

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

96

Principal Investigator Martin Blaser Trainee Investigator (if any) _____
 Application No. 80-012(P) Supporting Agency (if Non-ICDDR,B) _____
 Title of Study Review of Project status:
Salmonellosis in Dacca ☒ New Study
and Matlab ☐ 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).

- 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 abortion ☐ 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
- (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
- (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:
- ☒ Pilot protocol
- ☐ Umbrella proposal - Initially submit overview (all other requirements will be submitted with individual studies)
- ☒ Protocol (Required)
- ☒ Abstract Summary (Required)
- ☐ Statement given or read to subjects of 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.

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

Principal Investigator

Trainee

PILOT PROJECT

REVIEW OF SALMONELLOSIS IN DACCA AND MATLAB

ABSTRACT SUMMARY

Salmonellae are recognized as important enteric pathogens of man throughout the world. In developed nations salmonellosis is a public health problem of the first magnitude; estimations of its significance in the developing countries have been limited. In this protocol, we propose to determine the incidence of isolation of Salmonella from patients with diarrhea, to review the clinical and epidemiologic features of the infection as seen in Bangladesh, and in a retrospective chart review compare patients with salmonellosis with individuals with other enteric illnesses.

This study consists of chart and record reviews only. Full confidentiality of the records will be maintained.

The completion of these studies will lead to the submission of a full protocol for investigating the problem in a prospective study.

1. Population

In both proposals the microbiology laboratory records will be reviewed. For Proposal 2 the clinical and census records of ill patients will be reviewed.

2. Potential Risks

This will be a record review only; there will be no risk to the subjects of the study.

3. Procedures for Minimizing Potential Risks

Not applicable.

4. Safeguarding Confidentiality

The patient's name and medical information will not be identified individually and any report on this study will group individuals so that anonymity is maintained.

5. Potential Risk to the Subject

Not applicable.

6. Interview Information

There will be no interviews in this study.

7. Potential Benefits to the Subject

The benefits of this study would accrue only to society in general by helping provide information on the epidemiological setting and clinical features of salmonellosis.

8. Use of Records

Records of surveillance and hospitalized patients will be reviewed.

ICDDR,B
INTERNATIONAL CENTRE FOR
DIARRHOEAL DISEASE RESEARCH BANGLADESH
কলিকাতা ডিআইডি রিসার্চ ল্যাব



Cholera Research Laboratory

Memorandum

TO : Members of Disease Transmission
Working Group

FROM : Martin Blaser, Susan Zimicki,
Imdadul Huq, and Roger Glass

DATE : 25.2.80

SUBJECT : PILOT PROJECT: REVIEW OF SALMONELLOSIS
IN DACCA AND MATLAB

Salmonellosis is an enteric disease of major importance throughout the world but its role in causing diarrheal disease in Bangladesh has never been fully examined. Review of the existing microbiology and clinical records would permit a preliminary assessment of the significance of salmonellosis in Bangladesh and the clinical and epidemiologic features of the illness. To accomplish this, we propose:

Proposal 1: To review the microbiology laboratory records at Dacca and Matlab to determine the number of isolates of Salmonella from patients with diarrhea, the rate of isolation in comparison with Shigella and V. cholerae, the seasonality of isolation, and the types of Salmonella isolated. We will consult with Mr. Huq to determine the adequacy of culture procedures used in the past.

Proposal 2: For a sample of these patients identified as having Salmonella isolated from stools, we will obtain their clinical records and census data. This will allow a preliminary determination of the clinical features of the illness. We will then select a control population from the same set of records and compare the clinical and epidemiologic features of illness in cases and controls.

These two activities will allow us to gather background information by the prevalence and features of Salmonella infection. At the conclusion of the study, we will draft a full working protocol

for a prospective examination of the problem.

Personnel needs: One field worker in epidemiology will be needed in Matlab to help with the review of records and identification of cases and controls. An epidemiologic assistant will be needed to help with coding of records.