

Library

Date 22/7/84

ETHICAL REVIEW COMMITTEE TITLE ICDDR,B Library ICDDR,B.

Principal Investigator F. J. HENRY

Trainee Investigator (if any) 8

Application No. 84-035

Supporting Agency (if Non-ICDDR,B) _____

Title of Study Environmental Intervention Contamination and diarrhoea in rural Bangladesh

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

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

1. Source of Population:

- (a) Ill subjects Yes No
- (b) Non-ill subjects Yes No
- (c) Minors or persons under guardianship Yes No

2. Does the study involve:

- (a) Physical risks to the subjects Yes No
- (b) Social Risks Yes No
- (c) Psychological risks to subjects Yes No
- (d) Discomfort to subjects Yes No
- (e) Invasion of privacy Yes No
- (f) Disclosure of information damaging to subject or others Yes No

3. Does the study involve:

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

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 NA
- (d) Sensitive questions Yes No NA
- (e) Benefits to be derived Yes No
- (f) Right to refuse to participate or to withdraw from study Yes No
- (g) Confidential handling of data Yes No
- (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure Yes No

5. Will signed consent form be required:

- (a) From subjects Yes No
- (b) From parent or guardian (if subjects are minors) Yes No

6. Will precautions be taken to protect anonymity of subjects Yes No

7. Check documents being submitted herewith to Committee:

- Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).
- Protocol (Required)
- Abstract Summary (Required)
- Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)
- Informed consent form for subjects
- Informed consent form for parent or guardian
- Procedure for maintaining confidentiality
- Questionnaire or interview schedule *

* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:

1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific questions to be asked in the sensitive areas.
3. An indication as to when the questionnaire will be presented to the Cttee. for review.

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

23 JUL 1984

F. J. Henry
Principal Investigator

Trainee

SECTION I : RESEARCH PROTOCOL

1. Title: Environmental intervention, contamination and diarrhoea in rural Bangladesh.
2. Principal Investigator: F.HENRY
Co-investigators K.Minnatullah,Z.Rahim
3. Starting Date: August 15,1984
4. Completion Date: May 15,1985
5. Total Direct Cost: \$US 21,280.00
6. Scientific Programme Head.

This protocol has been approved by the Nutrition Working Group.

Signature of the Scientific
Programme Head

Date: 23/7/84

7. Abstract Summary:

A major handpump and latrine intervention project in Mirzapur offers a good opportunity to study the effect of the improvement on contamination and in turn on disease experience. Every month, microbiological analysis will be done on about 120 samples of water and food which will be obtained from storage pots, containers (before ingestion) and a variety of water-contact sites in both the experimental and comparison villages. Results will be related to the diarrhoea incidence recorded

from surveys done concurrently. A case-control methodology will also be used to analyse additional samples. The pattern of contamination and disease will be monitored over several months to determine any seasonal influence. This approach will help in understanding the complex mode of transmission and acquisition of diarrhoeal diseases.

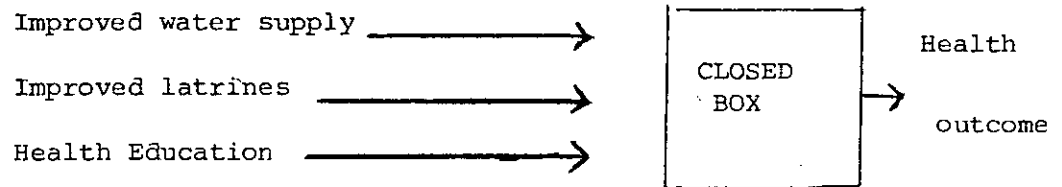
8. Reviews:

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

SECTION - II RESEARCH PLAN

A. INTRODUCTION

1. Objective:



The objective of this study is to 'open' the box (see specific aims).

2. Background

The chief reason usually put forward for investments in water and latrine facilities is the improvement in health. Attempts to evaluate the health benefits from these types of investments are therefore justified. Unfortunately, the experience to date is, on the whole, not very encouraging.

Many studies around the world, and particularly in Bangladesh, (1) have been unable to show a positive impact on health of improved water and latrine facilities. But does this mean there was no positive impact, or were the tools used to determine impact inadequate? Some workers argue that the level of investment is usually not high enough to produce positive results (2). Others contend that even where investment is large other adverse factors such as poor hygiene practices negate the potential of the water and latrine investment (3). These debates point to the fact that lack of information at the intermediate stage prevents proper interpretation of outcome. This study sets out to provide crucial 'intermediate stage' information so that explanatory data can be provided to interpret results obtained in the Mirzapur water and sanitation intervention project (4).

Most studies of the impact of water and sanitation suffer from faulty design and methodology (5). The Mirzapur handpump project, utilizing the experiences of the Teknaf water and sanitation project, attempts to minimize some of the major difficulties in interpreting these types of study. To its advantage the Mirzapur project has experimental and comparison areas comprising several separate communities, with comparable socioeconomic characteristics. Baseline information is available and a large scale intervention is planned. Outcome indicators include diarrhoea of different etiologies, parasites, other illness and nutritional status. But again, one of the key explanatory variables - contamination - was not considered in an appropriate way to yield interpretable results. The focus of this supplementary protocol is a systematic collection and microbiologic analysis of water and food consumed by young children in the experimental and comparison areas.

In El Salvador (6), 17.9% of foods consumed were contaminated by E. coli or E. intermedia. Faecal contamination in the home was suggested as an important source of these organisms. In Guatemala (7) it was shown that the water used during the preparation of tortillas was heavily contaminated with coliforms and this contamination was reflected in the tortillas before and after cooking. The association between contaminated feeds and malnutrition has been made and has led to the belief that contaminated feeds are the principal cause of gastroenteritis and consequent malnutrition. Between 1962 and 1965 some preliminary studies were carried out by the Cholera Research Laboratory on the bacteriologic contamination of water and food (8). 56.4% of 92 families with cholera cases had water sources and jars in the household with Vibrio Cholera present. Of 61 families with contaminated water sources, 65.6% had more than one case in them. Results also showed considerable

multiplication of Vibrios in stored rice within 24 hours particularly if salt is added and if the temperature is between 29°C and 33°C. This showed that storage of food overnight can quickly produce an effective dose for infection. Until recently, a relationship between the contamination of food and the risk of diarrhoea was not demonstrated. Black and others (9) have shown in Bangladesh that the proportion of a child's food samples that contained E. coli was significantly related to the child's annual incidence of diarrhoea associated with enterotoxigenic E. coli. But nothing is known about the community effect of improved water and latrines on contamination of water and food and in turn on acquisition of diarrhoea.

This approach provides the additional opportunity to investigate other issues of global importance. For example:

(i) Some workers have observed that many Third World countries cannot realistically meet the WHO Standards of safe water supplies and suggested that these standards should not be so rigid (10,13). Although the W.H.O. standards have been revised they are still arbitrary and do not relate to any particular threshold above which diseases might increase. We will investigate how different levels of contamination together with other environmental factors relate to diarrhoeal disease experience.

(ii) Rowland and colleagues (11) showed that in the Gambia, where diarrhoea abounds, both commercial milk products and traditional weaning foods are hazardous bacteriologically.

In Jamaica, Hibbert and Golden (12) observed that some children tolerated high levels of food contamination without experiencing diarrhoea, whereas others could not. This phenomenon will be investigated while associating nutritional, environmental and

socioeconomic indicators with morbidity.

(iii) Diarrhoeal diseases can be classified as water-borne or water-washed and consequently their control can be greatly affected by improved water quality or quantity (13). Controversy exists over the primary mechanism of diarrhoeal disease transmission, particularly cholera (14,15). Studies in Bangladesh have concentrated mainly on water source and usage (16-19) but have not adequately addressed the questions relating to quality vs quantity. The quantitative estimates of water use in this project in conjunction with the contamination studies planned here afford the comparison between water quantity and quality in relation to diarrhoeal disease.

(iv) The seasonal pattern of E. coli diarrhoea observed by Black et al. in Bangladesh is striking (20). Whether this occurs mainly through increased contamination of water or food which the child ingests or through another source is not clear, but will be studied.

3. Rationale

The difficulties of interpreting the health impact of water and sanitation interventions have led many donors and governments to develop negative attitudes in supporting such projects. Study design and methods are usually inadequate to explain any change or lack of it in these types of study. Focusing on an intermediate variable such as contamination can greatly assist in interpreting outcome results obtained and also in planning future intervention schemes.

B. Specific Aims

- (a) To compare the level of contamination in communities with and without improved water and latrines.
- (b) To determine the relative importance of quantity vs quality of water in acquiring different types of diarrhoeal diseases.
- (c) To determine the relative importance of contaminated water vs food in children with diarrhoeal diseases during different seasons.
- (d) To investigate the effect of distance from source, temperature and length of storage on the contamination of water and food.

C. Methods of Procedure

This supplementary protocol of the Mirzapur handpump project (MHP) has the advantage of having several baseline surveys done.

The major thrust here will therefore be on sampling and bacteriological analysis. Later, these results will be related to the data generated by the MHP.

Samples of water and food will be taken from 100 households and 20 water contact sites every month and analysed for the presence of/faecal coliforms, E. coli, shigella and salmonella and Y. cholerae. Sampling will be done with equal frequency in the intervention and comparison villages. With the use of an aerial map households will be selected according to varying distances from the tubewell and other water contact sites.

al bacterial
count

Because samples will be collected at different periods of the day, a variety of storage times will be available for the analysis. Levels of bacterial contamination will therefore be measured at differing intervals after the preparation of foods and collection of water. Temperature at the time of sampling will be measured.

Using the surveillance data of the M.H.P. a case-control methodology will be employed. A cohort of 10 children with diarrhoea and a matched cohort of children without diarrhoea will be studied by bacteriological analysis of water and food consumed (ideally the day after but) within a few days after the start of the episode. A short questionnaire regarding details of water and food ingested will be administered. This case-control study will be done once every month.

Using sterile glass vials, food and water samples will be obtained from the under 5 child's cup or bowl just before it is ingested. The vials will be stored in an insulated box with frozen cold packs and tested ~~at the Mirzapur laboratory~~ within a few hours after collection. Samples will be plated on Monsur's, SS and McConkey's agars and incubated for 18-24 hours. Standard methods employed at ICDDR,B will be used and plates will be examined for vibrios, shigella and salmonella. ~~in the Mirzapur laboratory.~~ Lactose positive colonies that are typical of E. coli will be collected from McConkey's plates for determining enterotoxigenic strains in the Dhaka laboratory. Millipore filters will be used in the faecal coliform estimations. Food samples will be blended before serial dilutions are prepared. Plating will then follow as for water samples.

To determine the relationship between water or food contamination and diarrhoea incidence, we will associate the bacterial results to disease experience at the community, household and individual levels.

We recognize that the relationship between a contaminated environment and disease is not always simple and direct and that the risk of contracting a disease depends upon the type of pathogenic organism; its virulence; the number of viable cells ingested, age of the potential victim; the general health of the individual and several other factors affecting the organism/individual link. However, the case-control approach outlined earlier will consider several of these factors in an attempt to understand why some children succumb and others do not.

In accordance with the aims and objective of this protocol, comparisons of water and food contamination levels will be made:-

- (a) between study and comparison villages.
- (b) between children with and without diarrhoeal disease.
- (c) between children with diarrhoea of different etiology.
- (d) between households using different quantities of water.
- (e) between households living at differing distances from a handpump.
- (f) between samples with different storage times.
- (g) between households with different hygienic practices.

Environmental contamination will be studied through several months of the year to assess the effect of different seasons and to compare this with the seasonal pattern of diarrhoea in children.

Initial analyses using cross tabulations will be done for the comparisons above, then subsequent analyses using standard multivariate techniques will be conducted after the MHP data are included.

D. Significance

We are fast approaching the mid-way point in the International Drinking Water and Sanitation Decade. A decade in which all of the world's population should have reasonable access to safe water supplies. But to date controversy still exists regarding what level of contamination is safe or not. This study will attempt to establish a contamination threshold above which diarrhoea rises substantially. Moreover, contamination can be related to the population/handpump ratio as well as to the distance from handpump, given this socio-environmental setting. This type of information could be crucial when the flurry of installation activities mount, as the end of the Decade draws near.

E. Facilities Required:

Office and laboratory space already detailed in the M.H.P. protocol will be utilized.

F. Collaborative Arrangements

As in M.H.P. protocol.

D. REFERENCES

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2. Kawata K. Water and other environmental interventions - the minimum investment concept. American Journal of Clinical Nutrition 31 2114-2123. 1978.
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5. Blum D. and R.G. Feachem. Measuring the impact of water supply and sanitation investments on diarrhoeal diseases: problems of methodology. International Journal of Epidemiology. 12 (3) 1983.
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Failure of sanitary wells to protect against cholera
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consequences in children.* Edited by J.A. Bellanti,
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ABSTRACT SUMMARY

1. This study will be conducted on 100 households longitudinally for 9 months. In the intervention area 50 households will be selected and they will be matched with 50 households in the comparison area. Samples of water and food will be taken from storage jars and children's bowls before ingestion. In addition, samples from children with diarrhoea will be collected soon after the onset of disease. An age-matched cohort without diarrhoea will also be studied. Because children under 5 years of age have the highest risk of diarrhoea and death, this study will concentrate on them; so that the level of contamination in the environment, and food eaten, can be related to disease experience.
2. This study will take the form of sample collection and analysis along with a questionnaire regarding the collection, preparation and use of water and food. No samples of blood, urine or stool will be collected. There are no overt or covert risks involved in these procedures.
3. Not applicable.
4. Although no risks are involved the information collected will be secured in locked filing cabinets.
5. Verbal consent will be obtained as no invasive procedures are involved.
b and c not applicable.
6. The interview will be conducted within the premises of the household at the time of sampling. The interview will last 5-10 minutes.

7. The selected households will be visited once every month. For the case-control study the cohorts will be visited soon after the onset of illness. Treatment facilities will be available to the study population through the handpump project going on concurrently. If parents are willing, seriously ill children will be taken to the nearby Mirzapur Hospital. Again, no risks are involved.
8. The health records available from Mirzapur Handpump Project will be used to supplement the data collected here. Due respect will be given for safeguarding confidentiality.

SECTION III - BUDGET

A. Detailed Budget

1. Personnel Services

<u>Name</u>	<u>Position</u>	<u>% time</u>	<u>US\$</u>
F. Henry	Principal Investigator	30	6960
K. Minnatullah	Co-investigator	as in MHP	
	Field Assistant	100	1230
	Helper	100	273
	Computer Programmer	20	531
	Coding Assistant	30	450
	Sub Total		9444

2. Supplies and Materials

For 1450 Samples

Biochem. tests for <u>V.cholerae</u>	1086
Biochem. tests for Salmonella ()	()
Biochem. tests for Shigella ()	()
Culture for E coli ()	2030
ST assay ()	()
Total Bacterial count and Faecal coliforms	5220
Glass vials, Thermometers, ice chests etc.	400
Stationery	50
Miscellaneous	50
Sub Total	8836

	<u>US\$</u>
3. Equipment	Nil
4. Patient Hospitalization	Nil
5. Out patient care	Nil
6. ICDDR,B transport 3242 miles at Tk. 14.50 per mile	2000
7. Travel and Transport of persons	Nil
8. Transportation of things Samples to Laboratory	500
9. Rent Communications and utilities	Nil
10. Information Services	Nil
11. Printing and Reproduction Xeroxing, Publication cost, Stencils etc.	200
12. Other contractual services Compter time at 800 Tk./hr. computertape etc.	200
13. Construction, Renovation, alteration	Nil

B. Budget Summary

	<u>US\$</u>
1. Personnel Services	9444
2. Supplies and Materials	8836
3. Equipment	-
4. Patient Hospitalization	-
5. Out patient care	-
6. ICDDR,B Transport	2000
7. Travel and Transportation of Persons	-
8. Transportation of things	500
9. Rent Communication Utilities	-
10. Information Services	-
11. Printing and Reproduction	200
12. Other contractual Services	300
13. Construction, Renovation, Alterations	-
	<hr/>
	21280
15% Incremental cost	3192
	<hr/>
Grand Total	24472

VERBAL CONSENT FORM

The ICDDR,B is presently investigating how the water and latrine facilities that are installed here will benefit the health of children in this community. To do this we are planning to collect some water and food samples from households and also analyse samples from various water contact sites. We will be collecting those samples every month for nine months so that the seasonal contamination level can be related to the seasonal diarrhoea rates. We will not be collecting blood stool or urine samples. All information obtained will be treated confidentially. You are at liberty to withdraw from the study at any time.

