Date JAN 10

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

Principal Investigator ROGER GLASS

Application No. 80-010(P)

Title of Study SURVEILLANCE OF OBACTER IN HATLOB

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).

Source of Population:
- Ill subjects (Yes) No
- Non-ill subjects (Yes) No
- Minors or persons under guardianship (Yes) No

Does the study involve:
- Physical risks to the subjects Yes (No)
- Social Risks Yes (No)
- Psychological risks to subjects Yes (No)
- Discomfort to subjects (Yes) No
- Invasion of privacy Yes (No)
- Disclosure of information damaging to subject or others Yes (No)

Does the study involve:
- Use of records, (hospital, medical, death, birth or other) (Yes) No
- Use of fetal tissue or abortus Yes (No)
- Use of organs or body fluids Yes (No)

Are subjects clearly informed about:
- Nature and purposes of study (Yes) No
- Procedures to be followed including alternatives used Yes No NA
- Physical risks Yes No NA
- Sensitive questions Yes No NA
- Benefits to be derived Yes No NA
- Right to refuse to participate or to withdraw from study Yes No NA
- Confidential handling of data Yes No NA
- 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)
   - ✓ 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.

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

Principal Investigator _____ Trainee _____

80-010 (P)
Rec'd 30/1/80

Attachment 1a

PILOT PROJECT

SURVEILLANCE OF CAMPYLOBACTER IN MATLAB

ABSTRACT SUMMARY

Campylobacter has recently been identified as an important and previously unrecognized enteric pathogen in man. It is difficult to isolate in the laboratory without special, selective media and techniques and proper methods for field collection of specimens has not been fully determined. Before a full protocol on Campylobacter can be initiated in Matlab, isolation, transport, and preservation techniques must be worked out for a field hospital setting. This pilot project deals with the determination of the optimal methods for transport of cultures from villages to the laboratory comparing four different transport techniques and media (Proposal A). It further would use the monthly surveillance of the children in the Diarrhea and Growth Study and a single survey of children in the Nutrition Growth Survey to determine the prevalence of Campylobacter among rural children and whether stool cultures or rectal swabs would have the highest yield (Proposal B).

The principal aim of this pilot project is, therefore, the development of laboratory capability to collect, transport, process, and identify Campylobacter in a field station so that a full-scale epidemiologic study could be performed later on.

1. Population

Proposal A would involve patients already registered in the routine hospital care network. Proposal B involves processing the routine rectal swabs taken from the Diarrhea and Growth Study as well as a routine rectal swab taken from patients in the Nutrition Growth Study.

2. Potential Risks

There are no significant risks to this study. Only rectal swabs and stool specimens will be collected.

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3. Procedures for Minimizing Potential Risks

There are no risks, so this section is non-applicable.

4. Safeguarding Confidentiality

Confidentiality of the data collected will be insured. Patients names will not be used in analysis or publication of the data. In all laboratory studies, only the hospital number will be used to identify patients.

5. Informed Consent

A signed consent form will not be used since the study risks are minimal. Only routine diagnostic procedures will be done - rectal swab, stool collection, and interviewing. Information on diagnostic procedures will be provided verbally and verbal consent obtained. For minors, consent will be obtained from the authorized, legal guardian or parent of the child. The verbal statement made will include the nature and purpose of the procedures, the benefits derived, the right to refuse to participate, and the confidentiality of the data.

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 from the treatment of other diarrheal diseases. Patients identified to have this disease will receive proper treatment.

8. Medical Records

This study requires use of Matlab hospital records.

Pilot Protocol for the Study of Campylobacter Infection in Children

ITRODUCTION

Campylobacter fetus ssp. jejuni is now recognized as a human enteric pathogen. :udies from all 6 inhabited continents have shown it to cause diarrheal illness 3-12% of the individuals studied.

The epidemiology of campylobacter enteritis is largely unknown. Most studies ive been done in developed countries, however recent work in several less developed :eas have also indicated its importance. A preliminary study of patients in Dacca :th bloody diarrhea has shown Campylobacter to be the causative agent in 8% of ises; it is thus an important cause of diarrheal disease in Bangladesh. Similarly, :udies in South Africa, Brazil and Zaire have shown it to be a common cause for .arrheal illness.

In North America and Europe carriage by asymptomatic adults is very infrequent. :udies in Belgium however showed that 1.3% of asymptomatic children carried C. fetus sp. jejuni in their stools; however these children were mostly from North Africa. a different study in South Africa a high percentage of asymptomatic, as well as iarrheal, children were found to excrete Campylobacter. C. fetus ssp. jejuni was ound as the sole bacterial pathogen from 31% of 0-8 month old children and 5% of symptomatic children. Among children aged 8-24 months the respective recovery ates were 38 and 40%.

Taken together, these studies suggest that children, especially in less eveloped areas, may have a high prevelence of infection with C. fetus ssp. jejuni; nfection may be either clinical or asymptomatic. Further clarification of this uestion is indicated.

However before such a study could be carried out examination of the best ethods for transport of specimens from villages to the laboratory need to be es- ablished. Thus this proposal has two parts.

ROPOSAL A

In order to determine whether Campylobacter fetus ssp. jejuni is a significant cause of diarrheal disease in rural Bangladesh it is necessary to establish a capability for culturing stools for that organism. A pilot study at the outpatient treatment center has indicated that use of selective methods will detect Campylobacter in fecal specimens. A similar system employing antibiotic-containing media, incubation at 42°C and a microaerophilic atmosphere could be instituted at the laboratory in Matlab. Patients with diarrhea attending the clinic would have stool cultures obtained for routine pathogens (i.e. Shigella) and for Campylobacter. Approximately 100 cases should be cultured and if Campylobacter is isolated, then a total of 25 positive cases should be collected.

Each of these cases would be visited in their village and repeat cultures obtained. Repeat cultures will be transported to the laboratory in 1) Carey-Blair media 2) Campy-thio media 3) fresh stools 4) and after being inoculated to selective plates at the village and then transported back to the laboratory in candle jars. Using these positive patients we could determine which are the best methods for transport of specimens. Whenever possible, family contacts and household animals would also be cultured, especially if they had a recent history of a diarrheal episod

PROPOSAL B

A field study would then be undertaken in the villages surrounding Matlab bazaar The population to be studied would be a random sample of children under the age of 5. The total number of children to be examined would be 500. All children enrolled in this study would have a stool specimen or a rectal swab taken. Swabs would be transported to the laboratory at the central hospital in Matlab using the methods shown to be most effective in Part A, and cultured for Campylobacter fetus ssp. jejuni. The parent of each child would be asked about age and sex of the child and whether the child had had recent diarrheal illness.

Those children who were positive would then be cultured three times within the next week, comparing the efficacy of fresh stools versus rectal swabs.

This pilot study would determine prevelence of Campylobacter infection among rural children, and whether stool cultures or rectal swabs would have the highest yield. If Campylobacter is found in these children, further studies could be designed to determine the duration of excretion, and epidemiological and clinical features of Campylobacter infection.

CONSENT FORM

COLLECTION OF REPEAT STOOL SPECIMENS FROM CAMPYLOBACTER PATIENTS IDENTIFIED IN HOSPITAL

Proposal A

You recently were hospitalized for diarrhea and had Campylobacter, a newly identified bacteria, isolated from your stool. If you are not already better, we can now prescribe further medication for your illness. To determine if whether you are still infected with this organism, we would like to reculture your stool. You may decide whether or not you wish to allow us to collect this specimen.

For purposes of this study, you will not be identified by name.

Proposal B

We would like to perform a rectal swab and a stool culture on your child to search for Campylobacter, a newly identified bacteria which causes diarrhea as well as other known diarrhea-causing organisms. We will also ask about your child's health in the past week. If your child is ill, a physician will see the child and prescribe appropriate treatment.

Your participation will help the Cholera Hospital develop better methods to diagnose diarrheal illness in the future. You may choose not to allow your child to be cultured. For purposes of this study, your child will not be identified by name.