Library.

achment 1.

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Date May 08, 1990

incipal Investigator DR. BILQIS AMIN HOQUE Trainee Investigator (if any) _____

pplication No. 90-008 (Revised) Supporting Agency (if Non-ICDDR,B) Expected to be ICDDR

tle of Study ENVIRONMENT & CHILD SURVIVAL IN RURAL BANGLADESH

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

rcle 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 (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.

(PTO)

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

Bilqis Amin Hoque
Principal Investigator

Trainee

(1) Title :ENVIRONMENT AND CHILD SURVIVAL IN RURAL BANGLADESH

(2) PRINCIPAL
INVESTIGATOR: Dr. Bilqis Amin Hoque

(3) CO-INVESTIGATORS: Drs. M.Yunus, M.Strong & Mr. Chakrabarty

(4) ADVISOR: Dr. D. Mahalanabis

(5) CONSULTANT: Drs. A. Briend, V. Fauveau

(5) STARTING DATE: As soon as the fund is available

(6) COMPLETION DATE: Three Years from starting date

(6) TOTAL DIRECT COST: US $ 167,137

(7) SCIENTIFIC PROGRAMME HEAD:Community Health Division

8) SIGNATURE OF THE SCIENTIFIC PROGRAMME HEAD

(9) <u>Abstract:</u>

This study aims at defining important environmental risk factors for child mortality from infectious diseases, and drawing guidelines for affordable , widely replicable interventions for child survival. The study will take place in Matlab, an area of rural Bangladesh with a population of about 200,000 under intensive demographic surveillance. It is estimated that about 370 children aged 1 to 59 months will die

from diarrhoea and about 250 from other infectious disease (including 200 from Acute Respiratory Infections) in this population during the two years of data collection. A Case-control design will allow to compare these 620 death cases (approx.) with the same number of alive controls. Environmental factors which will be examined include indicators of hygiene and sanitation at individual, familial and community level: kitchen/household hygiene, sanitation, water use, mineral content of drinking water, feeding practices, maternal behavior and indoor environmental pollution. Socio-economic variables will be recorded to eliminate possible confounding factors during the analysis.

RESEARCH PROPOSAL

1. Background

a. Statement of the problem:

Bangladesh is rated by UNICEF (1989) as one of countries of the world with a very high under-five mortality: 191 per 1000 live births. Diarrhoea is the major cause of death in under five children in rural Bangladesh. Child survival strategies have limitations to prevent these deaths: oral rehydration therapy (ORT) is little effective in reducing mortality from persistent diarrhoea or dysentery (2,3), which seem to be responsible for the largest number of diarrhoea deaths (1,3,4). Antibiotic treatment of dysentery is limited by the difficulties encountered in providing treatment at the community level and by increasing bacterial resistance to antibiotics (2,3). Treatment of

persistent diarrhoea, based mainly on dietary manipulations, is difficult at the community level. Improvement of water-sanitation facilities to the expected adequate levels or to the levels tested in succesful water sanitation projects is not feasible in near future.

ARI in Bangladesh (1,4), like in most of the developing countries (20,21,22), is the other leading cause of death among 1 to 59 months old children. Often environmental factors are listed among the possible risk factors for ARI. But evidence from developing countries/Bangladesh is at present lacking (20). Recently it was suggested that prevention from MCH_FP services in rural Bangladesh is not enough to control child deaths (4).

Therefore, considering the magnitude of child mortality and various limiting dimensions of its controlling measures it is essential that attempts are made to define further the important environmental risk factors. This will lead to the preparation of guidelines for cost effective and replicable environmental intervention appropriate in near future.

b) Background of the situation

i. Diarrhoea

In other countries, improvement of water supply and sanitation facilities was shown to be associated with a reduction of diarrhoea mortality. This reduction, however, was obtained by providing expensive interventions such as the provision of piped water in every household or by the installation of improved sanitary latrines (4, 5). These interventions are not feasible or appropriate to implement in rural Bangladesh.

A water and sanitation project recently completed in rural Mirzapur, Bangladesh showed that diarrhoea morbidity can be reduced by 25% in rural Bangladesh through a comprehensive approach based on provision of

handpumps, provision of improved latrines and health education (6). Handpumps and latrines were highly used by the people (7,24,25). Distance was found one of the major determinants for handpump water consumption (24).

However, the study was not designed to examine the effect of the different components separately and no final conclusion could be drawn on which component of the intervention was most effective for diarrhoea prevention. This study had a too small sample size to show any effect on mortality.

Another study in Teknaf, Bangladesh, suggested that installations of latrines were more effective to reduce diarrhoea related mortality than provision of handpumps (8). Teknaf is not representative of Bangladesh and handpump water was coveted by all the inhabitants in both the study and the comparison area (9). Furthermore, the study was also not designed to examine mortality effects.

In the Mirzapur and Teknaf Projects, however, diarrhoea prevention was done in a small controlled population through extensive efforts (1 handpump to less than 35 people on average, 1 latrine to almost every household and hygiene education programme) and this type of intervention cannot be replicated in wider scale in near future.

An intensive health education study in an area of Dhaka found that mother's handwashing before food preparation and disposal of feces outside the family compound were the two practices which most closely correlated with reduced incidence of diarrhoea (11). Handwashing by soap significantly interrupted shigellosis (12). Another pilot study found that under experimental conditions local handwashing agents have similar potentials as soap in reducing fecal coliforms of hand (13). But like water-sanitation studies these were also limited within controlled small

population and no attempts were made to relate it to diarrhoea mortality.

The effect of diarrhoea on nutritional status is a measure of its severity and it has been argued that this indicator could be used to measure the effect of preventive interventions on diarrhoea morbidity (14). But Mirzapur study showed, that diarrhoea has a transitory impact on nutritional status and that this indicator cannot be used as a proxy indicator of diarrhoea morbidity to assess the efficacy of a preverntive intervention (15). Besides, significant impact was observed on overall diarrhoea rate but the incidence of persistent diarrhoea at post water-sanitation intervention period remained at the same level as was at base-line level (9). In practice, this means that further studies giving a measure of the type and severity of diarrhoeas in relation to environmental factors are needed. Since types of diarrhoea mortality varies with age the proposed study on mortailty would provide the scope for further defining of the environmental risk factors.

Although data suggest that mineral content of tubewell water is a major determinant of water use (17,18) and of risk of diarrhoea (17) the Mirzapur study showed that the mineral content of water may have an impact on health . Children from households which had access to tubewell with water with a high iron content were found to be significantly taller than other children (19). However, this was not a causal association but one can hypothesize that iron contained in water was in partial or complete absorbable form and was absorbed. Iron deficiency has been shown to be associated with immune deficiency and it may be speculated that children having access to water with a high iron content can also have a better immunity and a lower mortality. This leads us to study the association between the mineral content of the water and the risk of dying.

ii. Acute Respiratory Infection

Substantial reduction of the still unacceptable infant and child moratility rates in the developing world will be difficult to achieve without a strategy to avert deaths due to ARI (23). As many as 300 agents are responsible for ARI, but while viruses are mostly involved in upper respiratory infections, bacteria are the agents which most often cause severe pneumonia (26).

ARI associated mortality in developed countries declined dramatically during the past few decades because of widespread use of antibiotic therapy, immunization with DPT, measles and influenza vaccines, improved health care management and adequate nutrition for infants and children. In developing countries, on the other hand, no such change has been witnessed as the standard of living continues to be associated with factors which increase the risk of severe respiratory infections in children (21).

Both indoor and outdoor air pollution can be associated with ARI. Evidence from developing countries on the contribution of passive smoking on the incidence and severity of ARI is at present lacking (21). In South Africa, among 132 infants with severe lower respiratory infection studied, 70% of the cases compared to only 33% of control infants had a history of heavy exposure to smoke from cooking and heating fires (32).

Among the possible risk factors for ALRI, environmental and behavioral factors have been suggested (32,33). Consideration to nutritional practices, hygiene-related behavior, treatment seeking behavior, housing, educational background of mother and domestic smoke pollution have been mentioned.

In Bangladesh there is a little information on ARI from such studies as Companiganj, Matlab and Teknaf (4,27-31). There seems to be a seasonal

peak of ARI related deaths from January to March. ARI was found the second leading disease of cause death among 1 to 59 months children (4) and 26% of all under-five deaths have been shown to be associated with ARI (42 per cent for post-neonates). But no investigation on environmental and behavioral options for ARI prevention in relation to deaths has been undertaken in this part of the world.

iii. Other infectious diseases

Other infectious diseases relate to about 6.6% of infectious deaths (No study has either reported on role of practiced environmental factors to these type of deaths.

iv. Environmental intervention of infectious disease:

Hardly any study has been conducted to evaluate the effects of national water supply investments on health (1). The effectiveness of water supply on childhood mortality is questioned when little effect is observed on death rates as the country has almost reached its target for the International Drinking Water Supply and Sanitation Decade and is regarded currently at one of the highest level of handpump coverage in the region (10). Besides, facilities in themselves do not mean anything unless they are used effectively. There are multiple transmission routes and therefore, evaluation should base on careful observation of the environmental facilities as well as environmental hygiene practices. Further definition of the environmental risk factors are required for design of intervention study. For example, handwashing has been reported as a risk factor for diarrhoea morbidity. Wide variation exists in the method of handwashing. Only water mud, ash and sometime soap is used for washing hands. Washing of hands, left or right or both hands, vary with the act preceeding the wasing. A research is in progress to develope appropriate

technique for handwashing (37). As such investment is not feasible for every risk factor, a design for an environmental intervention study would be weak at its efficiency potentials unless detail guidelines are available. In-depth environmental investigation is also likely to define the factors confouding the effects of such extensive effort.

Hence, there seems to be no alternative to the measure of the association of different environmental variables than mortality itself to determine which intervention is the most likely to reduce infection mortality.

2. Method of Study: Case Control Study

In statistical terms, death is a rare event and its association with different environmental factors can be determined by a case control design (34). In this study we propose to determine which practiced/existing environmental variables and behavioral practices are associated with the risk of dying from diarrhoea and other infectious diseases in a rural area under demographic surveillance system.

3. Justification

(1) Among the environmental risk factors related to poor personal hygiene, kitchen/household hygiene, maternal behavior, water supply and sanitation indoor pollution and child-feeding practices those associated with the highest risk of dying from diarrhoea (60% of infectious diasease) or infectious disease (63.4% of all deaths, including 21.3 % deaths from ARI) will be identified with specified definition of the factors.

(2) The ICDDR,B demographic surveillance area provides a uniquely ideal site for environmental mortality study. No cost is required for information on vital events and cause of deaths as it can be obtained

from the DSS system. A mortality study requires huge sample size (therefore, huge investment) and with this opportunity of information sharing, the study will need fund only for collecting information on environmental/behavioral factors against identified cases (deaths) and controls (survivors).

(3) Inclusion of deaths from all infectious diseases will strengthen the quality of data and allow unbiased analysis of deaths by considering all non-related deaths as controls for others.

(4) This study will provide pilot tested practical guidelines for appropriate interventions aiming at preventing deaths.

4. Objectives

a. To determine the association between existing environmental, behavioral and socio-cultural factors and mortality among children aged 1 to 59 months.

b. To suggest guidelines for interventions aiming at reducing mortality

5. Specific objectives

a. To assess the association between the suggested factors and diarrhoeal deaths

b. To assess the association between the suggested factors and ARI.

c. To assess the association between the suggested factors and deaths from other infectious diseases

d. To study the association between mineral content of water and risk of dying from diarrhoea.

e. To suggest guidelines for widely replicable, preventive, integrated approach to control diarrhoea.

6. Methodology

a. Study population and sampling:

The study will be conducted in the rural area of Matlab. Matlab is a rural deltaic subdistrict of Bangladesh, located 45 Km southeast of Dhaka.

As many other districts of the country, this area has a population density of 700 per square kilometer, a total fertility rate of six per women, an infant mortality rate of 100 per 1000 live births, and a precarious agricultural economy . Landholding is skewed with 18% of the households owning 47% of the land (15). About 40% of the males and 16% of the females over age 15 years have completed 4 years of schooling.

This area is unique for environmental research for several reasons: presence of the field station of the International Centre for Diarrhoeal Disease, existence of high handpump water supply coverage but inadequate use due to high iron content, geographical characteristics of the country, and presence of the Meghna-Dhonagoda Irrigation Project.

Since 1966,the International Centre for Diarrhoeal Disease research, Bangladesh (ICDDR,B) has maintained a Demographic Surveillance System (DSS) in the area, combining periodic censuses and longitudinal registration of vital events and migrations in a total population of approximately 200,000 (20). In 1978, a family planning and Health Services Project was initiated in half the study area, representing the MCH-FP area, whereas the remaining half, receiving only the services of the national health programme, represented the control area.

The Demographic Surveillance System:

Each household in the whole area is visited biweekly by one of 110 Community Health Workers (CHWs) to record all births, deaths, marriages and migrations. The CHWs work under the supervision of

Health Assistants (HAs) and other higher level supervisions. Most demographic events are reported to the Matlab office within a month of their occurrence.

Assessment of the cause of death

In case of a death, a Health Assistant accompanies the CHW to the household to enquire about the symptoms which preceded deaths. The complete history is reported on forms which are later read by a medical assistant who assigns the most likely cause of death under the supervision of two physicians. Details of the method of this 'verbal autopsy' are described in ref 4 and in Annex 1. Copies of the forms used to record death and other demographic records are enclosed.

The average handpump to people ratio of the area in DSS project is 60, when the national average is about 1 handpump per 110 people. However, the range of user size per pump varied from 6 to 230. The iron content (ferrous form) of the stored pump water ranged from 0 to more than 30 mg/l and varied with stored hours (35). The quality of the surface water used for domestic purposes, pond, is likely to vary as some have high banks, hardly flooded and use restricted for domestic purposes.

The Meghna_Dhonagoda Irrigation project is a medium-scale flood control, drainage and irrigation Project which is a polder embanking about 280,000 people of the area from the rivers Meghna and Dhonagoda. About 35% of the DSS area is included in the polder. Although the study is planned to consider the confounding effect of its presence by taking cases and controls from the same area, the presence of the polder has introduced heterogenous social and environmenatal dimensions in the existing charateristics. The area outside the polder is flooded

seasonally but experience from the severe flood of 1988 did not show significant effects on mortality rates.

b. Selection of cases

A case is defined as a child, aged 1 to 59 months, dying from any infectious disease in the study period.

c. Selection of controls

A control is defined as an age (plus minus one month) and sex and area matched child to the case, still alive on the day the case died. Control will be the first child meeting the matching criteria encountered on the census list starting from a randomly selected household from the whole list of households under the same demographic surveillance area. This will lead to the selection of one control from the same area (MCH-FP or comparison, in or out the embankment) as the case, avoiding overmatching.

d. Sample size

It is estimated that around 620 children will die within the two years of the study in the whole area under demographic surveillance. Approximately half of this children will die from diarrhoea. About 660 cases and same number of controls are required to detect a relative risk of 1.4 so that there is a 90% chance at the 5% significance level (35). Our sample collection may need to continue a little more than 2 years in order to get 660 cases. Therefore, to ensure the power of the study attempts will be made either to increase the number of the controls or to continue through 660 cases, whichever found logistically feasible and cost effective.

Besides, if one assumes that the relative risk of dying will be similar in this study to the relative risk of

having diarrhoea observed in Mirzapur in high risk groups, this sample size should have a reasonable chance to detect it.

e. Data collection

Several sets of variables will be collected for each case and each controls: water and sanitation factors, pollution in/around the kitchen and courtyard, feeding practice of the child, personal hygiene practices, maternal behaviour, and water quality parameters. For confounder/ interaction analysis information will also be collected on factors such as: socio-economic and cultural characteristics and, primary health facilities/immunization status. (see Annex 2 for questionnaire)

f. Laboratory analysis

Fecal coliform counts will be done on handwashed samples of mothers of all cases and control. Standard method by membrane filtration technique will be used. Hand washed samples will be collected following the literature method (36) which is currently being used for a handwashing study (37).

Mineral contents (dissolved) such as, Iron, Magnesium, Calcium and Manganese, will be determined for drinking water from stored water samples of every household. Conductivity of the stored water will also be determined to verify the soure of the water. Conventional method from the text of standard methods for water analysis will be followed.

Samples will be collected from first primary surface water source and tested for ammonia-nitrogen. The HACH DR/3 instrument for field monitoring will be used for this estimation of raw fecal pollution.

g. Pre-testing

All of the questionaires and laboratory methods will be tested through a period of a month, with at a least week worth satisfactory

observation of the accepted method. The pre-testing will be done in phases of week, allowing time for discussion and modification. Improvements (if needed) will be made in consultation among investigators, field staff and laboratory personnel.

h. Data analysis

All forms coming from the field will be entered immediately on a microcomputer in Matlab by a field research officer. A programme reproducing the questionnaire on the screen and with filters to prevent entry of out of range values will be used. It is expected that the data will be ready for analysis immediately at the end of the field study.

All data analysis will be done on a microcomputer. First, comparison of different variables will be made between cases and controls by bivariates methods. The effect of potential confounder variables will be tested by entering them in a conditional logistic regression model and checking how this affects the odds ratios associated with the risk factor of interest.

All the analysis will be done mainly using standard statistical programmes. Examples of few dummy tables are attached.

7. Project Adminstration

Dr Bilqis Amin Hoque will administer project funds, and the funds should be directed to the office of BUdget and Finance, ICDDR,B. A time phased plan of activities is shown in Figure 1.

8. Plans for Dissemination or Implementation of Results

The findings of the study will be disseminated through a multi-purpose approach, increasing the efficiency potential of the aimed guideline for environmental intervention of child survival. The approaches are: community campaign of the priority risk factors to people of the area, publication of the findings in journals and through paper presentations in national and

regional/international conferences.

The campaign will be detailed based on preliminary findings of the study. Around the 18 th month of data collection (75% of expected data) preliminary identification of the risk factors will be attempted by ranking process. The first few risk factors will be selected to develop environmental education messages for the campaign. Monthly group meetings will be arranged at one of the household (not of the case) of the bari (20 to 60 household) of the cases.

Demonstration of the advised practice will be done as much as possible. Monthly visits will be given to randomly selected 30% of the household to monitor the effects of messages on their behavior. This will allow for the pilot testing of the feasibilty of such intervention. However, this campaign is planned to progress in parallel to final data analysis and writing of the report. The results (at least the preliminary analysis) will be attached to the report as an appendix.

9. Ethical Concern

The investigators of the proposal are well aware about the emotional involvements and therefore, are commited to handle it with care as much as pissible. The interviewers will be trained (during pre-test) to speak to the case-mothers with emotional respect and patience. Except for the information on feeding, the child will be hardly mentioned. Since vital characteristics are recorded by the DSS project and most of the project requirement is related to environmental factors (which usually are not effected by death of a child) we expect less emotionl involvement.

Figure 1. Project Administration Plan

Activities	Quarters											
	1	2	3	4	5	6	7	8	9	10	11	12
	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
1.New Recruitments	xx.	...	...	...	...	...	...	...	...	...	...	...
2.Procurement of equipments	xx.	...	...	...	...	...	...	...	...	...	...	...
3.Training and pre-testing	xxx	...	...	...	...	...	...	...	...	...	...	...
4.Data collection	...	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	...	...	...
5. Data entry and management	...	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	...	...	...
6. Dissemination campaign	...	...	...	...	...	...	...	...	xxx	xxx	xxx	...
6. Data processing and analysis	...	...	...	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
7. Progress Report to the donor	...	...	x..	...	.x.	...	..x	...	...	x..	...	..x
8. Draft Final report	...	...	...	...	...	...	...	...	...	...	...	x..

References

1. An analysis of the situation of children in Bangladesh. (1987). UNICEF.

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

3. Fauveau, V., Yunus, Md,. Zaman, K., Chakraborty, J.. Sarder, A. M., (1989). Diarrhoea mortality in rural Bangladesh. Under ICDDR,B review.

4. Fauveau, F., Wojtyniak, B., Chakraborty, J., Briend, A. (1990). MCH_FP services in rural Bangladesh: is prevention enough?. British Medical Journal (in the press)

5. Victora, C.G., Smith, P.G., Vaughn,J.P., Nobre,I.C., et al.(1988) Water Supply, Sanitation and Housing in Relation to the Risk of Infant Mortality from Diarrhoea. International Journal of Epidemiology: 17(3), 651-654

6. Bertz,W.,Habicht, J.P., DaVanzo, J.(1984). Environmental Factors in the relationship between breastfeeding and infant mortality: the role of sanitation and water in Malaysia. Am. J. of Epidemiology: 119(4), 516-525

7. Aziz K.M.A., Hoque B.A., Huttly, S.R.A., Minnatullah, K.M. Hassan, M.K., Patwary, M.K., Rahman,M., Cairncross, S.(1989). Water Supply, Sanitation and Hygiene Education: Report of a Health Impact Study in Mirzapur. Bangladesh. Draft for review.

8. Rahman, M., Woktynaik,B., Rahman,M.M., Aziz, K.M.S. (1985). Impact of environmental sanitation and crowding on infant mortality in rural Banglades. The Lancet, July 6. 28-31

9. Report of the water and sanitation intervention study: Teknaf, Bangladesh, 1980-83. (1985). ICDDR,B

10. Glennie, E.R. (1985). Keynote Address, Proceedings of Workshop on water and sanitation intervention related to diarrhoeal disease in Bangladesh, December 17-19.

11. Stanton, B.F., Clemens J.D.,(1987). An educational intervention for altering water-sanitation behaviours to reduce childhood diarrhoea in urban Bangladesh. A randomized trial to assess the impact of the intervention on hygienic behaviours and rates of diarrhoea. Am. J. Epidemiol:125:292-301

12. Khan M.U.(1982). interruption of shigellosis by handwashing . Transactions of the Royal Society of tropical Medicine and Hygiene. 76:1357-67

13. Hoque B.A. and Briend A. (1990). Efficacy of Handwashing Agents in Ideal Condition of Handwashing Practice. Under ICDDR,B review

14. Esrey, S.A., Habicht, J.P., Latham, M.C., Sisler D.G. & Casella, G.(1988): Drinking water sources, diarrhoeal morbidity, and child growth in villages with both traditional and improved water supplies in rural Lesotho, southern Africa. Am. J. Pub. Health 78, 1451-1455.

15. Briend, A.,Hasan,Z., Aziz, K.M.A., Hoque,B.A.,(1989). Diarrhoea control programmes are not likely to reduce child malnutrition: observations from rural Bangladesh. Accepted for publication in Lancet.

16. Baltazar, J., Briscoe, J., Mesola,V., Moe,C. Solon,F., Vanerslice, J. Young,B. (1988). Can the Case-Control method be used to assess the impact of water supply and sanitaion on diarrhoea? A study in the Philippines, 66(5), 627-635

17. Ahmed F.(1981). Design parameters for Rurtal Water Supplies in Bangladesh, M.Sc. Thesis, Bangladesh University of Engnr. and Technology, Dhaka.

18. Skoda J,D.(1979). A survey in rural Bangladesh on diarrhoeal morbidity, water usage and related factors. Final Report 1979. UNICEF. Bangladesh

19. Briend, A., Hoque B. A., Aziz. K.M.A. , (1989). Iron in tubewell water and linear growth in Bangladesh. Under ICDDR,B review.

20. D'Souza,S., Bhuiyan A, Zimick, S., And Sheikh K. (1988). Mortality and Morbidity: The Matlab Experince: Technical Study 56e. IDRC, Canada

21. Stansfield,S.K. (1987). Acute Respiratory infections in the developing world: strategies for prevention, treatment and control. Pediatr. Infect Dis J. 6:622-629

22. Pandey, M.R., Sharma P.R., Shakya G.M. et al (1989) Importance of chronic diarrhoea and acute respiratory infection (ARI) for child survival Strategy in Nepal. Mrigendra Medical Trust, Kathmandu, Nepal.

23. Pio A, Leowski J, ten Dam HG. (1985). The magnitude of the problem of Acute Respiratory Infection. Proceedings of an International Workshop. Edited by R. Douglas, Adelaide, Australia, p23-16

24. Hoque, B.A. Huttly S.R.A., Aziz K.M.A. Patwary, M.Y. and Feachem R.G. (1989). Tubewell water consumption and its determinants in a rural of Bangladesh. J. of Tropical Medicine and Hygiene , 92, 197-202

25. Bilqis A. Hoque, S.R.A. Huttly, K.M.A. Aziz, Z.Hasan, and M.Y.Patwary (1990). Effects of Floods on the Use and Condition of Pit Latrines in Rural Bangladesh. In Press (Int. J. of Disaster)

26. Shann F. et al. (1984). Lancet 2 537-541

27. Chowdhury S.A. and Khan A.H. (1980). Causes of death Companiganj, Bangladesh 1975-78. Dhaka, Christian Commission for Development in Bangladesh.

28. Chen L.C. et al.(1980). Epidemiology and cause of death among children in a rural area of Bangladesh. Am. J. Epid. 9(1),25-33

29. Black R.E. et al. (1982). Longitudinal studies of infectious diasease and physical growth in rural Bangladesh. Am. J. Epid. 115, 305-314

30. Zimicki S. et al. (1985). Cause of death reporting in Matlab. ICDDR,B, Scientific Report No. 63

31. Shaikh K. et al (1985). DSS matlab: Vital events and migration tables 1983. ICDDR,B Report No. 64

32. Narian J.P. (1987). Epidemiology of acute respiratory infections. Indian J. Pediatr;54 153-160. 33. WHO. (1988). Programme for control of Acute Repiratory Infections: Biomedical and Epidemiological Research Priorities of the global scientific working group.

34. Briscoe J., Feachem R.G.and, Rahaman M.M.(1986).Evaluating health Impact. Water supply, Sanitation, and Hygiene Education. International Development Research Centre.

35. Bilqis A. Hoque, V. Fauvaeu and Briend.(1989). Iron in drinking water and growth in Matlab. A recently completed protocol. ICDDR,B

36. Pinfold J.V., Horan N.J. and Mara D.D. (1988). The Faecal Coliform Fingertip Count: A potential Method for Evaluating the Effectiveness of Low Cost Water Supply ans Sanitation Initiatives. J. of Tropical Medicine and Hygiene: 91, 67-70

37. Bilqis A. Hoque. (1990) Developmet of an appropriate handwashing technique. A protocol in progress.

Budget in U.S.Currency

	DONOR CONTRIBUTION IDRC				RECIPIENT CONTRIBUTIONICDDR,B			
	IYear	IIYear	IIIYear	Total	Year IYear	IIYear I	Total	
1. Personnel :								
Principal Invest	17560	19316	21248	58124	0	0	0	0
Co-investigators	0	0	0	0	3852	4237	4661	12750
Field R. Officer	6648	7313	4022	17983	0	0	0	0
Lab Res Officer	5400	5940	3267	14507	0	0	0	0
Adm. Assistant	850	935	1029	2814	0	0	0	0
5 Commun workers	3600	3960	4356	11916	0	0	0	0
Consultants	0	1000	2000	3000	0	0	0	0
2. Travel								
Matlab.Water tra	2500	3000	500	6000	0	0	0	0
Dhaka-Matlab	1500	1600	1000	4100	0	0	0	0
Dhaka	200	200	100	500	0	0	0	0
International	0	2000	2000	4000	0	0	0	0
3. Equip. & Supplies:								
Glassware	2500	500	0	3000	share autoclaces,			
Lab. Reagents	4500	4500	500	9500	instruments and pump			
Office Supplies	1400	1200	1500	4100	0.	0	0	0
4. Data Processing								
Data Management in								
Main frame	1200	1200	1500	3900	0	0	0	0
Disks/tape	500	500	300	1300	0	0	0	0
Person Computer	2500	0	0	2500	And share another at office			
5. Other direct Cost :								
Communication	500	500	500	1500	0	0	0	0
Xeroxing/print	1000	600	1500	3100	0	0	0	0
DSS Data Collect	0	0	0	0	487788	536567	0	1024355
Sub-Total	52358	54264	45321	146061	491640	540804	4661	1037105
Overhead Costs (10%)	5236	5426	4532	15194	49164	54080	466	103710
TOTAL	57594	59690	49853	167137	540804	594884	5127	1140815
GRAND TOTAL:	1307952							

Budget Justification

Personnel:

1. The Principal Investigator is a project staff and 100% of her salary has to come from the Project. She will be working 100% for the Project. She will be responsible for the implementation of the project, supervising the staff, supervising the laboratory works, undertaking the data management and its analysis., writing the report and disseminating the findings. She will verify 10% of the field and laboratory data.

ICDDR,B is contributing salary of the coinvestigators. Dr Yunus will help in overall scientific management of the project for 10% of his time. Mr Chakraborty will help in field management (10%). Dr Strong will advise and help as required.

2. Field Research Officer will be a Project Staff with 100% commitment for 2.5 years. He will be responsible for extracting DSS information and vital records from the Matlab DSS system, supervising the field staff and providing assistance for data management.

3. Laboratory Research Officer will also be 100% Project Staff for 2.5 years. He will be responsible for the laboratory analysis.

4. Adminstrative Assistant will provide secretarial help to the project. He/she will work for 10% of her time. The person will be responsible for supply typing and other administrative works.

5. Community Health workers will conduct the interviews and enter the data. Out of 5 persons 4 will be women. working 100% for the Project. They will be working in two groups, each of two women. Each of the group will be interviewing 3 or 4 households per woking day. During remaining part of the day they will be entering the data, preparing materials for the following sample collection. The fifth may be hired as a daily wager helping as required. He will help in transporting the sample collecting solution to the field, transporting the water samples to the laboratory, washing the sample bottles and other works to cordinate the sample collection. Lot of unforeseen works are to be faced in the field and that cannot be cost effectively met up by regular staff.

7. Consultants will assist in data analysis and report writing. Since they are ex-scientists of ICDDR,B, and are involved with other projects of the Centre, they are expected to contribute to the project in technical as well as in cost effective way.

Travel

8. Matlab water transport is required to visit the households of the samples.

9. Dhaka-matlab transport will be used to visit field by investigators and transportation of samples to the laboratory.

10. Dhaka transport may be used for internal transport

Equipment and Supplies

11. Glasswares are required to do the tests and to transport samples from field to the laboratory.

12. Laboratory reagents include chemical reagents for performing Calcium, Magnesium, iron, manganese and ammonia-nitrogen tests on about 1400 samples. It also includes cost of the microbiological media and filter papers for doing fecal-coliform estimation on 2800 hand samples (two hands per person).

13. Office supplies include the cost of papers and other office accessories directly used for the Project.

Data Processing

14. The mainframe cost is required to manage DSS data from mainframe, manage big files of the Project and to avail help from computer expert (5% salary of a programmer).

15. Disks will be bought and tapes will be rented for data storage and analysis.

16. A Personal computer will be bought for field station for data entry, data management and analysis (when the P.I. is in field).

Other Direct Cost

Communication cost is required for postal and other communication services

Xeroxing/printing will be usd for producing questionaires, forms etc.

DSS data collection cost is contribution from ICDDR, B. As mentioned, mortality study requires huge sample size and the Centre is bearing this cost for its research purposes. Salaries of the expatriates are not shown. It only shows the field cost.

Over-head cost is designed to provide support to central Divisions of ICDDR,B , such as finance, personnel, maintenance, etc.

ANNEX 2:Questionnaire Part I

Identification and determination of socio-economic level

Interviewer: ___ Questionnaire No: _____

Date of interview: _____

CID (census No): _____

Mother's schooling: _____ Father schooling: _____

Land owned:

none (1) less than 100 decimals (2) more than 100 decimals (3)

House: length ____ width _____ (feet)

Roof: tin (1) other (2)

Wall: bamboo (1) Tin (2)

Possession of watch / radio / wooden bed / torchlight

Location:

From river
From Canal
From Embankment
From Health Centre
From ICDDR,B

Questionnaire Part II

Water and sanitation variables:

Main source of water by activities:

Tubewell (1) Pond (2) Ditches (3) Canal (4) Dug well (5) River (6)

	Type	Distance from kitchen
Drinking water:	____	_____
Cooking:	____	_____
Washing food:	____	_____
Bathing:	____	_____

Stored Drinking water: yes/no
Hours of collection (approx.)_____
Conductivity of stored water _____

Apron around tubewell absent (1) cracked (2) broken (3)
ok (4)
Tubewell needs priming: yes / no

Volume of water discharged per 10 full strokes: _____

Number of users per tubewell: _____

Number of users per primary surface water source_____

If pond or ditch used:

Protected by high bank (yes/no)

Flooded in monsoon: yes /no

Distance of latrines: _____

Location of latrine :Uphill/downhill_____

Possibility of conection with latrine:

always/rain run-off/monsoon/flood/ none

Sanitation

Latrines:

	Females	Males	3-4 years	<3 years
No fixed place	_____	_____	_____	_____
Fixed place	_____	_____	_____	_____
Open latrine on low land	_____	_____	_____	_____
Open latrine on surface water	_____	_____	_____	_____
Sanitary latrines	_____	_____	_____	_____
Courtyard	_____	_____	_____	_____

Total number of people using the latrine: _____

Condition of the latrine:

Fecal matter on platform, yes/no
smell: yes/ no

Hygiene and household practices:

Any animal in the same compound yes / no

Celanliness of courtyard:

rubbish yes / no

children faeces yes / no

animal faeces yes / no

Feeding before getting sick:

fully breastfed / partially breastfed / non breastfed

Handwashing practices (description):
Following defecation
Following cleaning of child's bottom
Before feeding child
Before preparing food

Indore Smoke Pollution:
Smoking Mother/Father/Other
Type of kitchen fuel
Distance of kitchen from dwelling house

Immunization :
Age
Location

Was the child given any vitamin capsule:
Age:
Match the capsule with the demonstrated ones:

Heard about ICDDR,B

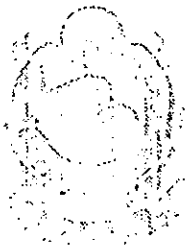
Hygiene Knowledge:
Why do we need to wash hands following defecation
Why do we need a sanitary latrine

^ B. Part III. Laboratory:

Contents of stored drinking water:
Iron
Magnesium
Manganese
Calcium
Conductivity

Contents of primary surface water:
Ammonia nitrogen

Handwashed samples: Faecal coliform count



-FP

left hand _____ Right Hand_____

^BANNEX 3. Examples of Dummy Tables:

Table1: Distribution of selected variables amongst cases and controls (same table by infectious disease cases, diarrhoea and ARI)

Variable	Cases	Controls	Test	P-value
Secio-economic factors:				
Demographic factors:				
Laboratory results:				
environmental factors:				

Table 2: Crosstabulation of deaths by type of water or sanitation facilities, or other environmental factors (same table for infectious disaese, diarrhoea and ARI)

	Type of facilities
Cases	
Controls	

Estimated odds ratio of the association=

Table 3:Conditional logistic regression with the potential risk factors and confounding variables

Respond to the external reviewers comments:

RReferee: Ms Betty Kirkwood

(1) As suggested the protocol has been redesigned as a study for infectious deaths instead of diarrhoea deaths. Therefore other risk factors, including breast feeding and infant feeding, will be investigated.
(2) Yes, the age range has been extended from 6_59 months to 1-59 months.
(3) Sample size may not be enough to separate diarrhoea deaths by type. However, attempts may be made during analysis.
(4) As the questionaires will be pre-tested we would design the method in the best possible way.

Referee: Dr. S. Cairncross

(1) Sample size has been redesigned according to the need of the study.
(2) Pre-testing of the method has been included.
(3) Suggested confounding variables will be investigated

Referee: Dr C. Victora

(1) Suggested attempts will be made in the analysis.
(2) As suggested the study has been redesigned for environmental risk factors for all deaths from infectious diseases.
(3) The study areas have been explained
(4) Conditional logistic regression will be used for testing the potential confounding variables.
(5) Six months have been shown for data analysis.

আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র, বাংলাদেশ।

<u>সম্মতি পত্র</u>

বাংলাদেশে অবস্থিত আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র ডায়রিয়া জাতীয় রোগ, কলেরা ও রক্ত আমাশয়, নিয়ন্ত্রণ লক্ষ্যে বিভিন্ন ধরনের গবেষণা করে থাকে। দেশে ও বিদেশের বহুসংখ্যক গবেষণা থেকে জানা গেছে পরিবেশের সাথে অসুখের সম্পর্ক আছে এবং এই পরিবেশের উন্নতির মাধ্যমে রোগ নিয়ন্ত্রণ সম্ভব।

পরিবেশ একটি বিরাট ব্যাপার। আমরা এই গবেষণার মাধ্যমে পরিবেশের বহুসংখ্যক দিক, পানি, স্যানিটেশন এবং পরিবেশ জ্ঞান/ব্যবহার সংযুক্ত কিছু বিষয় নিয়ে রোগের সাথে সেগুলির সম্পর্ক দেখতে চাচ্ছি। *আমরা আপনার [illegible] [illegible] [illegible],* বাংলাদেশে প্রচুর হারে মানুষ মারা যায় এই ধরনের রোগে। আমরা আপনাকে অনুরোধ করছি পরিবেশের যে সকল অবস্থা বিষয় [illegible] সাহায্য করতে, আমরা [illegible] বিষয় [illegible] ভবিষ্যতে সেগুলো [illegible] পাবো এবং সহজলভ্য পদ্ধতি উন্নত করার চেষ্টা নেওয়া হবে। আপনাদের গবেষণার [illegible] আপনাদের সকল তথ্য গোপনেই রাখা হবে।

আমরা পানির ব্যবহার, পায়খানার ব্যবহার, আশে পাশের পরিবেশ ও স্বাস্থ্যকর অভ্যাসের উপর কিছু প্রশ্ন করব। আপনি উত্তর দি না দিলেও আপনার [illegible] সুবিধা পাবেন।

প্রশ্ন গ্রহণে রাজি থাকলে অনুগ্রহ করে এখানে সই অথবা টিপ সই দেন।

সাক্ষী।

[illegible]

CONSENT FORM

(Environment and child survival in rural Bangladesh)

International Centre for Diarrhoeal Dosease Research, Bangladesh is studying environmental risk factors for deaths from infectious diseases. It has found in Bangladesh and abroad that certain environmenatl factors are associated with morbidity. We attempt to study those factors to find their association with deaths.

We are extremely sorry for what has happened to your child. Thousands of children in Bangladesh die from similar diseases. We request you to help us to identify the risk factors so that in future more realistic attempts can be undertaken to control the factors. We also plan to inform you our findings at the completion of our study.

We request you to respond on questions related to water use, latrine use and hygiene pratices. You have right to refuse to participate or withdraw and still receive support from ICDDR,B facilities.

If you are willing to agrre to our request and contribute to a research which has wider implication for the prevention of diarrhoea, please sign.

_____

P.I.
have completed

_____

Participant

Date: _____