ttachment 1. Date JAN 16, 80

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

6-6

Principal Investigator R. GLASS

Application No. 80-007 (P)

Title of Study PILOT STUDY OF CAMPYLOBACTER

Trainee Investigator (if any) _____

Supporting Agency (if Non-ICDDR,B) _____

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 NA
   (d) Sensitive questions Yes No NA
   (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 t Board: PILOT PROJECT
   ✓ 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 (nature of study, risks, types of quest ions to be asked, and right to refus to participate or withdraw (Required)
   ___ Informed consent form for subjects
   ___ Informed consent form for parent or guardian
   ___ Procedure for maintaining confidenti ity
   ___ Questionnaire or interview schedule *

* If the final instrument is not completed prior to review, the following informati should be included in the abstract summa
   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 sensiti areas.
   3. An indication as to when the questi naire will be presented to the Boar for review.

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

Roger Glass MD
Principal Investigator

Trainee

80-007 (P)
Rec'd 24/1/80

ATTACHMENT 1a

PILOT PROJECT

SURVEILLANCE OF CAMPYLOBACTER

ABSTRACT SUMMARY

Campylobacter has recently been identified as an important and previously unrecognized enteric pathogen in man. Campylobacter is difficult to isolate in the laboratory without special, selective media and techniques. Where these techniques have become available, Campylobacter has proved to be a major cause of diarrheal illness in the developed world and in several developing countries. The illness is most characteristically manifested by bloody diarrhea and can mimic shigellosis. Isolation techniques are currently being used at ICDDR,B with great difficulty and this proposal would allow us to collect diagnostic specimens of stool and sera and perform simple assays and family case studies until laboratory techniques can be perfected. Dr. Martin J. Blaser, a expert on Campylobacter, will be visiting the ICDDR,B for two months in February and March, and we hope his visit, supported by this pilot project, will help ICDDR,B develop diagnostic techniques for the isolation and identification of this organism. When these techniques are operational, a full protocol will be submitted.

1. Population

Proposal 1 would involve patients already registered in the routine surveillance network in the treatment center. Proposal 2 involves identifying 5-10 patients per day with bloody diarrhea in the treatment center from whom stool specimens and historical information would be collected.

2. Potential Risks

Stool specimens and sera will be collected from patients with Campylobacter. No other physical, psychological, social, legal, or other risks are involved.

3. Procedures for Minimizing Potential Risks

Since many patients who have Campylobacter will not be adequately diagnosed without these special techniques, the risk of getting proper

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treatment by entering into this pilot study will be improved.

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

The performance of a stool culture will involve no risk to the subject. Patients with Campylobacter will have an acute and convalescent sera drawn with its associated small risk of local pain.

6. Interview Information

Patients found to have Campylobacter will be interviewed for their signs and symptoms, and history of animal and food exposure. The interview will take 10-15 minutes.

7. Potential Benefits to the Subject

The treatment of Campylobacter requires antibiotics different than the treatment of other diarrheal diseases. Patients identified to have this disease will receive proper treatment.

8. Use of Records

Records of surveillance and hospitalized patients will be reviewed to compare their clinical course.

Cholera Research Laboratory

Memorandum

TO : Members of Disease Transmission Working Group

FROM : Roger Glass, Imdadul Huq, M. U. Khan and Barbara Stoll

DATE : 10.1.80

SUBJECT : PILOT PROJECT: SURVEILLANCE OF CAMPYLOBACTER

In February, Dr. Martin J. Blaser will be visiting the ICDDR,B for two months to help us develop diagnostic techniques for the isolation and identification of Campylobacter. In preparation for his visit, we would like to begin two surveillance projects to gather data on Campylobacter in the general population and in a subgroup of patients with bloody diarrhea.

Proposal 1: To determine the prevalence of Campylobacter in routine patients, all stool specimens submitted from the current surveillance network will be screened for Campylobacter in the microbiology laboratory. We will consult with Drs. Stoll and Khan to assure that the proper collection methods are achieved.

Proposal 2: For 5-10 patients per day with bloody diarrhea, a field worker will be assigned to the treatment center to gather full address information and collect a stool for Campylobacter culture. The field assistant will spend half of his time identifying patients particularly at risk (bloody diarrhea, fever) and gathering the appropriate biological specimens, and the other half of his time engaged in small family studies of patients who are Campylobacter-positive.

These two activities will allow us to gather background information on the prevalence of Campylobacter in our population and on the performance of family studies, so that a full working protocol can be coordinated with Dr. Blaser's arrival.

Personnel needs: One field worker in urban epidemiology will be needed to identify patients and perform family studies of patients, family members, and environmental samples at home.

CAMPYLOBACTER PROPOSALS

Proposal 1: Campylobacter in the surveillance network

The 2 percent surveillance system in the treatment center is presently registering approximately 200 patients per month. These patients are seen by a paramedic who records their history and symptoms, a physician who performs a simple physical examination, and a laboratory technician who collects a stool specimen for culture. This pilot project will attempt to examine the prevalence of Campylobacter among this random sample of patients being seen in the treatment center while providing the lab with fresh specimens of Campylobacter for improving their techniques. Since specimens are currently sent to Microbiology, this proposal will involve assigning an individual to work specifically with techniques for Campylobacter culture, isolation, and preservation.

Proposal 2: Campylobacter isolation from an enriched sample of patients

Since we expect Campylobacter to represent less than 6 percent of the diarrhea cases presenting in Dacca, and since we expect our isolation techniques will initially be less than 100 percent effective, this proposal would allow stool specimens from an additional 5-10 patients per day with bloody diarrhea and fever to be collected in the treatment center and sent for culture. Historical information on the surveillance form would also be gathered from these patients as well as a complete address.

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Patients identified to have Campylobacter from either proposal would be visited at home by a field assistant, and acute and convalescent (2 weeks later) blood specimens would be drawn for determination of sera conversion. The index case would be recultured daily for 5 days or until the stool was negative on three separate occasions. Family members would be cultured daily for Campylobacter for 5 days and samples of selected water, foods (milk), and animal feces would be collected for Campylobacter isolation.

This study would require 1-2 field assistants, full time, to organize the collection of specimens and historical information in the treatment center and to pursue the family studies. We should be prepared to do approximately 10-15 family studies per month. This proposal would allow us to gather biologic specimens to work out techniques for serologic study of patients with Campylobacter infection. We could also examine the duration of excretion of Campylobacter in infected individuals, the extent of within-family infection, and the possible role of food, water, and animals as a mode of transmission.

CONSENT FORM

COLLECTION OF SERA FROM CAMPYLOBACTER PATIENTS

You recently were ill and had Campylobacter a newly identified bacteria, isolated from your stool. If you are not already better, we can now prescribe a new antibiotic specific for this disease. We would like to follow your body's response to this disease by collecting a small quantity of blood now and again in two weeks, and would like to see you again at that time to find out if you are better. The drawing of blood may cause a little pain or swelling at the spot of collection. You may decide whether or not you wish to allow us to collect this specimen. Please inform us whether you give you consent to volunteer you/your child.