Ethical Review Committee, ICDDR,B

Principal Investigator: Dr. Bilquis A. Haque
Application No.: 94-009 (Revised)

Title of Study: Environment and Child Survival: Safe Household Intervention in Rural Bangladesh.

Trainee Investigator (if any) [ ]
Supporting Agency (if Non-ICDDR,B) [DC (probably)]

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

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

Source of Population:
(a) Ill subjects Yes [x] No [ ]
(b) Non-ill subjects Yes [x] No [ ]
(c) Minors or persons under guardianship Yes [x] No [ ]

Does the study involve:
(a) Physical risks to the subjects Yes [x] No [ ]
(b) Social risks Yes [x] No [ ]
(c) Psychological risks to subjects Yes [x] No [ ]
(d) Discomfort to subjects Yes [x] No [ ]
(e) Invasion of privacy Yes [x] No [ ]
(f) Disclosure of information damaging to subject or others Yes [x] No [ ]

Does the study involve:
(a) Use of records, (hospital, medical, death, birth or other) Yes [x] No [ ]
(b) Use of fetal tissue or abortus Yes [x] No [ ]
(c) Use of organs or body fluids Yes [x] No [ ]

Are subjects clearly informed about:
(a) Nature and purposes of study Yes [x] No [ ]
(b) Procedures to be followed including alternatives used Yes [x] No [ ]
(c) Physical risks Yes [x] No [ ]
(d) Sensitive questions Yes [x] No [ ]
(e) Benefits to be derived Yes [x] No [ ]
(f) Right to refuse to participate or to withdraw from study Yes [x] No [ ]
(g) Confidential handling of data Yes [x] No [ ]
(h) Compensation for treatment where there are risks or privacy is involved in any particular procedure Yes [x] No [ ]

5. Will signed consent form be required:
(a) From subjects Yes [x] No [ ]
(b) From parent or guardian (if subjects are minors) Yes [x] No [ ]

6. Will precautions be taken to protect anonymity of subjects Yes [x] 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 Ctte. 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.

Principal Investigator: [Signature] [Date: August 30, 1994]
Trainee: [Signature] A - 031974

Library: ICDDR,B LIBRARY
Location: DHAKA 1212
Date: August 09, 1994
1. Principal Investigators: Bilqis A. Hoque, Khoda Bokhs and Qamruzzaman Mahmood

2. Co-P.I.: K.M.A. Aziz

3. Title of the Project: Environment and Child Survival: Safe Household Intervention in Bangladesh

4. Advisors: A.H. Bequi and R. Bradley Sack

5. Starting Date: October 1, 1994

6. Date of Completion: September 30, 1999

7. Total budget requested: US$ 1,850,000 (Approx)

8. Funding Source: Probably SDC/USAID

9. Head of Division: Acting Divisional Director
Summary:

Interventions in Water Supply and Sanitation (WSS) have been found to be associated with the reduction of diarrhoea morbidity and mortality in all age groups and in all types of diarrhoeal diseases. The Government of Bangladesh (GoB) has been increasing its budget and efforts in WSS programs. It has shown remarkable success in safe water supply coverage. More than 85% of its people drink tubewell or tap water. Less than 40% of its people defecate in sanitary latrines. The success of WSS program has shown limited impact on diarrhoea and water related disease morbidity rates and so the effectiveness of the program may be doubted. Researches and evaluation surveys have indicated that stored water is highly contaminated, safe water is not used for all domestic purposes, kitchen and personal hygiene practices are poor and the actual sanitary disposal of feces is even lower than the estimated figure. Excreta of children is rarely disposed of in sanitary way and most of the sanitary latrines are maintained in unsanitary way. The earlier researches were conducted mostly in small scale and under controlled conditions. The study of application of those researches in a combined package and through a replicable process with executing agencies will contribute to the GoB efforts for improving country's WSS situations.

Therefore, there is urgent need for WSS applied research through which WSS educational package and its delivery process model can be tested and developed.

Goal:

proposal.rrc/disk-7/94
To provide technical assistance to the Government of Bangladesh for improving the water and sanitation situations in the country.

Objectives:

a) To investigate, test and develop a community and public sector participatory program for improving the water and sanitation practices and,

b) To study the operational parameters of the delivery and evaluation process.

Specific Objectives:

1. To motivate the community and increase their utilization of the components of a water and sanitation household package, consisting of:

   i) Increasing knowledge about modes of diarrhoea transmission through water, and about sanitation and personal hygiene practices.

   ii) Increasing use of tubewell/tap water for domestic purposes (at least 25% increased use through more effective neighbourhood sharing and adequate maintenance of tubewells).

   iii) Increasing safe household practices for the storage, handling and ingestion of household water.

   iv) Increasing the sanitary disposal of feces of all age groups (to at least 50% effective usage coverage of sanitary latrines)

   v) Increasing appropriate handwashing, food hygiene, and
domestic waste disposal practices.

2. To assess the delivery, the community organization, mobilization, and educational components of the program.

3. To assess the impact of the project interventions in reducing the diarrhoeal morbidity among children under 5 years of age.

4. To determine the sustainability of the promoted activities in the original area as the program moves to adjacent areas.

5. To improve local capabilities for planning, implementing and evaluating water and sanitation programs.

6. To develop a mechanism for multi-institutional and intersectoral collaboration for water and sanitation program.

Methodology:

A longitudinal applied research will be conducted in rural Matlab (DSS area) and Urban Dhaka (Zone 3) to test and develop the proposed WSS model. Areas will be designated as intervention and comparison areas. The intervention areas will receive the project inputs; such as WSS education through community and collaborating GoB workers. The comparison area will receive the normal GoB services. Community groups, such as, school teachers and students, political and social leaders, volunteers, religious leaders, will be motivated and trained to advocate the educational package in the target. GoB workers in the collaborating agencies (DPHE, Primary Health Care and DCC) will also advocate the educational messages matching their normal activities.

The study will be conducted in two phases, phase I for situation analysis, planning and testing in a part of the proposal.rrc/disk-7/94
population (18 months period) and phase II for implementation and development of the model in the whole study population (42 months). During phase I about 40,000 people will be studied in each of the intervention and comparison area. In phase II people in the whole of DSS area in Matlab and Zone 3 of Dhaka will be covered.

The performance of the intervention will be monitored by determining the changes in water use, excreta and domestic waste disposal, food hygiene, personal hygiene, new installation and functioning conditions of tubewells/taps and latrines, and roles played by the different community groups and GoB workers in the project.

The expected outcomes are improvement of the advocated behaviours/practices, development of a community involved process for safe WSS and development of a inter-sectoral collaboration model for preventive health programme.

Budget: Estimated budget is U.S. $1,850,000 approximately.
Environment and Child Survival: Safe Household Intervention in Bangladesh

P.I. Bilquis A. Hoque (ICDDR,B), Khoda Fokha (DPHE), and Qamruzzaman Mahmood (DCC)

Co-P.I. K.M.A. Aziz

Advisors: A.H. Baqui and R.B. Sack

Background:

Statement of the Problem:

Diarrhea is one of the major causes of morbidity and mortality in Bangladesh (2). The preventive strategies recommended to control diarrhea are: promotion of breast feeding, weaning education, measles immunization, use of ORT and improving water supply and sanitation and personal hygiene (3). The effects of breast feeding and weaning education are directly or indirectly influenced by safe water, sanitation and hygiene practices. Appropriate vaccines for diarrhoeal diseases are yet to be available. The effectiveness of ORT in treating shigella dysentery and other dysenteric diarrhoea is limited and ORS has little impact on overall diarrhoea incidence. The increasing resistance of shigella to different drugs is also a growing problem.

Interventions in Water Supply and Sanitation have been found to be associated with the reduction of diarrhea morbidity and mortality in all age groups (4,5) and in all types of diarrhoeal diseases. The outreach of WSS provisions and practices relates to multidimensional health and development issues which range from short-term to long-term benefits (6).
For the majority of people in developing countries household environments are poor and unhealthy because of poor water and sanitation. Collectively poor sanitation, insufficient and unsafe water supplies, poor personal and food hygiene and other household environmental factors (hereafter referred as WSS) are associated with 30 percent of the global burden of disease (7). The International Decade for Drinking Water Supply and Sanitation, agenda 21, and the World Bank Reports of 1991 and 1992 recommend equitable and sustainable safe water and sanitation and safe household environments for all people. It may be pointed out that in industrialized countries mortality and morbidity of infectious diseases decreased before immunization programs were introduced. There, development brought WSS provisions within the convenient reach of the people, and at least part of the decline in mortality from infectious disease was due to reduced contact with pathogenic micro-organisms.

In Bangladesh, unlike many developing countries, the domestic use of microbiologically contaminated, but abundantly available water is the primary problem rather than a shortage of water. People drink tubewell water which is safe at its source but found to be highly contaminated at its consumption points (6). People rarely dispose of feces in sanitary ways (already said) and exhibit poor hygienic practices (7). As in many developing countries, diarrhoeal diseases are endemic and cholera epidemics regularly occur. The country and the agencies supporting it have identified WSS interventions as one of the major priorities for health and proposal.rrc/disk-7/94
development. These observations clearly indicate that governments of the developing countries urgently need guidance for feasible WSS programs and that research has an important role in this regard.

An integrated WSS intervention in rural Mirzapur, Bangladesh, showed that diarrhea morbidity could be reduced by 25% in children below 5 years of age (5). Another study in Teknaf, Bangladesh, suggested that installation of latrines was more effective in reducing diarrhoea-related mortality than provision of handpumps (8). In the Mirzapur and Teknaf studies, however, WSS provisions were given to the people by the project free or at a highly subsidized cost. In both of those projects extensive hygiene education was also provided at the doorstep of every household by project workers. This type of intensive intervention will be difficult to replicate on a wider scale in the near future.

The Government of Bangladesh (GOB) has been increasing its budget and efforts in WSS programs. It is still attempting to develop strategies for a proven, effective and sustainable WSS program. The GOB, with assistance from UNICEF and donor agencies, has tested integrated promotional programs for sanitation through social mobilization in Banaripara, Barisal. A recent rapid evaluation of that program indicated potential problems related to i) the sustainability of the promoted sanitation messages and the home-made hygienic latrines and ii) the involvement of the partners, in the programmatic implementation (13).

The water sanitation problem is more acute in cities, specially in rapidly growing cities like Dhaka and Chittagong. In
other countries significant differences have been observed in diarrheal incidence by type of water used and type of water and sanitation facilities (14). Although the cities of the country have gone through extensive development over the years the environmental situations have worsened due to its limited capabilities to cope with the growth rates. According to Dhaka City Corporation there has been rarely any planned community based intervention program to improve the water and sanitation situations.

An intensive health education study by women volunteers in an area of Dhaka found that mother's handwashing before food preparation and disposal of feces outside the household compound were the two practices which most closely correlated with the incidence of diarrhoea (9). This research clearly indicate the potentials for cost-effective water-sanitation projects in urban areas. Furthermore, the country has shown remarkable success in rural water-sanitation activities and it is logical that those experiences be used in urban development.

All research efforts have helped to develop WSS ideas, technologies and strategies, but rarely has any pilot study been conducted to test a comprehensive environmental program which involves widely feasible environmental, educational activities and its community participatory delivery process at household levels. We propose a pilot environmental applied research program to study i) an appropriate comprehensive household environmental education package built on the basis of earlier experiences and improved with the community and ii) the development of a feasible widely proposal.rrc/disk-7/94 8
replicable process to implement the package. The basic components of the package have been selected mainly based on recently completed four studies: i) Environment and Child Survival ii) Handwashing Practices in rural and urban areas, iii) An Integrated approach for Sanitation in Banaripara and iv) Environment and Shigella Dysentery in Dhaka. The preliminary findings of those four studies are summarized in appendices 1-4.

The process of the delivery of the package proposes extensive community participation by people of all groups (women, men children, leaders), public sectors and NGOs and private organizers (in concerned field) existing in the area. The package and process have been designed based on the known necessity and feasibility factors found i controlled researches and during discussions with concerned public sector officials. The components of the program (educational package and delivery process) will be updated/improved/modified as found appropriate during the project period. So, this applied research study will contribute in the development of a complete country program with the concerned agencies which was not attempted earlier.

Goal:

To provide technical assistance to the Government of Bangladesh for improving the water and sanitation situations in the country.

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sector participatory program for improving the water and sanitation practices and,
b) To study the operational parameters of the delivery and evaluation process.

Specific Objectives:
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   iii) Increasing safe household practices for the storage, handling and ingestion of household water.
   iv) Increasing the sanitary disposal of feces of all age groups (to at least 50% effective usage coverage of sanitary latrines)
   v) Increasing appropriate handwashing, food hygiene, and domestic waste disposal practices.

2. To assess the delivery, the community organization, mobilization, and educational components of the program.

3. To assess the impact of the project interventions in reducing the diarrhoeal morbidity among children under 5 years of age.
4. To determine the sustainability of the promoted activities in the original area as the program moves to adjacent areas.

5. To improve local capabilities for planning, implementing and evaluating water and sanitation programs.

6. To develop a mechanism for multi-institutional and intersectoral collaboration for water and sanitation program.

Justification:

The safe WSS household program if found to show desirable environmental, behavioural and health improvements, would have implications for national policies and programs. It would show that a community participatory intersectoral environmental health project for preventive health practices could be maintained at the household levels.

The Government of Bangladesh (GOB) has launched a social mobilization program for rural sanitation through which they would like to involve as many partners as possible to promote sanitation. The GOB, therefore, would appreciate guidelines for implementing a widely replicable and sustainable WSS program in rural and urban areas both. The preliminary planning of the program has been done with the interested GOB, NGO and UN and donor agency partners.

Strategies:

i) The ICDDR,B and concerned public sectors of GoB will implement the project activities under the guidance of a steering committee formed with members from collaborating agencies.

ii) The water and sanitation situations will be improved through educational intervention with hardware inputs as available in proposal.rrc/disk-7/94
the existing GoB programs.

iii) The situation analysis survey will be conducted to assess the needs and make detail plans for installation and maintenance activities, training and implementation process.

iv) The concerned public sector of GoB will be responsible mainly for installation and maintenance of the water and sanitation provisions according to the identified needs and available resources.

v) The ICDDR,B will provide technical assistance to the GoB in installation and maintenance activities and be responsible for monitoring, evaluation and training activities.

vi) The activities will be conducted in rural and urban area simultaneously so that the experiences and resources can be shared.

The Intervention:

The intervention will consist of developing a household environmental education package and its delivery process through community participation. The concept of 'community participation' has three recognized advantages though problems with it are not unexpected (15). i) Local governments see it as more cost-effective than alternative approaches that would draw more heavily on scarce national resources (16). ii) Both common sense and innumerable field experiences (17) show us that those development projects in which local people themselves are somehow actively involved are, other things being equal, going to be more successful and sustainable. This concept is morally consistent with the principles
of equality and self-reliance that have been referred to as 'self-help' by various authors (18).

The package will consist of promoting messages stated under specific objective; Sl. No. I. Those messages are expected to bring the desired knowledge, attitude and behavioural changes among the men, women and children of the study area. We know water and sanitation related diseases are transmitted through multiple parallel modes. Interruption of the transmission mode will require control of all or as many as possible modes. We have selected the contents of the educational package based on our findings during risk studies.

In order to support the behavioural changes it is obvious that the availability of water and sanitation provisions have to be improved. The improvement in availability will be attempted in three ways: increasing the effective usability of the existing facilities through community participation, improving the functioning conditions of the existing facilities through essential and planned maintenance by the users and assistance in installation of new provisions according to the GoB’s programs. The changes or activities will be advocated through a process in which interested and identified groups of the local community people, public sector workers, NGOs and private producers will actively participate in its planning, implementation and evaluation.

The school teachers and students, religious leaders, political leaders, women, men, existing clubs, public health workers and thana health workers will promote and motivate people to follow and
realize the messages of the project. These partners were decided during recent meetings with people from those groups. Representatives from GoB (DPHE, Primary Health Care and City Corporation), WHO, UNICEF and the National Education Board expressed an interest to become collaborators in several meetings to open up a dialogue on collaboration.

The local community groups will be motivated and expected to participate in the project in following ways:—

Public Sector (GoB) workers:

All the workers of the collaborating agencies involved in educational activities will be trained on the water and sanitation issues. It is expected that the DPHE, Primary Health and City corporation workers will participate in the project activities. These workers usually promote water and sanitation practices and this training will help to standardize the messages.

Social leaders:

The political, specially elected leaders, and religious leaders will meet with the project planners and workers in seminars as required. During the seminars they promote the water and sanitation activities. Interested leaders will participate in the need assessment and planning of the activities. They will also identify local workers who will be trained as volunteers for the project in their local areas.

Schools:

Two teachers (one male and one female) will be identified from every school in the area and trained about the project activities.
These teachers will educate the students of their schools about the educational package through monthly seminars. Essay and debate competitions on water and sanitation topics will be sponsored. The students will be encouraged to discuss the water and sanitation issues with the family members and practice the personal hygiene.

Female Volunteers:

Interested female volunteers will be identified and trained on water and sanitation issues of the project. They will be also trained to maintain their handpumps and latrines. They will be encouraged to discuss the water and sanitation messages, collect the maintenance cost from the users and assist in proper functioning of the facilities.

Clubs:

The local non-political clubs will be included as partners in the project. The interested members of the club will be trained on project issues. They will be encouraged to promote messages at all levels, and organize meetings and social events on project related issues.

Methodology:

The study will be conducted in the ICDDR'B's MCH-FP comparison area in rural Matlab and Ward 59 in Lalbagh thana Dhaka.

The International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) a research institution unique in the world for the control of diarrhoeal diseases, has been conducting demographic research activities in a population of 200,000 persons for approximately 30 years in rural Matlab. In 1978, a family planning proposal.rnc/disk-7/94
and health services project was initiated in half of the study area, representing the Maternal and Child Health - Family Planning (MCH-FP) area (intervention area); the remaining half (comparison area) has continued to receive only the services of the national program. The children in the intervention area have one of the highest vaccination coverage rates in the developing world. Furthermore, the Community Health Workers CHWs regularly visit the households, deliver ORS packets as required and refer sick children to the clinics and hospitals. Deaths from diarrhoea have decreased, as has overall infant and child mortality. In spite of all of these child survival investments, the diarrhoea morbidity and especially cholera incidence have not decreased significantly. Diarrhoeal diseases remain the single major cause of childhood deaths.

In Lalbagh thana ICDDR,B is conducting Urban MCH-FP activities. We have been specially requested to provide technical assistance to the Dhaka City Corporation in improving the WSS situations in Ward 59 in Lalbagh thana. The Dhaka City Corporation will be undertaking the sanitation activities under the Integrated Flood Protection Project in that area. It was felt that simultaneous undertaking of rural and urban WSS activities will be beneficial from research and resource views.

The Study Population:

The project is planned to be a phased environmental sanitation activity which will consist of: Phase I: preliminary development of the program (package and process) over a period of eighteen months in selected part of the areas; comparison area in Matlab and Ward proposal.rrc/disk-7/94
59 in Lalbagh thana and Phase II: the activities to be gradually extended to the entire MCH-FP area and Lalbagh thana over a period of another 42 months while development of the program continues and the sustainability issues are followed in the area of phase I.

During Phase I, the intervention will be given in an area having about 40,000 population. Another similar size population will be studied in the comparison areas (MCH-FP comparison area in Matlab and Ward 58 in Lalbagh thana) to compare the findings of this project interventions. It may be mentioned that in this area area people are provided with MCH-FP services by the ICDDR,B and in the comparison area people live under similar conditions as in most of the other rural areas. During phase II the activities will be extended in the other MCH-FP areas.

Sample Size:

Although the activities will be conducted in the whole of ICDDR,B area in Matlab and in Zone 3 of Dhaka, for evaluation purpose we will randomly select specific number of samples. The sample size has been calculated based on the expected difference of 10% diarrhoea episode/child/year between intervention children and comparison children. In Mirzapur a difference of 25% was observed when about 20% of the people were using tubewell water for all domestic purposes and about 90% of the adults were defecating in sanitary latrines in the intervention area. Here we expect similar change in water use but 50% people defecate in sanitary latrines, we assume that the difference in diarrhoeal attacks between intervention and comparison areas will be 10%: the required proposal.rrc/disk-7/94

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equation to calculate the sample size is as follows:

\[
\frac{E}{6\sqrt{\sigma_1^2 + \sigma_2^2}} = Z_{1} + Z_{\alpha}
\]

Where \( E \) is the difference between two groups that will have to be detected, \( \sigma \) is the standard deviation of the variable of interest, and \( n_1 \) and \( n_2 \) are the sample size in each group and \( Z_1 \) and \( Z_\alpha \) are two values of the normal variates which depend on the level of significance and power of the test.

Here 10% reduction means \( E = 0.03 \)

\[
5 = 2
\]

\( n_1 = n_2 = n \)

We have assumed that there will be 3 diarrhoeal episodes per child per year, the standard deviation of the number of episodes will be 2, the family size is 5, and 15% of the population will be less than or equal to 5 years of age.

For 5% level of significance i.e. 95% C.I., \( Z_1 = 1.96 \) and 80% power of the test \( Z_\alpha = 0.84 \).

Putting all these values in equation (1) \( n_1 = n_2 = 672 \).

\( n = 672 \)

Assuming a design effect of 1.5, the required number of children in each area is 1,008. This many children will be available in 1,550 households (assuming 15% of the population will be less than or equal to 5 years of age).

This means that for studying the project impacts we will randomly select 1500 households from each of the intervention and
comparison populations.

To detect the change in behaviour we will study the same families assuming that there will be at least 10\% difference against every promoted behaviour between the intervention and comparison populations.

Program Management:

Although investigators from ICDDR,B and identified representative from GoB will jointly oversee their respective activities, a Central Steering Committee will guide project activities. The Committee will be supplied (by ICDDR,B) with the available information and requested to need quarterly. The Central Steering Committee will be formed with the representatives of the collaborating agencies, and representatives of interested major policy making agencies. The consultants may also participate in important meetings.

A local Steering Committee will also be formed with ICDDR,B investigators, local representatives from the partner organizations and representatives from volunteers, teachers and different group of local leaders, such as, religious leaders and political leaders. The program of the project and the performance of the partners and promotors will be discussed in quarterly meetings of the local steering committee. At the field level the main line of action will be through the program officer. A conceptual line of communication is shown in Figure 3. Active participation of the community in the action, information, and experience-sharing will be emphasized throughout the project.
Programme monitoring, development and evaluation:

The program will be monitored, developed and evaluated through multi-method approaches according to the various components of the programme. The change in knowledge attitude and practices in phase I will be studied through several cross-sectional surveys: baseline, six-monthly follow-up and final surveys. The follow-up and final surveys will be designed to include the seasonal variations. During these surveys the targeted behaviours will be studied through interviewing, check list and focus group discussions. The process will be monitored through different surveys also (Figure 5). The data collected in relation to behavioural change will also indicate about the overall performance of the process. The information will be more or less collected for all members in a household as specified in the enclosed forms. These forms will be, however, improved after baseline survey, pre-testing and required modification at different stages.

Implementation:

Phase I will be conducted over a period of 18 months during that period the first 3 months will be for preparatory activities, the following 12 months for implementation and data collection in an identified union and ward and the last 3 months for preliminary data analysis and planning of the phase II.

Data analysis plan:

All forms coming from the field will be entered immediately on a microcomputer. 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, descriptive bi-variate analysis and comparison of different variables will be made, stratifying them by areas, components and SES groups. The factors found statistically significant will be further studied to understand the confounding and interacting mechanisms. The process will be studied also based on the performance data of the promoters and measured impacts of the project. The improvement in behaviour will be assessed by comparing the practices between people in intervention and comparison areas. To study the differences between integrated primary health care (including environmental sanitation) and environmental sanitation intervention. The promoted practices by people in SHE-MCH-PP intervention and SHE-comparison intervention will be compared also.

Plans for dissemination:

The findings of the study will be disseminated through a multi-purpose approach, both during the implementation and at the completion, of the project. As the project will be conducted as a multi-partner and multi-collaborator project with community, GoB, donor and UN agencies, dissemination through various seminars and workshop will continue from the beginning to the end of the activities. The central and local steering committee meetings are planned to facilitate the dissemination process, in addition to their advisory and management roles. National workshops will be held at the end of phase I and phase II.
The reports and scientific papers will be shared with concerned national, regional and global agencies. The investigators will present their findings in different meetings also.

2. Program Activities:

2.1. ICDDR,B
- P.I. overall responsible; coordinates activities and provides training to the workers on environmental activities.
- Co-P.I's share responsibilities as suitable and provide training to workers on anthropological activities.
- Investigators: share responsibilities and provide training to the workers as suitable.
- Program Manager (1); responsible for field activities and to assist the P.I.
- Research Officer (2); supervise the field work.
- Education workers (6): educate the volunteers, school teachers, students, leaders, health workers, pump mechanics and other involved partner/promoters. They will interact with research workers and improve messages accordingly.
- Community workers and public health educators: promote messages.

2.2. Community:
Volunteers:

Promote the messages, maintain pumps, install latrines and participate in community
planning/activities in relation to surface water protection (community activities)

School children:
Promote messages within fellow students, within family and in neighbourhood, and help in latrine installation and other community activities.

School teachers:
Promote messages among students and community and participate in community activities.

Religious leaders:
Promote messages after prayers and in the community, and participate in community activities.

Political and elected leaders:
Create awareness/encourage community participation and participate in community activities.

2.3. GoB/Public Sector (DPHE, PHC and DCC):
Promote messages through their workers. The working mechanism for this promotion will be filled within their existing system.

2.4. Steering Committee: Review activities and data quarterly and accordingly interact with their respective workers.
Project Management:

A. Research Activities:

A1. Data Collection, handling and analysis
   - P.I. Overall responsible
   - Co-P.I.'s Anthropological data and work with P.I.
   - Investigators: Assist P.I. and Co-P.I.
   - Consultants and Steering committee: Advisory.
   - Research Officers (2): supervise data collection and assist P.I. and Co-P.I.
   - Health Workers/Mechanics (6); supervise data collection as well as collect special information.
   - Community Health Workers (), collect data.
   - High School children: collect data.
   - RKS and DSS: demographic and mobility information.

A2. Report drafting
   P.I.
   Co-P.I.s at ICDDR,B and GoB offices.
   Investigators.

A3. Report review and finalization
   P.I., Co-P.I., Investigators, Consultants and members of Steering Committee.
Data Collection Procedures on WSS education package in the randomly selected study population.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Type and Frequency of Data collection Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Sources of water and its use Interview</td>
<td>Cross-sectional surveys at baseline, six-monthly follow-up and final surveys (for all households), 5-7 focus groups in each area during each survey.</td>
</tr>
<tr>
<td>2. Handwashing and kitchen hygiene surveys (Interview and bacteriological)</td>
<td>Interview during surveys. Hands of about 10% of women, men and children in each area will be sampled for fecal coliform counts during the surveys.</td>
</tr>
<tr>
<td>3. Hygiene behaviour on water use and sanitation practices (Interview)</td>
<td>During the baseline follow-up and final surveys.</td>
</tr>
<tr>
<td>4. Water Handling and storage practices (Interview and laboratory test)</td>
<td>During the surveys. Water from 10% of the sources and storage containers of households will be sampled to test conductivity and fecal coliform counts.</td>
</tr>
<tr>
<td>5. Use of latrines and tubewells (Interview and check list)</td>
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<td>6. Knowledge related to safe environmental household (Interview)</td>
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<td>Sharing DSS data and during cross-sectional surveys at baseline and final (for all households)</td>
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<td>9. Diarrhoeal morbidity</td>
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Data collection on package delivery process.

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| 1. Women in package promotion and maintenance of handpumps | (a) Functioning conditions of all tubewells and latrines during the cross-sectional surveys.  
(b) Interviewing the community people during surveys. |
| 2. Men, leaders and school children in promotion. | Interviewing the community people during the surveys. |
| 3. NGOs, private producers and GoB workers. | Interviewing the community people during the surveys. |
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  - 20,227 Transportation costs
- International
  - 3,000
  - 3,000
  - 3,000
  - 3,000
  - 3,000
  - 15,000 Dissemination of findings in regional & international meetings

### Equipment/Furniture

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  - 5,000
  - 1,000
  - 1,000
  - 1,000
  - 23,000 Computer, laboratory stuff & furnitures

### Miscellaneous

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  - 1,000
  - 1,000
  - 1,000
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- 124,075
  - 121,383
  - 123,711
  - 141,175
  - 158,905
  - 677,249

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Figure 1: Conceptualization of the Interventions

Interventions
1. Education on safe WSS household package
2. Training women to maintain pumps
3. Training volunteers to install & maintain latrines
4. Education & training on protection of ponds

Individual Level
Components: Knowledge, Skill, Values & Motivation
Media: Volunteers, Students & Govt. workers

Community Level
Components: Motivation, Values & Activities
Media: Religious leaders, Political leaders, School teacher, Govt. workers & Students

Environmental & Sanitation Practices
1. Household water use & management
2. Feces disposal
3. Hygiene practices

Sanitation Facilities

Morbidity

Water quality at source
Figure 3: Partners and lines of Communication

Central Steering Committee: P.I. Program Officer (ICDDR,B) Representatives of DPHL, UNICEF, LGRD, Health, CDD, WHO and Education Board

Local Steering Committee: Local representative of the same agencies and community leaders (religious, political) and community men and women

Promotion

Data Collection

Research Officers

Field Supervisors

Education Workers

Volunteers

DPHE Pump Mechanics

Students

GoB Health Workers

Leaders

Non-ICDDR,B Partners

ICDDR,B Workers
Figure 5: Time Frame:

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Environmental risk factors have been found to be associated with morbidity and mortality but detailing is needed to design interventions. This matched case-control study aimed to define risk factors for mortality from infectious causes in children 1 to 59 months of age. About 650 cases (death children) and controls (alive children) were studied to determine their domestic water use, feeding, hygiene, indoor pollution, socio-cultural, demographic and immunization variables. Interviews, observations, and laboratory (physical, biochemical, and bacteriological) techniques were used to collect the data. The study was conducted in rural Bangladesh, Matlab, between 1991-1993.

The main causes of death were diarrhoeal diseases (36.3%), acute respiratory infections (24.2%), other infectious diseases (39.3%), and accidents (12%). Preliminary analyses indicate that, after controlling for socio-cultural factors, deaths were associated with: unsanitary latrines, contaminated water used for cooking and washing, large numbers of persons per tubewell and improper handwashing before eating/feeding. This study suggests that there are environmental issues which could be addressed through low cost interventions which are feasible under existing conditions.

An intervention study with the Government of Bangladesh and other local concerned agencies is planned to be undertaken in 1994.
Appendix II

Post-defecation Handwashing in Bangladesh: Practice and Efficiency Perspectives

Bilqis A. Hoque, D. Mahalanabis, Alam, M.J., Islam, M.S.

Inadequate handwashing after defecation and anal cleaning practices in the subcontinent is an important source of faeco-oral transmission of enteric diseases. To better understand the process as traditionally practised 90 women in semirural Bangladesh were observed washing hands after defecation. Several components of handwashing practices were identified: the cleaning agent, using left or both hands; frequency of rubbing hands, type and amount of water used to wash, and the drying of hands on worn clothes. A subsequent experiment was conducted to assess the influence of currently practised handwashing and after washing hands according to standardised procedure on faecal coliform count of hands.

As a rubbing agent, soil was commonly used (40%); soap was used by 19% and was reported unaffordable by about 81% of the non-users. Good handwashing behaviour was positively associated with better social and economic indicators including education of the women observed. Both hands were unacceptably contaminated after traditional handwashing (the geometric mean count of left were 1995 and right hand were 1318 faecal coliform units/hand). After standardising the observed components of hand washing procedures the use of any rubbing agent, i.e. soil, ash or soap produced similar acceptable cleaning. Use of a rubbing agent (e.g. soil, ash or soap), more rubbing (i.e. 6 times), rinsing with more safe water (e.g. 2 litre of tubewell water) and drying with a clean cloth or in the air produced acceptable bacteriological results. Components of traditional handwashing practices were defined through careful observation and experiments on handwashing with standardised components showed that efficient and affordable options for handwashing can be developed; this knowledge should be helpful in disease control programmes.
Appendix III

An "Integrated Approach" to Promote Sanitation in Banaripara, Bangladesh.


The Directorate of Public Health Engineering, with assistance from UNICEF, conducted a community-based integrated intervention program for sanitation in Banaripara thana of Barisal. They aimed to promote sanitation through various community groups general administration, schools, local leaders, religious leaders (imams), and Government Community Health Workers (CHW). Ring-slab and home-made latrines were promoted as sanitation options. The project continued from July 1990 through December 1991. The project was described as "Integrated" because it involved co-operation with different groups in the community.

Some members of the Environmental Health Sciences group, ICDDR,B, made a field trip to the area in February 1992 to make a rapid appraisal of the current sanitation situation. Due to time and communication constraints, we conducted a quick survey of 210 households (from 30 villages) and interviewed household members on sanitation, and socioeconomic characteristics. Specific characteristics of latrines were checked on the spot.

About 73% of the households visited used home-made or ring-slab latrines; more home-made latrines were used than ring-slab (59% vs 41%). About 70% knew what was meant by sanitary disposal of faeces. The local schools played a major role in promoting the program. This has positive implications for involving schools in nation-wide sanitation promotion. But their participation should be carefully planned and such institution should be encouraged to construct an adequate number of sanitary latrines for their own workers and students. The impact of other community groups, imams, local leaders and health workers could not be determined, but it seems reasonable that they should be motivated and given adequate orientation for active participation.

Given the limitations of the quick survey, the program appears to have achieved remarkable success in improving latrine coverage compared to the average nation-wide use of sanitary latrines. In-depth evaluation and follow-up study is recommended to estimate the sanitation coverage, determine the sustainability of the program and to develop guidelines for widely replicable programs.
Appendix IV

Environmental Risk Factors for Shigella Dysentery in Dhaka City Bangladesh.

Dilqis A. Hoque and Dilip Mahalanabis

Shigellosis is a major health problem and as the bacteria are developing resistance to available antimicrobials the importance of understanding amenable environmental risk factors is increasing. A case-control study was conducted to identify the risk factors for shigella-positive dysenteric children (case) attending Diarrhoea Treatment Centre (DTC) compared to shigella-negative water diarrhoea children (control 1) attending the same DTC and randomly selected children (control 2) living in the same community as case. The cases were children aged 1-10 years and controls were matched for sex and age. Data were collected for various of 542 cases and equal number of each type of controls.

Preliminary analysis indicate that use of non-piped water source, presence of an unprotected surface water source (within 15 meter), unsanitary disposal of children feces and inadequate handwashing practices were significantly associated with shigellosa dysentery. The effects were more prominent between case and controls 2. These findings have programme and policy implications for improving household and neighbourhood environment.

(1) Scientist, Community Health Division
(2) Divisional Director, Clinical Science Division

International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B)
Questionnaire Part I

Identification and determination of socioeconomic level

Interviewer: ______ Questionnaire No:_____

Date of interview: _________

Type of sample ______________

CID (census No.): ____________

Sex ________ Date of birth _________ Age (m) _______

Address:

Mother's schooling: ______ Father's schooling: ______

Occupation of father: Primary ______ Secondary ______

Occupation of mother: Primary ______ Secondary ______

Family size ___________ Number of <5 years children ______
(eating from same pot) (eating from same pot)

Number of male children ______ Birth order of sample ______

Marital status of mother ________

*Roof: tin (1) Bricks (2) other (3) Mixed (4) Bamboo (5) Straw.

*Wall: Bricks (1) Bamboo (2) Tin (3) Mixed (4) Bamboo (5) Straw.

*Floor space area ______________ Step ________

*House: sharing (1) _________ Number of rooms __________

Possession of watch/radio/wooden bed/torchlight/T.V. _________

*Electricity _________ *Number of electrical fans ________

*Kitchen: sharing __________

Use bed-net ___________ Number of person/bed not ________
Questionnaire Part II: Environmental factors: 

1. Water use variables:

Main source of water by activities:

<table>
<thead>
<tr>
<th>Source</th>
<th>Distance from kitchen</th>
<th>Number of Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drinking water:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cooking:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Washing food:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bathing:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Source defecation:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Piped connection (1) Yard tap (2) Street tap (3) Tubewell (4) Pond (5) Ditches (6) Canal/River (7) dug well (8)

Protection around used water sources:

*Apron around tap/tubewell ______, absent (1) cracked (2) broken (3) o.k

*Drainage around tap/tubewell __________

*Leakage in pipe line ____________

*Possible contamination of surface water source: Yes/No _______

*Functional condition of tubewell, water/stroke: Leakage: Yes/No

*Installed new tubewell: Yes/No

Any treatment of drinking water ____________

*Condition of drinking water storage container: covered/open _______

shape ____________

size ____________

Frequency of drinking water collection ________________

Amount of water stored for personal use ________________

How diarrhoea spreads: ____________________________

Water quality at source, stored container and pond

pH, conductivity, fecal coliform counts, vibrios, and COD.

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Questionnaire Part 3: Sanitation variables:

Installed new latrine: Yes/No  If installed which type: Yes/No
* Latrine used:

<table>
<thead>
<tr>
<th></th>
<th>Females</th>
<th>Males &lt;5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>No fixed place</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fixed place</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Open latrine on low land</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Open latrine on surface water</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sanitary latrines (describe)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disposal of wastes (describe)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total number of people using the latrine:  

*Condition of the latrine: Clean (1) Dirty (2)

- Smell: yes/no
- Flies: yes/no

Handwashing methods following defecation: Agent used ________

- Both hand/left hand ______

Handwashing arrangements in/near latrine: water stored ________

- Agent stored ________

*Cleanliness of courtyard:

- Rubbish yes/no
- Children feces yes/no
- Animal feces yes/no

*Disposal of domestic waste: ________

(Bury in a fixed place (1), Dispose in fixed place (2), Throw in a hole (4) No fixed place (5).)
Feedings

Fully breastfed/partially breastfed/non breastfed

Food in last 3 days: breakfast/lunch/dinner

Wash hands before feeding: Both hands/single hand

Soap/ash/mud/others/water:

Wash hands before eating: Both hands/single hand

Soap/ash/mud/others/water

Enteric bacterial counts:

Left hand ________ Right hand _________

*Immunization ___________

*Measle vaccine ______________

*Vitamin A _________________

Diarrhoea in 14 days Type _____ Treatment _______

Heard about ICDDR,B __________ Approx distance _______

Heard about any other health facilities ______ Approx. distance ___

WSS Promotion:

How diarrhoea spreads?

How water plays role in the transmission of diarrhoea?

How disposal of excreta plays role and the transmission of diarrhoea?

Has any body promoted WSS practices?

If yes; Who:

What:

When:
Questionnaire Part 4: Process evaluation

1. How diarrhoea can be presented (promoted):
   - Use of tubewell water (for what purposes) _______
   - Use of sanitary latrines (which type by whom) _______
   - Handwashing (how and when) ________________
   - Heating foods __________
   - Cooking foods __________
   - Flies __________
   - Protecting ponds

If any answer is 'yes': Who told them. How many times and when.
RE-REVIEW OF PROPOSAL

Environment and Child Survival:
Safe household intervention in rural Bangladesh

I think the area that requires most attention is that concerning the "process" through community participation, regarded as a key component of the intervention that sets it aside from previous water and sanitation interventions. The description of this process is rather vague (the same paragraph as in the previous proposal remains, page 15, which makes an extensive list of people to be involved and broad statements such as "teachers will teach the package to their students"). Secondly, the monitoring and evaluation of this process is not at all clear. I would imagine that some of the other collaborators on this project, eg UNICEF, other NGOs would have experience in this area and can strengthen this aspect of the proposal.

Other specific comments:

1. The preliminary findings from the relevant research studies in Bangladesh, apparently in appendices 1-3, were missing.

2. A point previously raised was whether the measurement of health impact, ie diarrhoea morbidity, was appropriate at this stage. This component remains but has been expanded to include mortality. Is this feasible in the size of populations to be studied in Phase 1, will cause-specific mortality be used or overall? If this adds any significant cost to the study, financial or otherwise, I would seriously question its inclusion at this stage.

3. The sample size section still requires some attention. Some of the numbers do not seem to tie up, eg n=672, design effect of 1.5 -> 1400 children and then 1500 households. If an absolute difference of 10% in targeted behaviours is intended then a much smaller number of households will be sufficient for this aspect. This then again raises the question about measuring diarrhoea morbidity - it will involve more resources than if attention is confined to behaviours. There is a sentence on selecting one high school and several primary schools - how does this fit in with household selection, which is where it is currently placed? And why are these schools needed?

4. On page 21, the comment on the follow-up and final surveys being designed to include seasonal variations is unclear. The monitoring and evaluation of Phase 2 is not well explained. On consulting Figure 5 (Time Frame) this did not clarify things for me - for example, there are numerous follow-up surveys in 1996-99: data management and analysis apparently finish before data collection.

5. No justification has been given for the various budget items. Considering the large sum of money requested, this justification should be presented. The monthly rate figures, % of time and actual sums don’t seem to add up. Eg 1673x.72x12=14455 not 15539. I would doubt that 20% of a social scientist’s time for 4 months per year only will be sufficient for a project of this nature. Are all the fixed personnel needed throughout the project - if things expand in Phase 2 surely different numbers of staff are needed in the two phases.
6 - Some of the data collection procedures (Fig 4A) are still unclear. Why, for example, does all pond water need to be tested during the surveys? What is the purpose of video recordings of hygiene behaviours on only 9 households? Is this technique feasible in this area?

7 - The questionnaire should be revised when the specific indicators are defined. Otherwise it could easily end up collecting far more data than is necessary while perhaps missing other key factors.

8 - Few targets are given for the various outcome indicators.

9 - How sustainability is defined and will be measured remains unclear.
The revised protocol has addressed several of my points to my satisfaction. It is a much better protocol than the earlier version I reviewed. It is a very interesting study, and I hope it proves to be successful. I would suggest that the study proceed, but three points I mentioned earlier remain unclear and should be addressed by the study team.

First, I raised the prospect of contamination. That is, messages and activities from the intervention area may spill over into the control area (National package). This was not addressed, and I still see it as a possibility. Although the study should proceed even if contamination occurs, contamination should be minimized if possible and measured, for use in the analysis. Similarly, how areas will be chosen for the study and measurements is not clear.

Second, no justification was given for diarrhea assumptions (i.e., rate, distribution and standard deviation). I still have some problems with this aspect of the study. First, two groups are being compared, intervention and control. The variability of the subgroups (e.g., schools, homes, women's groups, etc.) were not considered in the calculation. Even if there are enough replicates within the intervention unit, the sample size will never be large enough to do proper statistical tests. That is because there is only a one (intervention) to one (control) comparison. Although the child is the unit of interest, it is not the unit of comparison. If the present design continues as proposed, the investigators should know that no probability of error can be ascribed to the study. Only a hint of plausibility can be known. Perhaps this is enough for the implementing agencies.

Third, the process evaluation should be described in more detail. In addition, how this information will feed back into the intervention should be described. I am assuming that the promotion of the intervention will be flexible and evolve over time even though the intervention itself remains constant.

I hope these comments have been helpful. You should know that I will be leaving McGill in August. I have accepted a position at UNICEF, in New York, in the Water and Environmental Sanitation Section. You should contact me there in the future.
To : Chairman, Research Review Committee

From : Dr. Bilqis Amin Hoque

Subject: Resubmission of proposal entitled, "Environment and Child Survival: Safe Household Intervention in Bangladesh".

With reference to the above kindly note that this proposal has been reviewed again by two external reviewers and we have incorporated their comments as much as possible. Their comments and our responses may be stated briefly as follows:

1. Preliminary findings from the mentioned relevant research studies missing;
   - incorporated

2. The description of the process and monitoring is rather vague;
   - further explained

3. Whether the measurement of diarrhoea morbidity and mortality was appropriate at this stage;
   - diarrhoea morbidity has been included to compare the health benefits between the existing selective health program and the proposed MCH-PP and WSS combined program. The mortality data will not be collected as it will require a huge sample. The DSS is collecting this information and to meet our interest will be compared across the groups.

4. The sample size still require some attention;
   - The calculation of the sample size has been rechecked and found o.k. It has, however, been further explained describing the assumptions made in the calculation.

5. The monitoring and evaluation of phase 2 is not well explained;
   - we have revised the explanation. We really cannot show the details because that will be improved and developed based on the experiences in phase 1.

6. No justification has been given for the various budget items;
   - incorporated.
7. Why does pond water need to be tested?
   - the improvement in knowledge about contamination and sanitary disposal of fecal and domestic wastes, may help to reduce contamination of ponds. The testing of pond water will allow for determination of changes.

8. The questionnaire should be revised when the specific indicators are defined;
   - revised and will be finalized after pre-testing.

9. There is only one intervention to one comparison so no probability of error can be ascribed to the study;
   - we will select the samples from 2 communities in each area as suggested.

10. The process evaluation should be described in more detail;
    - incorporated.

11. The prospect of contamination;
    - it will be difficult to avoid contamination as rightfully pointed out. Attempts will be made to measure the contamination and take care as much as possible during the analysis.

Thank you.