell = 2, pond = 3,
canal = 4, river = 6, other (specify) = 7

4. Source of water for bathing:

/___/

Piped water supply = 1, tubewell = 2, pond = 3,
canal = 4, river = 6, other (specify) = 7

5. Drinking water stored in container:

/___/

No = 1, pitcher = 2, bucket = 3, drum = 4,
big earthen vessels = 5; other (specify) = 6

6. Water container covered:

/___/

not covered = 1, covered = 2, N.A. = 3

7. Handling of water from container:

/___/

Sinking jug = 1, decanning = 2, no definite pattern = 3,
other (specify) = 4

/___/

Shipping log = 1, decreasing, AS, no definite pattern = 3.
Other (specify) = 4. *(faint text)*

(faint text)

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HOUSEHOLD OBSERVATION (CONTINUED PAGE 2)

8. Preparation of child's food:

/---/

 specially cooked for child = 1, part of adult food = 2,
 both (1+2) = 3, N.A. = 8

9. Food fed to the child:

/---/

 Freshly prepared each feed = 1, left over (from the
 day before) = 2, prepared at one time a day = 3

10. Prepared food served to the child:

/---/

 Hot = 1, cold = 2, N.A. = 8

11. Prepared food stored:

/---/

 Covered = 1, uncovered = 2, N.A. = 8

Table A. Comparison of variables between cases and controls .

Variables	Cases [mod/severe dehydration] n=	Controls [none/mild dehydration] n=
Age (months) [Mean ± standard deviation]		
Male (%)		
Female (%)		
Family size		
Family income		
Maternal education		
Duration of diarrhoea (h) prior to hospitalization [mean±S.D.]		
Duration of vomiting (h) prior to hospitalization [mean±S.D.]		
Median frequency of diarrhoea in 24 h prior to hospitalization		
Receipt of medication prior to attendance ICDDR,B		
Use of oral rehydration fluid prior to attendance in ICDDR,B		
Nutritional status		

Table B. Frequency of breastfeeding among cases/controls according to age..

Breastfeeding in months.	Age (months)						...
	0-1	2-3	4-5	6-7	8-9	10-11	
None							
1 month							
3 months							
6 months							

Table C. Percentage of breastfed and non-breastfed children between cases and controls

	Cases	Controls	RR	Adjusted	RR
Exclusively breastfed					
Partially breastfed					
Never breastfed					