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FACE SHEET)

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Date 18 Sept 96

90

rincipal Investigator Thomas Handzel Trainee Investigator (if any)

pplication No. 96-017 Supporting Agency (if Non-ICDDR,B) Population Council

itle of Study Drinking Water Quality and Diarrheal Disease in an Urban Slum Community: Household Intervention to improve water

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 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 NA

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

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

Principal Investigator

Trainee

ENTERED 21 JUN 1998

CHECK-LIST FOR SUBMISSION OF PROPOSALS TO THE RESEARCH REVIEW COMMITTEE (RRC)

[Please tick (✓) the appropriate box]

1. Has the proposal been reviewed, discussed and cleared at the Division level ?

   Yes [X]

   No [ ]

   If 'No', please clarify the reasons: _____

2. Has the proposal been peer-reviewed externally ?

   Yes [✓]

   No [ ]

   If the answer is 'NO', please explain the reasons: _____

3. Has the proposal scope to address gender issues ?

   Yes [✓]

   No [ ]

   If the answer is 'YES', have these been adequately incorporated in the proposal. Please indicate: Issues related to water collection & use will be addressed in the focus group discussions

4. Has a funding source been identified ?

   Yes [ ]

   No [✓]

   If the answer is 'YES', please indicate the name of the donor: _____

5. Whether the proposal is a collaborative one ?

Yes [X]

No [ ]

If the answer is 'YES', the type of collaboration, name and address of the institution and name of the collaborating investigator be indicated:

Dr. Mark Sobsey Dept of Environmental Sciences & Engineering
U. North Carolina, Chapel Hill

6. Has the budget been cleared by Finance Division ?

Yes [ ]

No [ ] NA

If the answer is 'NO', reasons thereof be indicated: _____

7. Does the study involve any procedure employing hazardous materials, or equipments ?

Yes [ ]

No [✓]

If 'YES', fill the necessary form.

18 Sept 96
Date

Signature of the
Principal Investigator

Research Protocol

Title: Drinking water quality and diarrheal disease in an urban slum community: Household interventions to improve water quality.

Principal Investigator: Thomas Handzel
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Budget: $23,000

Head of Program: Mr. Syed Shamim Ahsan
Director Health and Population Extension Division
ICDDR,B

Signature of Division Director:

Drinking Water Quality and Diarrheal Disease in an Urban Slum Community: Household Interventions to Improve Water Quality

INTRODUCTION:

The role of contaminated drinking water continues to play a significant role in the etiology of diarrheal disease. Although large investments have been made in the water sector diarrhea illnesses continue to be one of the largest causes of morbidity and mortality in developing countries. For much of the water decade efforts have focused on improving water quantity or access to adequate volumes of drinking water and less so on achieving adequate quality of drinking water. In Bangladesh large investments in water supply have produced a high level of access to tubewell water. Diarrheal diseases, in addition to outbreaks of cholera, hepatitis and dysentery, however, continue to be a major cause of morbidity. In urban areas the situation is often more acute with irregular and unreliable supplies of drinking water a common occurrence. As drinking water is normally stored within the home there is also the likelihood of contamination of the drinking water from dirty vessels or from poor handling and storage practices. In response to this situation there has been increased interest in household level interventions to improve drinking water quality. The goal of these efforts being to either treat contaminated waters at the household level or to reduce the amount of contamination that occurs due to poor handling and storage of water.

The goal of this project is to investigate the relationship between drinking water quality and diarrheal disease in an urban slum community and to devise, optimize and pilot test simple and appropriate measures to improve the quality of water being consumed and in turn lower the incidence of water borne diseases.

OBJECTIVES

The main objectives of this study are three fold. First, to determine the role of contaminated drinking water in the epidemiology of diarrheal disease among children in an urban slum setting. Secondly, to design and optimize simple and appropriate intervention strategies which can be implemented at the household level to improve drinking water quality and reduce the transmission of diarrheal pathogens. Third, to field test these interventions to determine their effectiveness, appropriateness and sustainability.

Specific Aims

1. Determine the association between drinking water quality and the incidence of diarrhea among under five children in an urban slum community. This will be accomplished by a diarrhea and drinking water surveillance program among randomly selected households in Agargaun slum.

2. Determine the feasibility and effectiveness of household level disinfection using sodium hypochlorite as a means to treat drinking water originating from unsafe sources. Determine minimal concentrations required for household disinfection, means of distributing disinfectants and simple educational messages to maximize compliance.

3. Examine the factors associated with contamination of drinking water after the point of collection. Assess effectiveness of educational interventions to improve storage and handling of drinking water and consequently reduce secondary contamination of drinking water .

4. To assess ease of use, effectiveness and sustainability of household level interventions under actual field conditions.

Outcomes

The main outcomes of interest are the microbiological quality of the drinking water and the incidence of diarrhea among under five children in the households under surveillance and the microbiological quality of drinking water in the intervention and non intervention households for the field trials. Through focus group discussions and surveys we will also try to assess compliance, ease of use and sustainability. The overall goal is a simple but effective means of improving drinking water quality within the home that is sustainable and replicable in other environments. The diarrhea and water quality surveillance will also permit a comparison of incidence of diarrhea in children drinking relatively safe water vs. those consuming unsafe water. This will provide as estimate of the role of contaminated water in the transmission of diarrheal disease and the degree to which improvements in water quality can reduce morbidity.

Significance of Study

The study will provide valuable data on the role on the transmission of diarrheal pathogens via contaminated drinking water. As the study site is confined to one large slum area it will permit an intensive monitoring of environmental risk factors associated

with diarrheal illnesses. Furthermore, the study aims to test simple and appropriate household level interventions which can improve the quality of water being consumed by poor families and potentially reduce the burden of diarrhea illnesses especially small children.

Since the methods proposed are both simple and inexpensive they can easily be replicated in other urban or rural areas of Bangladesh. The emphasis of this project will be on simple affordable and sustainable means of improving the quality of drinking water. The interventions will be applicable to both rural and urban areas where safe water supplies are either not available or unreliable.

BACKGROUND

Access to safe drinking water supplies continues to be a significant obstacle to efforts aimed at reducing morbidity and mortality rates in developing countries (Bern et al., 1992). In many peri-urban areas both the quantity and quality of the water supplies may be inadequate. Due to increases in urban migration and the expansion of squatter areas in many cities the number of persons without access to potable water supplies is increasing. In some areas the municipal system may not reach periferal areas. Low pressure within the system combined with leaky pipes and illegal connections to the water mains may result in significant contamination of the water supply in the distribution system. Chlorination may be inadequate or applied only intermittently. As residents of slum or squatter areas are often neglected by municipal authorities such problems may go unnoticed and unresolved.

In addition, since the water supply in peri-urban is usually intermittent water must be collected and stored within the home. Due to poor storage practices or dirty storage vessels drinking water which originates from a clean source may become highly contaminated prior to the time it is consumed.

Since water collected from safe sources may become contaminated during storage providing households with the means to protect or treat their drinking water supplies within the home may be a viable alternative. Efforts to improve drinking water quality at the household level are concerned with two strategies: to treat water that is contaminated at the source or to safely collect and store water that is of good quality at source (Mintz et al., 1995). Household treatment options have usually focused on boiling, filtration or disinfection. Boiling is often rejected because of fuel requirements and the associated time and money constraints. Filtration has not proved successful due to the costs of the filters or the failure of most types of units if not rigorously maintained. Disinfection at the individual level has usually been confined to emergency purposes due to costs involved, logistical problems or taste problems.

As it is effective, inexpensive and widely available, chlorine disinfection has great promise if the obstacles to its acceptability (primarily taste) are overcome. One of the difficulties encountered is ensuring a consistent and effective concentration of chlorine

that is not objectionable to users. This is especially difficult when water is stored in the home in containers of various sizes.

In general practice the goal of chlorine disinfection at the community level is to maintain a maintain a residual concentration of 0.5 mg/l. The actual concentration that is applied depends on the particular water quality characteristics. By determining the chlorine demand of the water supply and standardizing the size of household storage vessels each household can apply a standardized amount of disinfectant to their water supply each time it is collected. A recent study in La Paz, Bolivia, tested household disinfectant using calcium hypochlorite and standardized containers. E. coli and fecal coliforms were routinely detected in the control group but were absent in the intervention households (Quick et al., 1993).

As interventions of this sort must be appropriate to the cultural and environmental conditions of each community these conditions must be investigated before implementation.

Secondary contamination of water supplies

Numerous studies have demonstrated that drinking water stored in the home is of poorer microbiological quality than that at the source. Drinking water may become contaminated at several points between the source and the point of consumption. The containers themselves may be contaminated from other uses or become contaminated when the container is transported to the home. During storage the water in the container may be contaminated when water is removed from the container when hands or other objects enter the container.

The epidemiological importance of this type of contamination remains unclear but there is recent evidence that secondary contamination of drinking water does contribute to increased morbidity. Three recent studies have looked at the storage of drinking water in relation to diarrhea. A study in Calcutta found that narrow necked storage containers reduced the transmission of cholera from an index case to other household contacts (Deb et al., 1986). Households that used either an improved container or added disinfectant to their containers had fewer secondary cases of cholera than households where traditional practices were followed. An intervention study in Malawi provided improved containers to refugee households and found that the mean fecal coliform count in the improved containers was significantly lower than in the unimproved containers. Incidence of diarrhea in under five children was also significantly reduced in the intervention households (Chartier et al., 1993). Finally, a case control study of Shigella dysenteriae type 1 in Zambia found that the odds of being a case were significantly greater in households that removed drinking water by dipping utensils into the storage containers in comparison to households that did not remove water in this fashion (Tuttle et al., 1995). These studies suggest that either improved storage containers or educational efforts to change storage practices may improve drinking water quality and result in lower incidence of diarrheal diseases.

Water quality indicators

The three indicators that will be used in this study are fecal coliforms, Escherichea coli (E. coli) and enterococci. Fecal coliforms are traditionally used as indicators of fecal contamination in both temperate and tropical environments. E. coli is considered to be a more specific indicator as it is thought to be exclusively of fecal origin and may thus be more indicative of the sanitary quality of drinking water. Enterococci are included as in a recent water quality study in the Philippines E. coli and enterococci were found to be the indicators significantly associated with the prevalence of diarrhea in the study population (Moe et al., 1991).

Each of the indicators will be enumerated by substrate based methods rather than the membrane filter method. As interfering bacteria often proliferate in stored water the enumeration of fecal coliforms and E. coli can be problematic. Secondly the specificity of E. coli detected by these methods varies widely.

The newly developed substrate based methods are based on biochemical reactions specific to the target organisms. The fecal coliform/ E. coli medium contains the substrates 0-nitrophenyl-B-D galactopyranoside (ONPG) and 4-methylumbelliferyl-B-D glucuronide (MUG). When galactosidase, an enzyme specific to coliforms, is produced it cleaves the ONPG to produce a yellow color. E. coli produces glucuronidase which hydrolyzes MUG to produce a fluorescent compound which can be seen under UV light (Edberg et al., 1990). Since the only enteric bacteria which are known to produce B-glucoronidase are E. coli, Shigella, Yersinia species it is considered a more specific indicator (Feng, P.C.S. and Hartman, P.A., 1982).

Water samples can thus be analyzed simultaneously for both sets of organisms. Samples producing yellow color are scored positive for coliforms and those subsequently fluorescing are scored positive for E. coli. A similar substrate based method specific for enterococci has just recently been developed and will be included in this study.

METHODOLOGY

In order to achieve the stated objectives several types of data will be collected from the field and the laboratory using both qualitative as well as quantitative data. There are several phases to the study which are summarized as follows:

Preliminary survey

A preliminary survey of Agargaun Bustee will be undertaken to gain preliminary data on numbers of families in the area, types of drinking water sources available, sanitary facilities, surface water sources and areas prone to flooding. A rough map will be drawn with the major geographical and environmental factors highlighted. A sample of drinking water supplies will be analyzed to determine the quality of water available to both tubewell and tapwater using households.

Baseline Survey

The preliminary survey will be followed by a baseline survey from a randomly selected sample of households in the slum. The baseline survey will consist of questions on family composition, socioeconomic factors, water and sanitation related factors, knowledge of hygiene and behavioral risk factors. The baseline survey should take approximately 35 minutes to complete. Simultaneous with the baseline survey drinking water samples will be collected from 10% - 20% of the households in the baseline survey. From each of these households a sample of drinking water from the storage container will be collected as well as a sample taken directly from the source from which it was collected. The difference between the paired samples will provide a means for estimating the amount of contamination that occurs after the point of collection (secondary or household contamination).

All samples will be collected in sterile containers and transported on ice to the laboratory where they will be tested within 4 hours of collection. Water samples will be tested at the Environmental Health Laboratory at ICDDR,B. Samples will be tested for fecal coliforms and E. coli by defined substrate technology (IDEXX laboratories, Westbrook, ME). Each sample will be mixed with the substrate containing ONPG and 4-methylumbelliferyl B-D glucoronide (MUG) and added to a 51 well quantitray and sealed. Samples will be incubated for 24 hours at 44.5 degrees. Wells which turn yellow will be considered positive for fecal coliforms. Those which fluoresce under a UV light will be scored positive for E. coli. Samples tested for enterococci will be incubated at 41 degrees for 24 hours. For each indicator the number of positive wells will be provide a most probable number of organisms per 100 ml sample according the Most Probable Number Table provided by the manufacturer.

Focus groups

Following completion of the baseline survey a series of focus groups will be conducted. The discussions will center around the collection, storage and treatment of drinking water. The focus group discussions will be used to determine the problems faced by women in securing a safe water supply and how best to implement household level interventions. In particular we will assess their attitudes towards household disinfection using a weak solution of sodium hyochlorite. We will also discuss different types of water storage containers and how to reduce contamination of stored water. The results from these discussions and the laboratory results will be used to develop the pilot community trial to test the effectiveness and appropriateness of household water treatment.

Surveillance

Immediately following the baseline survey diarrhea surveillance of under five children will begin. Each household will be visited each week by a community health worker. At the time of the visit the mother or caretaker will be asked a short series of questions regarding the health of the child on the day of the visit and during the preceeding six days. The visit should take five to ten minutes and will be concerned only with diarrhea and associated symptoms (vomiting, fever, type of stools etc.).

Laboratory Studies

Prior to conducting any field trials we will conduct a series of laboratory based studies to determine optimal conditions for the interventions. The results of these studies will then be used to develop the methodology for the field trials.

Disinfection studies:

In order to determine the effectiveness of household level treatment using a chlorine based disinfectant we will examine the inactivation kinetics under various environmental conditions. In particular we look at the effects of temperature, initial water quality parameters, effect of various containers and different types of stock solutions.

Since chlorine disinfection is already well understood the following studies will be focused on applications of chlorine disinfection to local field conditions. In order to mimic field conditions we will use contaminated tap and tubewell waters. Sample vessels will be filled with water form local sources and tested for fecal coliforms, E. coli and enterococci. Initial readings for temperature, turbidity, pH and iron will also be taken. A fixed concentration of the disinfectant will be added and samples will be drawn at specified time intervals. Each sample will be tested for the same microbiological indicators as well as for free residual chlorine by the DPD method. Each experiment will provide inactivation curves showing reductions in the level of organisms over time along with the residual level of chlorine.

In order to evaluate the effect of environmental factors we will repeat the inactivation studies while changing the following parameters:

- Initial level of organisms - As high initial concentrations will require higher concentrations we will add various amounts of wastewater to the collection vessels and repeat the above experiment. The goal will be to determine the minimal initial

concentration required to achieve a residual chlorine level of 0.5 mg/l and no fecal indicator organisms per 100 ml.

- In order to evaluate the effect of temperature we will conduct the study at two or more temperatures.

- Type of containers. Containers will effect the inactivation in two ways - the container itself will consume a portion of the disinfectant and thus reduce the residual concentration and secondly open containers will increase volatilization of the disinfectant.

The stability of stock solutions over time using sodium hypochlorite and bleaching powder will be studied. Each solution will be tested daily for 14 days to determine the loss in potency over time. As above, we will examine the effect of the type of storage container (plastic vs. glass, clear vs. colored) and temperature on the stability of the solutions.

Stored Water Studies

During the baseline study we will collect approximately 200 stored water samples along with the source water from which it was drawn. A standardized form will be used to collect information on storage conditions and the type of container used. The data collected will be used to determine which factors are related to high counts in the storage containers. In particular we will look at different types of storage container, length of storage, whether or not it was covered, where the container is kept in the home etc.

We will also examine the changes in the concentration of indicator organisms over time while controlling for the type of container. In particular we will be interested in changes in the concentration of E. coli over time and ratio of fecal coliform to E. coli over time. In order to evaluate the role of organic material in the storage container we will conduct these experiments in used containers having a biofilm on the inside and again on new containers without a biofilm.

Field trials:

Household disinfection trial

A sample of households will be selected from the baseline survey each reportedly using a contaminated water source. The purpose of the study will be explained to each potential participant and informed consent will be requested before participation. Each participating household will then be randomly placed into either the intervention or non intervention group. The intervention group will be provided with a stock solution of

sodium hypochlorite and either a kolshi or plastic container each with a predetermined capacity. The chlorine stock solution will be added to the water storage containers either by project field staff or by the users themselves. If added by household members instructions will be given on how to add the solution to the water supply after collection. Demonstrations will be given in each home. Once provided they will be visited daily for one week to check for problems or misunderstandings. Following the first week they will be visited twice weekly to replace stock solutions and to monitor compliance. The final concentration in the containers will be approximately 0.5 mg/l which is similar or less than that applied by WASA the local water utility in Dhaka.

Water samples will be collected from a sample of households on a weekly basis. Samples will be collected from an intervention household and from a non intervention household using the same water source. The stored water will be tested for fecal coliforms and E. coli and the residual chlorine level of the water will be recorded.

Approximately 75 households will be enrolled in the study and the trial will run for approximately 12 weeks. The outcome variable will be the drinking water quality in the storage container. Random testing for chlorine residual will be used to estimate rates of compliance. Final surveys will solicit information on problems encountered and reasons for use or non use of the disinfectant.

Education Intervention

A second group of 75 households will be enrolled and given educational messages concerning proper storage of drinking water. The messages will be based on the results of the focus groups and water samples collected during baseline but are likely to be concerned with regular cleaning and prevention of contamination reaching the inside of the containers. Water samples will be collected routinely from the study households and compared with samples taken from non-study households using the same source of water.

Analysis of Data

The data from the disinfection studies will be used to produce inactivation curves as mentioned previously. Separate curves will be generated for each indicator organism and test condition to determine optimal conditions for treatment.

Data from the stored water samples collected during the baseline will be used to analyze the effect of storage conditions on levels of secondary contamination. All counts of indicator organisms will be log transformed prior to analysis. Concentrations of indicator organisms will be analyzed with respect to time of storage, type of container, whether covered or not, number of persons in the household etc.

The diarrhea surveillance data will provide incidence data for approximately 800 households for five months. The rate of diarrhea will be used to evaluate the role of contaminated drinking water. In particular we will compare rates of diarrhea among

households using tap water vs. those using tubewells. Similarly the water quality data will be used to categorize households into low medium and high risk based on the levels of indicator organisms during each sampling period. For each of the analysies we will control for socioeconomic variables as well as significant environmental variables such as sanitation facilities and hygiene related behavioral practices.

The field studies are designed to be randomized controlled trials to determine the actual reduction of indicators under field conditions. The outcome variable of interest will thus be the microbiological quality of the stored drinking water and comparisons will be made between the levels of indicator organisms in the intervention and non intervention groups.

Approximate Time Table of Activities

Activity	**month**					
	1	2	3	4	5	6
Preliminary survey	X					
Baseline survey	X					
Surveillance		X	X	X	X	X
lab based studies		X	X			
Focus groups		X	X			
Field trial - disinfection				X	X	X
Field trial - education				X	X	X

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