

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Date July 3rd, 1983

2/8/83

Principal Investigator MARIAN CRAIG Trainee Investigator (if any) _____

Application No. 83-034(D) Supporting Agency (if Non-ICDDR,B) _____

Field of Study Geo-coding the Matlab Project status:

- map to locate cholera by
household.
- (☒) New Study
(☐) Continuation with change
(☐) No change (do not fill out rest of form)

Give 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 ☒ N.A.
(b) Social Risks Yes ☐ No ☒ N.A.
(c) Psychological risks to subjects Yes ☐ No ☒ N.A.
(d) Discomfort to subjects Yes ☐ No ☒ N.A.
(e) Invasion of privacy Yes ☐ No ☒
(f) Disclosure of information damaging to subject or others Yes ☐ No ☒ N.A.

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

5. Will signed consent form be required:

- (a) From subjects Yes ☐ No ☒ N.A.
(b) From parent or guardian (if subjects are minors) Yes ☐ No ☒ N.A.

6. Will precautions be taken to protect anonymity of subjects Yes ☐ No ☒ N.A.

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) ☒
N.A. 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)
N.A. Informed consent form for subjects
N.A. Informed consent form for parent or guardian
N.A. Procedure for maintaining confidentiality
N.A. 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.

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

Marian Craig
Principal Investigator

Trainee

SECTION - I: RESEARCH PROTOCOL

1. Title: Geo-coding the Matlab map to locate cholera by household
2. Principal Investigator: Marian Craig
Co-Investigators Susan Zimicki and Rezaul Karim
3. Starting Date: July 4th, 1983
4. Completion Date: October 30th, 1983
5. Total Direct Cost: US\$ 1,477
6. Scientific Programme Head:

This protocol has been approved by the Community Services Research Working Group.

Signature of Scientific Programme Head: 

Date: 31/7/83

* This signature implies that the Scientific Programme Head takes responsibility for the planning, execution and budget of this particular protocol.

7. Abstract Summary:

This limited study protocol continues work begun under the protocol entitled 'Mapping the Matlab Study Area'. Specifically it is proposed to map the household location of all Matlab Surveillance area hospitalised cholera cases from 1966 to 1983, in order to describe the distribution of Vibrio cholerae at a higher level of spatial resolution than has been attempted to date. This specific aim will entail the construction of a valuable institutional resource, namely a household map of the Matlab Field Trial Area together with a computer file linking all changes in household number since the inauguration of the DSS. This will make possible bari-level location of all events recorded by household number.

8. Reviews:

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

SECTION - II: RESEARCH PLAN

A. INTRODUCTION

1. Objective

To map the location of every cholera case presenting at the Matlab Treatment Centre since 1967, in order to describe patterns of diffusion of Vibrio cholerae through Matlab Thana at a higher level of spatial resolution than has been attempted to date. This represents the next step of the project begun under the protocol entitled 'Mapping the Matlab Study Area', and is essentially a protocol for descriptive analysis of data.

2. Background

Mapping Disease

To the extent that this protocol represents the direct continuation of work begun under the protocol entitled 'Mapping the Matlab Study Area', the reader is referred to the background material presented in that protocol. It discusses the role of mapping in epidemiology and the need for an accurate map of high spatial resolution in a field area which has been intensively studied for twenty years with no more than an inaccurate sketch map to guide sample design and data interpretation. The fieldwork for the household map will be complete on July 31st, and has already revealed inaccuracies in village location on the "standard" map of Matlab. Studies in Matlab often involve large data sets, spatial analysis of which lends itself to the rapid mapping which is possible using computer graphic facilities. A classical example of the application of computer graphics in the area is the work on the relationship between cardio-vascular mortality and water hardness in the U.K.^{1,2}. In studies of disease diffusion Cliff et al. (1981)³ use computer graphics to handle 80 years of measles data for Iceland.

The Descriptive Epidemiology of Cholera

The study by Glass et al. (1983)⁴ of endemic cholera in rural Bangladesh represents the most detailed analysis of geographic trends in the

distribution of cholera in Matlab. Village rates for the period 1966-77 are calculated and show that villages near Matlab Bazar have higher rates than those further away, suggesting that this may reflect access to care rather than true distribution patterns. Non-uniform access to Matlab Treatment Centre confounds many attempts to analyse disease spread at thana level. (Data on travel time to Matlab T.C. is available⁵ making it possible to weight hospitalization rates by distance. (Zimicki et al. (1983)⁶ analyse their results in terms of distance). However, there is unlikely to be a straight-forward linear correlation between distance and hospitalisation rates - socio-economic factors must confound the distance effect. Awareness of the danger of cholera must mitigate the distance affect to same extent, but the importance of this factor probably changes as an epidemic progresses.

Do these problems render meaningful analysis of the diffusion of cholera in Matlab impossible? In other words, is a high level of spatial resolution in plotting cholera cases warranted by the very partial picture which hospital data gives? The negative answer is that one is obliged to work with the data available. However, it may be that spatial analysis of patterns of spread relies to a lesser extent on true community incidence rates because index cases will at least show the front, or leading edge, of an epidemic. It will be possible for example to describe the differences in diffusion of the classical and El Tor biotypes through Matlab in the 1982 epidemic.

It may of course be misleading to talk in terms of an epidemic wave passing through Matlab. Glass et al. (1983) state that each year the first cases of cholera have begun almost simultaneously at distant points in the Matlab area and furthermore that in 1979 the first three recognised cases were of different phage types. A map showing the location of cholera cases at the household level will give us a more detailed picture of the descriptive epidemiology, but will it extend our understanding of patterns of spread? In the light of increasing

evidence for inter-epidemic survival of toxigenic V. cholerae (01)^{7,8} in the environment, future attempts to explain occurrence and spread at the above-neighbourhood level will have to take into account detailed environmental parameters, in projects like that of Huq, Colwell et al.(1982)⁹ on the ecology and survival of V. cholerae in the aquatic environment in epidemic and inter-epidemic periods.

However, this protocol confines itself to improving the descriptive epidemiology of Vibrio cholerae, to refining the spatial analysis of the retrospective data available and to improving the data base for on-going and future analysis of the environmental variables which are increasingly believed to hold the key to explanations of the ecology, transmission and control of cholera.

B. SPECIFIC AIMS

1. To create a master file linking all changes in census household number for each household location in the Demographic Surveillance System.
2. This file will be used to identify the equivalent 1974 household location of all 1966 - 83 cholera cases.
3. These cases will be plotted on a geo-coded master map of all Matlab households using Cambridge University (U.K.) computer graphic facilities.

C. METHODS

1. To create a 1966 - 1983 cholera file

Most of the data required to create a file of all confirmed cholera cases presenting at the Matlab Treatment Centre from 1966 - 1983 is already on tape. Some additional coding will have to be done. The table below lists the data sources for this file.

Year	Source	No. of cases	Coding and key-punching required
1966 - 1977	R.E. Black's Matlab Cholera Retrospective Ten-Year Review. (Study No. 187. On tape)	5165	No
1978	R.E. Black's Matlab Treatment Centre Etiology Surveillance (Study No. 201. On tape)	875	No
1979 - 1980	Oral therapy field trial Matlab Treatment Centre data (On tape)	1016	No
1979 - 1980	Matlab Treatment Centre Hospital Register and Microbiology reports for the DSS area excluded from the field trial		Yes
1981 - now	Matlab Treatment Centre Hospital registers and microbiology reports. (Sept '82 - Jan '83 complete.)	1647	Yes

2. To create a master file linking changes in household numbers through changes before and after censuses

Under the protocol entitled 'Mapping the Matlab Study Area' Community Health Workers in the comparison and treatment areas of the DSS are entering 1974 census numbers on bari maps of their working areas, using a combination of aerial photograph tracings and mouza maps. (This fieldwork will be completed by July 31st.) 1974 numbers are plotted because CHWs are most familiar with this number and can therefore translate it easily from their mental maps of their working areas. (In cases of post-1974 in-migration the 1982 census number is recorded.)

Therefore, in order to locate, for example, a cholera case identified by other than the 1974 census number, it will be necessary to link household census numbers forwards or backwards to the 1974 number, through one or more changes depending on the date of the case. In other words, the identification of the equivalent 1974 household location will necessitate the creation of a permanent master link file of changes in household number. It is probable that the Yeti files can be used for the linking procedure from 1974 backwards. This will be ascertained by doing a trial run on a sub-set of villages. The table below demonstrates the series of changes of census number an individual in the DSS may go through.

Name	Vaccine Trial or Census Number				
	1966 (Old Trial Area)	1968 (New Trial Area)	1970 (Old Trial Area)	1974 (All DSS)	1982 (All DSS - area exclu- ding in 1978)
Majeda	V43-402		V43-73-01	V43-76-02	V43-89-02
urna Laxmi		D84-62-02		D89-60-02	D89-59-02

N.B. Majeda represents the maximum number of changes of census number an individual in the present DSS can have been through.

A file linking all household numbers will be an institutionally valuable tool. Indeed, if the household map of the DSS area is to be useful beyond application to the cholera data, such a file will be essential. Once 1974 household numbers have been geo-coded (see below) it will be possible to map all events identified by a household number since the inauguration of the DSS system (with the exception of the area excluded in 1978, which has not been mapped).

3. To map cholera cases presenting at the Matlab Treatment Centre
from 1967 - 1983

- a) 1974 household locations will be geo-coded using computer graphic facilities of the Department of Geography, University of Cambridge, U.K. An X,Y co-ordinate will be assigned to each square of a grid of sufficiently high spatial resolution to assign a unique location to each bari, household numbers having been recorded in bari units by CHWs. Thus a file listing geo-codes for each 1974 household number (and each 1982 number for DSS entry since 1974) will be created.
- b) The linked household number file will be used to assign the equivalent 1974 census household number to each cholera case.
- c) The cholera maps will be plotted using the Cambridge computer graphic facilities. Decisions about the temporal and spatial resolution of the maps will be taken in Cambridge when work with these facilities begins. The speed with which maps can be drawn using computer graphic techniques means that data can be plotted efficiently at high levels of spatial and temporal resolution. Clearly, during epidemic periods maps of distribution at frequent intervals will be more revealing than during periods when few cases present at the Treatment Centre each week.

0. RATIONALE AND SIGNIFICANCE

The Matlab Household Map as an Institutional Resource

The existence of a master link file of household census numbers and a file of geo-codes for 1974 household numbers will enable analysis of the spatial distribution of any events recorded by household number in the Matlab Field Trial Area and as such will constitute a valuable institutional resource. A system for up-dating the geo-code file will be established in which new houses and baris will be mapped and assigned geo-codes. The geo-coded master map will be brought back to ICDDR,B in November. Maps will have to be drawn by hand unless graphic software is acquired for the new system.

Thus, although the immediate reason for constructing the Matlab household map is to locate cholera cases, many other aspects of work in Matlab will benefit from such a map with its accompanying link file e.g., morbidity surveillance, analysis of variations in contraceptive prevalence, analysis of the impact of sub-centres on treatment patterns.

Finally, the 'Mapping the Matlab Study Area' protocol was executed under the explicit assumption of the eventual production of a geo-coded master map using Cambridge computer graphic facilities.

REFERENCES

1. Pocock, S.J. et al. 1982. 'Analysing Geographic Variation in Cardiovascular Mortality: Methods and Results'. J.R. Statist. Soc. A, 145, Part 3: 31-3-41.
2. Lazar, P. 1982. 'Geographical correlations between disease and environmental exposures'. In Perspectives in Medical Statistics 21-38. London: Academic Press.
3. Cliff, A.D. et al. 1981. 'Spatial Diffusion: An Historical Geography of Epidemics an Island Community'. Cambridge: C.U.P.
4. Glass, R.I. et al. 1982. 'Endemic Cholera in Rural Bangladesh, 1966-1980' Amer. J. Epidem. 116, 6:
5. Rahman, M. et al. 1982. 'Village characteristics and contraceptive practices'. Presented at VII Annual Contributor's Conference, Bangladesh Fertility Research Programme.
6. Zimicki, S. et. al. 1983. 'A Field Trial of Home-prepared Oral Rehydration Solution in Rural Bangladesh'.
7. Colwell, R.R. et al. 1981. 'Occurrence of Vibrio cholerae serotype O1 in Maryland and Louisiana estuaries. Appl. and Env. Microbiol. 42: 555-8
8. Huq, A. et al. 1983. 'Ecological relationships between Vibrio cholerae and planktonic crustacean copepods. Appl. and Env. Microbiol. 45, 1: 275-83
9. Huq, M.I. et al. 1982. Protocol on 'Ecology and survival of Vibrio cholerae and related pathogenic vibrios in the aquatic environment of Bangladesh during cholera epidemic and inter epidemic periods.'

ABSTRACT SUMMARY

None of the questions for the Ethical Review Committee apply because this study involves only old data sets, and will not involve any contact with any patient or population surveyed.

SECTION - III: BUDGET

		<u>Project Requirement</u>	
		<u>Taka</u>	<u>US\$</u>
1.	<u>PERSONNEL SERVICES:</u>		
	Principal Investigator	*	*
	Co-Investigators	**	**
	Coder for 1700 cases @ 250/day = 7 man-days	750.00	31.25
	Data Entry Technician for 1700 records of record length 40 = 5 man-days	500.00	20.83
	Programmer for master link file of census numbers = 2 man-months	5,000.00	208.33
	Secretarial time = 1 man-week	2,700.00	112.50
	Sub-total:	8,949.00	372.91
2.	<u>MATERIALS AND SUPPLIES:</u>		
	Computer tapes for data transfer to Cambridge (45,000 records = 2 tapes)	480.00	20.00
	Miscellaneous computer costs (diskette rental and paper)	1,000.00	41.67
	Office supplies and xeroxing	1,000.00	41.67
	Sub-total:	2,480.00	103.34
3.	<u>COLLABORATIVE FACILITIES:</u>		
	Geo-coding and mapping using the computer graphic facilities of the Department of Geography, University of Cambridge, U.K.	24,000.00	1,000.00
	Total:	35,430.00	1,476.25

* Marian Craig is funded by the Social Science Research Council, U.K. and the University of Cambridge, U.K.

** Co-investigators are funded on separate budgets.