

Date SEPT 25 1980

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Dr. B. STOLL

Trainee Investigator (if any) _____

Application No. 80-039(P)

Supporting Agency (if Non-ICDDR,B) _____

Title of Study PILOT STUDY- Retrospective Project status:

review of patients with blood cultures () New Study
type for salmonella typhi () 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
 - Any particular procedure Yes ☐ No ☒ NA
 - Will signed consent form be required:
 - From subjects Yes ☐ No ☒
 - From parent or guardian (if subjects are minors) Yes ☐ No ☒
 - Will precautions be taken to protect anonymity of subjects Yes ☒ No ☐
 - 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)
 - ___ 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:
- 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.
 - Example of the type of specific questions to be asked in the sensitive areas
 - An indication as to when the questionnaire will be presented to the Cttee. for review
- Do you agree to obtain approval of the Ethical Review Committee for any changes involving the rights and welfare of subjects before making such change. Yes ☐ No ☒ NA

Barbara Stoll

Principal Investigator

Trainee

80-039(P)

Rec'd.

22/10/80

LIMITED STUDY: RETROSPECTIVE CHART REVIEW OF PATIENTS WITH
BLOOD CULTURES POSITIVE FOR SALMONELLA TYPHI
HOSPITALIZED AT ICDDR,B OVER A ONE YEAR PERIOD

INVESTIGATORS: DR. BARBARA J. STOLL, DR. M. ALAM

STARTING DATE: SEPTEMBER 1980

COMPLETION DATE: OCTOBER 1980

TOTAL COST: Under \$ 100

This limited study was discussed and approved by the Pathogenesis
and Therapy Working Group.

G. molla

This limited study will review the charts of approximately 80 patients with blood cultures positive for salmonella typhi who have been hospitalized at ICDDR,B within the past year. We will collect clinical and laboratory data (see attached data sheets). In particular, we will look at the age and sex distribution of patients, signs and symptoms of diarrhea (including the patient's own history, the nurses' description of stool character, the stool microscopic examination and culture), other symptoms, physical findings, laboratory data and hospital course. The purpose of this study is to begin to look at diarrhea in enteric fever as a prelude to designing a full prospective study.

Data will be collected on precoded data sheets (attached) and will be punched onto computer cards. Analysis will be performed by card sorting - no computer time will be required. The only cost will be 3 days of card punching and sorting time (500 Tk) and 500 Tk. for miscellaneous expenses.

Abstract Summary

1. The study population will be patients hospitalized at ICDDR,B over the past year who have had blood cultures positive for salmonella typhi. Only charts will be examined.
2. No risks are involved.
3. Not applicable.
4. All records will be kept strictly confidential by the Principal Investigator. Patients will be referred to by number only.
5. Not applicable.
6. There is no interview-only retrospective data will be collected.
7. There are no potential benefits to patients. However, this pilot study will help us to design a larger prospective study on the mechanism of diarrhea in enteric fever.
8. Only medical records will be examined.

SALMONELLA TYPHI CHART REVIEW

Name _____	Patient Number _____	(1-5)
Date of Admission (Mo/D/Yr) _____	_____/_____/____	(6-11)
Age (Years/Month) _____	_____/____	(12-15)
Sex (0=F, 1=M) _____	_____	(16)

History

Days of Illness PTA _____	_____	(17-18)
Fever (0=No, 1=Yes, 2=UK) _____	_____	(19)
If yes, duration of fever PTA (days) _____	_____	(20-21)
Headache (0=No, 1=Yes, 2=UK) _____	_____	(22)
Abdominal pain (0=No, 1=Yes, 2=UK) _____	_____	(23)
Anorexia (0=No, 1=Yes, 2=UK) _____	_____	(24)
Weakness (0=No, 1=Yes, 2=UK) _____	_____	(25)
Diarrhea (0=No, 1=Yes, 2=UK) _____	_____	(26)
Character of Stools:		
watery(0=No, 1=Yes, 2=UK) _____	_____	(27)
bloody (0=No, 1=Yes, 2=UK) _____	_____	(28)
mucoid (0=No, 1=yes, 2=UK) _____	_____	(29)
soft (0=No, 1=Yes, 2=UK) _____	_____	(30)
Received antibiotic PTA (0=No, 1=Yes, 2=UK) _____	_____	(31)

Hospitalization

Weight on admission _____	_____/____	(32-34)
Temperature on admission _____	_____/____	(35-38)
Abdomen: tender (0=N, 1=Y, 2=UK) _____	_____	(39)
distended (0=N, 1=Y, 2=UK) _____	_____	(40)
bowel sounds (0=absent, 1-present) _____	_____	(41)
Stool Description by nurses: (0=N, 1=Y, 2=UK) _____	_____	
watery _____	_____	(42)
loose _____	_____	(43)
bloody _____	_____	(44)
mucoid _____	_____	(45)
soft _____	_____	

Blood culture (0=typhi, 1=paratyphi A)	_____	(47)
Stool culture (0=N, 1=Y)		
salmonella typhi	_____	(48)
salmonella other	_____	(49)
shigella	_____	(50)
cholera	_____	(51)
other	_____	(52)
Widal (0=negative, 1=positive, 2=not done)	_____	(53)
WBC (thousands/hundreds) - admission	_____ / _____	(54-57)
Differential: bands	_____	(58-59)
polys	_____	(60-61)
lymphs	_____	(62-63)
monos	_____	(64-65)
eos	_____	(66-67)
Stool ME: (0=N, 1=Y)		
loose	_____	(68)
formed	_____	(69)
blood	_____	(70)
mucous	_____	(71)
RBC (highest number)	_____	(72-74)
WBC (highest number)	_____	(75-77)
PH (0=acid, 1=alkaline)	_____	(78)
Fat (0=0, 1=1, 2=2, 3=3, 4=4)	_____	(79)
Parasites (0=N, 1=Y)	_____	(80)
Electrolytes : Na	_____	(81-83)
K	_____ / _____	(84-85)
CO ₂	_____ / _____	(86-88)
<u>BX</u>		
Antibiotic (0=N, 1=Y)		
chloramphenicol	_____	(89)

Duration of therapy prior to defervescence (days)	— —	(93-94)
Total duration of therapy (days)	— —	(95-96)
Side effects of chloro (0=N, 1=Y)	—	(97)
Complications (0=N, 1=Y)		
pneumonia	—	(98)
prolonged fever (>5 days after rx)	—	(99)
perforation	—	(100)
GI bleeding	—	(101)
death	—	(102)
if died, what day	— —	(103-104)
duration of hospitalization (days)	— —	(105-106)