

ETHICAL REVIEW COMMITTEE, ICDDR,B.

96

Principal Investigator Dr. A.R. SamadiTrainee Investigator (if any) N/AApplication No. 8-006(P)Supporting Agency (if Non-ICDDR,B) INITitle of Study Study of SeasonalVariation of Cholera in Dacca over thePast Eighteen Years.

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

4. Are subjects clearly informed about:

- (a) Nature and purposes of study Yes No
 (b) Procedures to be followed including alternatives used Yes No
 (c) Physical risks Yes No
 (d) Sensitive questions Yes No
 (e) Benefits to be derived Yes No
 (f) Right to refuse to participate or to withdraw from study Yes No
 (g) Confidential handling of data Yes No
 (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure Yes No

5. Will signed consent form be required:

- (a) From subjects Yes No Not Relevant
 (b) From parent or guardian (if subjects are minors) Yes No

6. Will precautions be taken to protect anonymity of subjects Yes No Not Relevant

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.

We 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

Trainee

SECTION I - RESEARCH PROTOCOL

- (1) Title: Study of Seasonal Variation of Cholera
in Dacca over the Past Eighteen Years.
- (2) Principal Investigator: Dr. A.R. Samadi
- Co-Investigator: Dr. I. Huq
Dr. M.U. Khan
Dr. M.M. Chowdhury
- (3) Starting Date: 15th February, 1981
- (4) Completion Date: 15th April, 1981
- (5) Total Direct Cost:
- (6) Scientific Program Head:

This Protocol has been approved by the Disease Transmission
Working Group.

Signature of Scientific Program Head: *A. Samadi*

Date: 9.2.1981

(7) Abstract Summary:

The purpose of this retrospective study is to document the seasonal patterns of cholera in Dacca in the past 18 years. It will be attempted to find any rational explanation for peak incidence of cholera and its seasonal shift from November and December to October and November by comparison of cholera distribution curves with average monthly rainfall and temperature curves for corresponding years. This

information is necessary for implementation of any water and sanitation intervention in regard to cholera.

(8) Review:

- (a) Ethical Review Committee: _____
- (b) Research Review Committee: _____
- (c) Director: _____
- (d) BMRC: _____
- (e) Controller/Administrator: _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objectives:

The objectives of this study are:

1. To document the seasonal patterns of cholera in Dacca over the past 18 years and try to explain the reason for peak incidence.
2. To find and try to explain any possible seasonal variation in incidence of cholera in Dacca.
3. To find and explain the changes in biotype of vibrio cholera over the past eighteen years in Dacca.

2. Background:

The seasonality of cholera is an important aspect of epidemiological studies. Although some short term ad hoc studies of cholera seasonality has been done, a comprehensive longitudinal study from the establishment of CRL has not been performed. The seasonal patterns of cholera varies in different parts of the world. In some countries such as Phillipine and India the peak incidences occur during the rainy seasons (1). In Bangladesh the major peak incidences occur a month later after rainy season in the winter with a minor peak in late spring (2,3). In recent years the peak incidence of cholera occurred a month earlier and some people attribute this shift to change of cholera biotype from classical vibrio to El Tor (4). The seasonal pattern of cholera has not

yet been studied in relation to rainfall and temperature curves. It will be attempted in this study to examine the seasonal pattern of cholera in relation to monthly average rainfall and temperature curves over the past eighteen years with a view to finding any correlation.

As far as the biotypes of cholera is concerned, however, the El Tor biotype was identical in Chittagong during 1963, (5,6). The classical vibrio was responsible for epidemics until 1972 when at that time the El Tor was the cause of epidemics in neighbouring countries of Bangladesh (7,8). It is felt that it is worthwhile to examine thoroughly the biotype of cholera in the context of demography of Dacca with a view to finding any suitable explanation.

3. Rationale:

The seasonal pattern of cholera over the past eighteen years will be compared in relation to rainfall and temperature. The reason for the peak incidence of cholera after rainy season and the shift of peak of cholera a month earlier after 1973 has not been explained so far. This study may enable us to develop some hypothesis in these areas and contribute to our knowledge regarding the epidemiology of cholera in Dacca. These informations are necessary for implementation of any water intervention in regard to cholera.

The change of biotype of vibrio cholera to El Tor so far has not been explained. This study may contribute towards our understanding in

regard to predominance of El Tor variant in Dacca.

B. SPECIFIC AIMS:

- a. To find out the trends in seasonal patterns of cholera for the last eighteen years.
- b. To find and explain the shift in seasonality of cholera.
- c. To attempt and develop any rational hypothesis regarding the major peak incidence of cholera after rainy season and the minor peak incidence in late spring.
- d. To find any explanation in regard to predominance of El Tor varinat in relation to major demographic events.

C. METHODS OF PROCEDURE:

Bacteriological proved cases of cholera in patients admitted to ICDDR,B (formerly CRL) hospital and their contacts who have been studied over the past eighteen years will form the subject of this retrospective study. The monthly distribution curves for each year will be prepared and these curves will be examined in relation to average monthly rainfall and temperature curves for corresponding years.

The biotype of cholera for each year will be examined in relation to important demographic events.

D. SIGNIFICANCE:

The above mentioned informations are necessary for implementation of any water and sanitation intervention studies in future.

E. FACILITIES REQUIRED: None

F. COLLOBORATIVE ARRANGEMENTS: None

REFERENCES

1. Kafiluddin A.K. (1973). Modern Epidemiology
2. McCormack W.M. et al (1969). Endemic cholera in Rural East Pakistant. Am. J. Epidemiol 89(4): 393-404.
3. Phillips R.A. (1968). Asiatic cholera. Annual Review of Medicine. 19: 69-80.
4. Oberle H.W. et al (1978). Diarrhoeal Disease in Rural Bangladesh: Epidemiology and the cost and mortality averted by rehydration therapy, manuscript copy.
5. Yen CH, Rahman et al (1964). Epidemiological observations on a recent outbreak of cholera in East Pakistan - a preliminary report. East Pakistan Me. J. 8: 22-26.
6. Woodward W.E. et al (1972). The spectrum of cholera in rural Bangladesh II. Comparison of El Tor Ogawa and classical Inaba infection. Am. J. Epidemiol. 96(5): 342-351, 1972.
7. Greenough W.B. III. Vibrio cholerae, International Centre for Diarrhoeal Diseases Research, Bangladesh (1979). Scientific Report No. 22 April.
8. Felsenfeld O. (1966): A review of recent trends in cholera research and control, with an annex on the isolation and identification of cholera vibrios. Bull WHO 34: 161-195.

SECTION III - BUDGET

A. DETAILED BUDGET

<u>Name</u>	<u>Position</u>	<u>%</u>	<u>Annual Gross Salary</u>	<u>Salary 2 months</u>	<u>Project</u>
Dr. A.R. Samadi		10%	67,326	1122	-
Dr. M.U. Khan		2%	36,000	120	-
Dr. M.I. Huq		2%	30,000	100	-
Mr. M.M. Chowdhury		3%		56	
Printing and Medical Illustrator					\$ 200
			Sub total	1,300	\$ 200
				=====	=====

SAFEGUARDING CONFIDENTIALITY:

Confidentiality of the hospital data will be ensured. Patients names and specifications will not be used in analyses of data.