

REVIEW BOARD ON THE USE OF HUMAN SUBJECTS, ICDDR,B.

20

Principal Investigator Md. Alloshaddique Hossain Trainee Investigator (if any)

Application No. 80-020(P) Supporting Agency (if Non-ICDDR,B)

Title of Study (Pilot Study): Distribution of

Project status:

Intestinal Parasites in Patients Attending Matlab

New Study

Dianthosa Treatment Centre : Feb - Aug : 1977.

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

N.A.

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

NA

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 Board:

Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).

Protocol (Required) Pilot study.

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 Board for review.

We agree to obtain approval of the Review Board on the Use of Human Subjects for any changes involving the rights and welfare of subjects before making such change.

Md. Alloshaddique Hossain

Principal Investigator

approved Eslam MD

Trainee

REF
WC 698.JB2
H829d
1980

80-020(P)
Recd 22/5/80

SECTION I - RESEARCH PROTOCOL

1. Title : Distribution of intestinal parasites in patients attending the Matlab diarrhoea treatment centre, February - August 1977.

2. Principal Investigator : Md. Moshaddeque Hossain

3. Starting date : 1 May 1980

4. Completion date : 30 June 1980

5. Total Direct Cost :

6. Scientific Program Head :

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

* Signature of Scientific Program Head : 

Date : 3/5/1980

7. Abstract Summary :

The informations obtained by microscopic examination (ME) of stools of diarrhoeal patients at Matlab during February - August 1977 as a part of protocol No. 77012 will be added to the data tape in the computer library.

These data will be analysed to study the distribution of intestinal parasites by age and sex, to find out if there is any association among the parasites themselves or between the parasites and other enteric pathogens isolated from the patients, and to determine whether the parasites were more commonly found in more severely dehydrated patients.

8. Reviews :

a. Research Involving Human Subjects : _____

b. Research Review Committee : _____

c. Director : _____

d. BMRC : _____

e. Controller/Administrator : _____

PILOT STUDY

DISTRIBUTION OF INTESTINAL PARASITES IN PATIENTS ATTENDING THE MATLAB DIARRHOEA TREATMENT CENTRE, FEBRUARY - AUGUST 1977.

ABSTRACT SUMMARY

The informations obtained by microscopic examination (ME) of stools of diarrhoeal patients at Matlab during February - August 1977 as a part of protocol No. 77012 will be added to the data tape in the computer library. These data will be analysed to study the distribution of intestinal parasites by age and sex, to find out if there is any association among the parasites themselves or between the parasites and other enteric pathogens isolated from the patients, and to determine whether the parasites were more commonly found in more severely dehydrated patients.

1. Stool ME records at Matlab (Feb-Aug 1977) will be reviewed in this study.
2. This study will be limited to reviewing already collected data. So there will be no risks to the subject population.
3. Not applicable as there are no risks to the population.
4. The patients will not be identified by name during the study or in reports. Individual medical information will be grouped for analysis, so anonymity will be maintained.
5. Not applicable
6. Not applicable
7. The benefits of this study will accrue only to the medical profession and society. In general by providing information on the prevalence of intestinal parasites and their association with other enteric pathogens if any.
8. Stool ME records at Matlab (Feb-Aug 1977) will be reviewed in this study.

ICDDR,B
INTERNATIONAL CENTRE FOR
DIARRHOEAL DISEASE RESEARCH, BANGLADESH
আন্তর্জাতিক ডিআইডি গবেষণা কেন্দ্র



Cholera Research Laboratory

Memorandum

TO : Members of Disease Transmission
Working Group

FROM : Moshaddeque Hossain and
Roger Glass

DATE: 19.3.80

SUBJECT : PILOT STUDY: THE DISTRIBUTION OF
INTESTINAL PARASITES IN PATIENTS
ATTENDING THE MATLAB DIARRHEA
TREATMENT CENTER, FEBRUARY
THROUGH AUGUST 1977

During Dr. Black's visit to the ICDDR,B, we became aware that information collected from 2,000-3,000 microscopic examinations of stool samples from diarrheal patients, as part of Protocol No. 77-012, had never been reviewed and might contain interesting and important information. We would like to have this data coded and added to the data tape presently in the computer library. This would be analyzed to study:

1. the distribution of intestinal parasites by age and sex;
2. possible associations between the distributions of parasites and other microorganisms isolated from the same patients;
3. whether parasites were more commonly found in patients with more severe diarrhea.

Previously, Drs. Rabbani, Gilman and Islam (1979) observed a significantly higher prevalence of Strongyloidiasis in patients hospitalized with dysentery than in those with watery diarrhea. Whether an association like this might represent a true biological phenomenon, a result of common environmental exposures, or case-selection biases is difficult to ascertain. Likewise, Dr. Sack has observed in the Travelers' Diarrhea Clinic that many patients

with severe diarrhea seem to purge more advanced forms of Entameba histolytica than patients with normal or small volume stools. By comparing the isolation rates of parasites among patients with diarrhea of specific etiology (e.g. ETEC) but different volumes of purging, we could assess Dr. Sack's clinical observations. This study would be limited to information already on computer tape or collected in the files of this study and full confidentiality of patients in the data set would be maintained.

Selected tables to be compiled and analyzed are appended.

MH/RG:pj

Attachments

BUDGET SUMMARY

This study will involve the analysis of data already collected and coded.

The budget costs will include time for Dr. Hossain (50% x 2 months), Dr. Glass (10% x 2 months), a keypunch operator (1/2 day), and a computer programmer (20 hours). The total cost of this project will be less than \$1,500.

TABLE 2

NUMBER OF PARASITES IDENTIFIED BY MICROORGANISM FOR AGE GROUP 0-4

<u>Parasite</u>	<u>Microorganism</u>					<u>No Pathogen</u>	<u>Total</u>
	<u>ETEC</u>	<u>Shigella</u>	<u>Vibrio</u>	<u>NAG</u>	<u>Rotavirus</u>		
Ascaris							
Trichuris							
Hookworm							
<u>E. histolytica</u>							
<u>G. lamblia</u>							
No parasites found							
ME not done							
Total							

(Same table for children 5-14, and adults 15+.)

TABLE 3

ENTEROTOXIGENIC E. COLI

<u>Stool Volume</u> <u>(Purging Rate)</u>	<u>Parasite Found</u>					<u>All Parasites</u>
	<u>Ascaris</u>	<u>Trichuris</u>	<u>Hookworm</u>	<u>E. histolytica</u>	<u>G. lamblia</u>	
Small						
Medium						
Large						
Total						