tachment 1.

Date April 15, 1990

ETHICAL REVIEW COMMITTEE, ICDDR,B.

ncipal Investigator Drs. K. M. A. Aziz Trainee Investigator (if any) None
bbas Bhuiya, M. Yunus, M. Strong
plication No. 90-007 Supporting Agency (if Non-ICDDR,B)
le of Study Socioeconomic, demographic, and cultural factors related to patients at Dhaka Diarrhoea Treatment Center: An Epidemiological & Ethnomedical analy

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

cle 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 NA
(f) Right to refuse to participate or to withdraw from study (Yes) No
(g) Confidential handling of data (Yes) No
(h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure (Yes) No

5. Will signed consent form be required:
   (a) From subjects Yes (No)
   (b) From parent or guardian (if subjects are minors) Yes (No)
6. Will precautions be taken to protect anonymity of subjects. (Yes) No
7. Check documents being submitted herewith to Committee:
   ___ Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).
   ___ Protocol (Required)
   ___ Abstract Summary (Required)
   ___ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)
   ___ Informed consent form for subjects
   ___ Informed consent form for parent or guardian
   ___ Procedure for maintaining confidentiality
   ___ Questionnaire or interview schedule *

* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:
1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific questions to be asked in the sensitive areas.
3. An indication as to when the questionnaire will be presented to the Cttee. for review.

(PTO)

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

90-007

16.4.90

1a.	PRINCIPAL INVESTIGATORS	:	Dr. K.M.A. Aziz Dr. Abbas Bhuiya Dr. M. Yunus Dr. M. Strong
1b.	COLLABORATING INVESTIGATOR	:	None
2.	TITLE OF PROJECT	:	Socioeconomic, demographic, and cultural factors related to patients at Matlab Diarrhoea Treatment Centre: An epidemiological and ethnomedical analysis
3.	STARTING DATE	:	As soon as the protocol is approved.
4.	DATE OF COMPLETION	:	14 months from starting date.
5.	TOTAL BUDGET REQUESTED	:	US$ 52,750.00
6.	FUNDING SOURCE	:	
7.	DIRECTOR, ICDDR,B	:	Professor Demissie Habte This protocol has been approved by the Community Health Division

8. AIMS OF PROJECT

a) General aims:

1. Socioeconomic, demographic, and cultural factors of the Matlab diarrhoea treatment centre (DTC) patients will be identified, and compared with the similar variables in the community population.

2. The results of this study might be helpful in developing interventions for improved management of diarrhoea at home and DTC levels.

b) Specific aims:

1. Management of acute watery, dysenteric and chronic diarrheas at home level will be studied retrospectively and prospectively through epidemiological and ethnomedical approaches to explain the decision making process in seeking or not seeking treatment at the DTC.

2. The relationship of family structure with the seeking of DTC admissions will be studied.

3. Trends in DTC admissions will be examined and an explanation will be sought in the contexts of socioeconomic, demographic, and cultural factors.

c) Significance

Over the years since the establishment of Matlab DTC in 1964 mainly epidemiological information have been collected and analysed. Little attention has been given to the socio-economic and cultural aspects of the management of diarrhoea. By combining epidemiological and ethnomedical methods of data collection and analysis this study will make an attempt to contribute in areas leading to development of interventions to the efficient of DTC and improved diarrhoea management at the home level through behavioral modifications.

9. ETHICAL IMPLICATIONS:

This study will not involve any specimen collection from the study subjects. In-depth open-ended interview based on selected topics will be conducted among the caretakers of under five years old diarrhoea patients. Informations will be sought which are usually shared among the household members and are not considered private. However, informed consent will be obtained prior to the interview and observation.

10. BACKGROUND, RESEARCH PLAN AND BIBLIOGRAPHY

10(a). BACKGROUND

Matlab DTC of International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) has been serving populations ranged between 1,10,000 to 2,50,000 defined geographically at Matlab Upazila of Bangladesh and enrolled through prospective demographic surveillance system since 1966, for research.

Over the past two decades or so there have been more than forty thousand admissions of diarrhoeal cases in the Matlab DTC. By identifying the socioeconomic and cultural factors of the DTC patients, it will be possible to identify the population groups that are comparatively more conscious about the utilization of diarrhoeal treatment facilities and thereby the recipients of the available free services. This study proposes to bring in light the socioeconomic, demographic, and cultural factors of the DTC patients.

It is difficult to identify the risk factors without a grass-roots view of the victim's daily life. This view can be revealed by the real life observations of the anthropologist. By observing and participating fully in the life of people being studied by the epidemiologist, the anthropologist is trained to record the details of day-to-day events and family relations, to elicit local attitudes, beliefs and values and to take notice of larger socioeconomic forces which impinge on the community. Together, these grassroots insights into the culture enable the anthropologist to evaluate social inputs in terms of their relative importance as determinants of treatment seeking behavior.

There is a need for partnership between anthropology and epidemiology. Theoretical and methodological affinities between these fields were pointed out by anthropologists as early as 1958 by Fleck and Ianni (1958). As they saw it, a common meeting ground for the two disciplines rested on the concept of multiple causation of disease. In sharp contrast to the widely accepted "Doctrine of Specific Etiology". this new approach maintained that getting sick depends upon a complex interaction of many variables - one of which is the disease agent (Dubos 1965). Other factors in this "causal network," as Dunn (1975) has labeled it, include the host's general metabolic state and immune response, the political and economic environment, and cultural beliefs and practices. These multiple factors or "insults" impinge directly on an individual or group causing its level of health to risk and fall accordingly (Audy 1971; Duun 1976) To stay healthy, people must balance these multiple factors. Exposure to a pathogen does not necessarily result in infection, infection is not always sufficient to cause illness, and the impact that illness has on the overall health of an individual is not a constant (Audy 1971). When one or more insults outweighs the coping ability of the individual or group, the scale is tipped in favor of disease. A true appraisal of human illness, Fleck and Ianni argue, must "consider all elements of the environment and, must focus upon man, the host, rather than upon the parasite which invades him (1958:39)". The theoretical underpinnings of this multi-factorial approach have been more fully developed by, among others, Audy (1971), Dubos (1959, 1965), May (1960), and Armelogos et al. (1978).

Alland (1966), however, argues that the dictum which includes all

human behaviour in disease analysis, is overwhelming, vague and non-directional. In sharpening this model, two anthropologists have constructed scheme which allow the investigator to dissect any broad behavioral category into discrete, manageable units for analysis. Duun (1976) bases his classification of a behavior on three criteria; (1) it either enhances or undermines ones health; (2) it is a deliberate or non-deliberate health action; (3) it is influenced by the community or outside of it.

It is important to consider how ethnomedicine - or popular medical beliefs and practices - has contributed to the epidemiology of infectious diseases. Medical anthropologists have long shared a curiosity for the health beliefs and behaviors which exist outside the mainsteam of medicine. Ethnomedicine is the formalized area of study which grew out of this curiosity. Hughes defines the term as "those beliefs and practices relating to disease which are the products of indigenous cultural development and not explicitly derived from the conceptual framework of modern medicine (1968:87)." Thus, an ethnomedical study explores what has come to be called "the popular health culture" of the members of a society (Polgar 1962). Although not always recognized, a body of beliefs about disease, its relation to other aspects of life, its causes, and its cures, exists in all human groups. These health beliefs and their behavioral derivatives have evolved over much time as adaptive responses to the particular diseases that threaten each culture.

In an attempt to review, systematically, the major contributions of ethnomedicine to the epidemiology of infectious diseases, it seems

best to divide the field into three (sometimes overlapping) areas: disease recognition, etiology and management. Each of these components of a given medical system is two sided in that it has the potential to either enhance or hinder the health level of a community.

Community Recognition of Infectious Diseases: Working within the limited framework of its own historical health experiences, every culture is responsible for creating a process with which to recognize and classify illnesses. Clearly the entire folk decision-making process must be viewed in a cultural context. Cultures regularly are called upon to differentiate between serious dysfunctions and those that are minor, transient, or "natural". Diarrhoeal ailments of childhood and conditions that are endemic or regularly prevalent in an area are often explained as "natural". They may be treated with home remedies or, in many cases, go untreated. Of particular interest to the epidemiologist is that word of such illnesses may never reach beyond the walls of the victim's rural home - and rarely past the boundaries of the village.

The seasonal diarrhoeas are regarded by the Zulu people as illnesses that "just happen" and thus require no outside intervention or consultation by local healers (Ngubane 1976).

The human body has many ways of telling an individual that he/she is suffering from infection and that a special kind of attention is required to rid the body of disease. The first step in curing the ills of a community is, clearly, to first recognize the popular conceptions upon which a people base their recognition of a disease, then negotiate an acceptable approach.

When measles victims contract diarrhea in rural Bangladesh, mothers choose not to administer the often life-saving oral rehydration therapy available to their child in the belief that the body is actually flushing out unwanted impurities (Shahid 1983:153). They commonly make an effort to hasten the eruption of measles based on a similar theory that the rash, held inside the intestines, must surface in order to properly cleanse the body.. External applications of *nim* and *lai* leaves are used while patients are forced to ingest both nim and *karala* leaves (Shahid 1983).

Among the villagers of northeastern Brazil there exists a popular conception that the lung is connected directly to the intestinal tract. As a result, mucous and blood in the stool are not recognized as indicators of serious enteric infection, but rather of the inevitable release of mucal build-up in the lungs. Rather than seeking medical attention for the diarrhoea, mothers choose to treat their infant's cold (Nations 1982).

The folk definition and recognition of a condition as "serious" can reveal a number of clues to the epidemiologist about the nature of the disease. Under this topic of discussion falls a report of the cholera epidemic in Mali. Word of this "new" illness reached Mali in 1970 across the Guinean border - where it had hit for the first time in history. Descriptions of its acute onset, rapid clinical course, dramatic signs and symptoms, and high case fatality ratio dubbed the disease "Apollo". After all, what name conveyed the feeling of speed better than that of the epidemic was unlike anything the Malians had encountered before. Traditional healers blamed the disaster on the whims of an overpowering God against whom their non-western remedies

would have little success. But, vaccinations had proved effective against earlier attacks of measles and smallpox, so they supported the nationwide immunization program (Imperato 1974).

Community Etiology of Disease: Belief systems of a culture influence the second step in the decision-making process as well: what is the causative agent cited for the illness and how should it be treated? Western industrial countries with belief systems based in "scientific-technological" values offer treatment such as anti-helminthic drugs, insecticides, and surgery directed at biological agents of disease. The traditional cultures, with different ideological input, attribute parasitic disease to imbalances in the equilibrium of a healthy body, soul loss, movement of real or imaginary parts of the body from their normal position, magical origins, or the "will of God", to name a few. Treatment, in keeping with these basic beliefs, is directed at specific "culture-bound" agents and can be understood only in light of the accepted etiology.

Few ethnomedical studies specifically deal with childhood diarrhoea in terms of the folk decision-making process. In South India (Lozoff et al, 1975) beliefs about the cause of childhood diarrhea among medical personnel and Indian families differ significantly. Open-ended interviews with fifty-six families in Vellore, India revealed that the most common folk explanation for diarrhea was "heat in the body", producing stools with froth, pus or blood. Severe dehydration was conceived as an entirely independent condition caused by ritual impurity or pollution. As a result, popular treatments for diarrhea and dehydration require either a rebalancing of the hot-cold equilibrium, or ritual purification of the child's body,

respectively. The authors argue that modern rehydration therapy must be adjusted to meet the essential requirements of both folk and biomedical belief systems (Lozoff et al. 1975).

Community Treatment of Disease: Just as etiologies differ drastically between cultures, so too do the treatments chosen to free the affected individual from illness. The attitudinal system of the endemic population determines to whom the patient will go for treatment, the type of treatment accepted, preventive measures followed, and the success of intervention on the part of extra-community medical systems. In the light of the above mentioned conceptual frameworks the proposed study would attempt to investigate the ethnomedical aspects of diarrhea management keeping in view the socioeconomic and cultural conditions.

10(B). RESEARCH PLAN

This study will make use of several sources of data: (a) retrospective data available from DTC admission sheets along with periodic ICDDR,B censuses and Matlab Demographic Surveillance System (DSS); (b) prospective data based on current DTC patients (index cases) and comparable diarrhoeal cases from the neighbourhoods of the index cases.

The proposed study will have access to information on all the DTC admissions of children under five years of age numbering about 40000, a half of which will be randomly selected for the present study. Every case includes information on symptoms at the time of admission indicating the level of severity on arrival at the DTC, thus identifying who are reporting to the DTC at the early stage of the disease and who are arriving late in the DTC complicating the patient

management. In addition to these informations on age at admission, type of diarrhoea at admission (i.e. acute watery, dysentery, and chronic), use of ORT prior to admission, pathogens isolated, and the outcome of treatment will be taken into consideration.

Further to the data available in the DTC socioeconomic indicators will be identified through dwelling area and its construction material, occupation of father, land owned by the household, parental education obtainable from the periodic censuses of ICDDR,B.

Demographic factors will include household size, family type and structure, bith order, age, and sex of the patients available from the Matlab Demographic Surveillance System (DSS).

Cultural factors will include changing aspects of community perception of diarrhoea and its management. These data will be collected through in-depth open-ended interviews and observations based on 25% samples of DTC patients categorized by diarrhoea type. The interview and observation will be based on selected topics (i.e. community recognition of diarrhoea, community beliefs centering the causation of diarrhoea and community treatment of diarrhoea) capable of revealing diarrhoea management aspects.

The prospective data will consist of 400 one-hour in-depth interviews conducted among the caretakers of DTC patients, a similar number of caretakers of these index cases who have not visited the DTC will be interviewed in-depth. Following return to the home the DTC patient will be observed for a continuous period of six hours regarding compliance to DTC instructions. In addition to these caretakers of

two comparable cases selected from the neighbourhood matched by diarrhoea type per index case will be interviewed in-depth and observed. In-depth interview and observation will offer clues to explain the reason for reporting and not reporting to the DTC.

Analysis Plan:

The data analysis will involve both quantitative and qualitative methods. The retrospective data will be amenable to quantitative methods and the prospective data will be amenable to qualitative methods. The ethnomedical information obtained through qualitative method will be useful in explaining the questions on hows, and whys raised by epidemiological analysis of retrospective data.

The linkages of DTC Data with the closest census and DSS informations will be made by using the mainframe computer. The DTC data over time will be analysed by using cross tabulations and frequency distributions with respect to the listed variables in the research plan.

The analysis of the in-depth interview and observational data will be made by following the anthropological descriptive methods. These data will be further analysed with the quantitative data generated from the DTC cases and comparable neighbourhood cases.

This study design will allow quantitative epidemiological analysis based on case control methods.

10.(C) REFERENCES:

Alland, A., Jr.

1966 Medical Anthropology and the Study of Biological and Cultural Adaptation. American Anthropologist 68(1):40-51.

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1971 Measurement and Diagnosis of Health. *In* P. Shepard and D. McKinley (eds.), Environ/Mental: Eassays on the Planet as a Home, pp.140-162. New York: Houghton Mifflin.

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1983 Beliefs and Treatment Related to Diarrheal Episodes Reported in Association with Measles. Tropical and Geographical Medicine 35:151-156.

11.

BUDGET SUMMARY

8 months effective May, 1990

	Amount (US$)
Personnel (1 SFRO, 1 FRO, 5 SHA, 6 HA)	43,500
Matlab Water Transport	1,500
Country-boat	550
Stationery	500
Travel and per diem	1,000
Total cost (for 8 months)	47,050

6 months effective January, 1991

Personnel (One DMO)	3,000
Computer service	2,000
Stationery	200
Report writing and Publication	500
Total cost (for 6 months)	5,700

Grand Total: US$:52,750

12.

Flow Chart 1

INVOLVEMENT OF FIELD WORKERS FOR A PERIOD OF 8 MONTHS

Coding of DTC clinical Data from 1966 to 1975. Work on about 20,000 patient sheets will require 195 man days.

Linking of clinical data with demographic and socioeconomic information through mainframe computer: 50% of 40,000 data on <5-year old cases from DTC will be linked

Interview of 400 index cases in the DTC over a period of 8 months. 1 hour per interview will require 66 man days.

Observation and interview of 400 index cases in the home over a period of 8 months. One interview and observation will require one Working day. Total requirement 400 man days.

Observation and Interview of 800 comparable cases in the community spread over a period of 8 months. One interview and observation will require one working day. Total requirement 800 man days.

Data entry and analysis in PC will require 120 man days.

Classification of ethnomedical information will require 30 man days of supervisors.

The field study will require 320 man days of supervisors.

13.

TASK OF PRINCIPAL INVESTIGATORS

1. Dr. K.M.A. Aziz

Implementation and analysis of ethnomedical part

2. Dr. Abbas Bhuiya

Computer Linkage and quantitative analysis

3. Dr. M. Yunus

Implementation and analysis of clinical and epidemiological part

4. Dr. M. Strong

Computer linkage planning and analysis

Project Title: Socioeconomic, demographic, and cultural factors related to patients at Matlab Diarrhoea Treatment Centre: An epidemiological and ethnomedical analysis

Principal Investigator(s): Drs. KMA Aziz, A Bhuiya, M Yunus and M Strong

Summary of Referee's Opinions: Please see the following table to evaluate the various aspects of the proposal by checking the appropriate boxes. Your detailed comments are sought on a separate, attached page.

	Rank Score		
	High	Medium	Low
Quality of Project		✓	
Adequacy of Project Design	✓		
Suitability of Methodology	✓		
Feasibility within time period	✓		
Appropriateness of budget			
Potential value of field of knowledge	✓		

Conclusions

I support the application:

a. without qualification /✓/

b. with qualification

- on technical grounds /___/
- on level of financial support /___/

I do not support the application /___/

Name of Referee: Prof. Jahan Ara Begum ...Signature: .....

Position: Professor of Community Medicine Date: .....16th April 199

Institution: National Institute of Preventive and Social Medicine (NIPSOM)

Detailed Comments

Please briefly provide your opinion o this proposal, giving special attention to the originality and feasibility of the project, its potential for providing new knowledge and the justification of financial support sought: include suggestions for modifications (scientific or financial) where you feel they are justified.

(Use additional pages if necessary)

The proposed study has the potential of contributing important information for the improvement of diarrhea management at the community level. The results of the study will be particularly useful to Bangladesh as well as to developing countries where there is a high prevalence of diarrhea.

This study is likely to generate new information in relation to the ways of treatment and practices in management of diarrhea. The design of the study is adequate. The authors have considered to use epidemiological and anthropological methods in the study. This will offer the study a comprehensive scope of analysis. My comments and suggestions are given below:

1. Details of the topics to be included in the interview and observation need to be mentioned in the protocol. List of topics may be given in an Appendix.

   While making observation on management of diarrhea at home attention to both traditional and modern practices may be given.

2. In collecting anthropological data adequate training of the field worker is very important. No mention of such training has been made in the protocol.

Project Title: Socioeconomic, demographic, and cultural factors related to patients at Matlab Diarrhoea Treatment Centre: An epidemiological and ethnomedical analysis

Principal Investigator(s): Drs. KMA Aziz, A Bhuiya, M. Yunus and M. Strong

Summary of Referee's Opinions: Please see the following table to evaluate the various aspects of the proposal by checking the appropriate boxes. Your detailed comments are sought on a separate, attached page.

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Quality of Project	✓		
Adequacy of Project Design	✓		
Suitability of Methodology	✓		
Feasibility within time period	✓		
Appropriateness of budget			
Potential value of field of knowledge	✓		

Conclusions

I support the application:

a. without qualification /✓/

b. with qualification

- on technical grounds /___/
- on level of financial support /___/

I do <u>not</u> support the application /___/

Name of Referee: Prof. Khurshida Khanom ...Signature: ....Khurshida.....

Date: ...16-4-90.....

Position: Professor of Health Education....

Institution: National Institute of Preventive & Social Medicine (NIPSOM)

Detailed Comments

Please briefly provide your opinion o this proposal, giving special attention to the originality and feasibility of the project, its potential for providing new knowledge and the justification of financial support sought: include suggestions for modifications (scientific or financial) where you feel they are justified.

(Use additional pages if necessary)

This is an important study, which is likely to contribute in pin pointing ways and means of diarrhea management at the home.

In this proposed investigation the investigators plan to utilize both epidemiological and anthropological methods in identifying management system of diarrheal disease at the community level.

In Bangladesh, epidemiological studies on the topic are available. By adding anthropological approach the study is likely to contribute new information on community diarrhea management. The result obtained through this study might be useful to the program planners and health workers in improved management diarrhea. This is a well designed study and can be implemented as per plan. However, I have the following comments and suggestions to make:

1. It is not clear to me how many cencuses were conducted by the ICDDR,B since 1966. Years of census are also not mentioned.

2. While interviewing and observing the diarrheal cases in the community detail information on ORS must be included.