

Library 2

Date JUNE 27, 1988

ETHICAL REVIEW COMMITTEE, ICDDR,B.  
Dhaka 1212

Principal Investigator DR. ANWARUL HAQUE Trainee Investigator (if any) \_\_\_\_\_

Application No. 88-017 Supporting Agency (if Non-ICDDR,B) \_\_\_\_\_

Title of Study EVALUATION OF FINGER Project status:  
BLACK BLOOD FOR SALMONELLA TYPHI ( ) New Study  
ISOLATION FROM SUSPECTED PATIENTS ( ) 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 abortions  Yes  No
- (c) Use of organs or body fluids  Yes  No

Are subjects clearly informed about: NA

- (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: NA
  - (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 NA  Yes  No
- 7. 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:

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 Cttee. for review.

(PTO)

I agree to obtain approval of the Ethical Review Committee for any changes involving the rights and welfare of subjects before making such change.

Principal Investigator

JUL 18 1988

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SECTION I : RESEARCH PROTOCOL

1. Title : Evaluation of finger prick blood for Salmonella typhi isolation from suspected patients.
2. Principal Investigator: Dr. Anwarul Haq  
• Co-Investigator : Prof. M.S. Akbar  
Shishu Hospital, Dhaka
3. Starting Date : August 1, 1988
4. Completion Date : October 30, 1989
5. Total Direct Cost : US\$ 8,960
6. Scientific Program Head:

This protocol has been approved by the Laboratory Science Division.

Signature

Date

*Iran Cifuentes*  
June 26, 1988

7. Abstract

A recently completed study has shown that 200 ul of blood collected from vein can give upto 87% success for Salmonella culture from confirmed Salmonella patients. Now, in this study

finger prick as it was originally planned to do in earlier study. Materials and Methods will remain same as it was in the previous project (86-020 P) in which 200 ul of blood that was drawn from vein. On success this method can become a tool for blood culture in field situation.

8. Reviews:

- a) Ethical Review Committee \_\_\_\_\_
- b) Research Review Committee \_\_\_\_\_
- c) Director \_\_\_\_\_

## SECTION II : RESEARCH PLAN

### A. INTRODUCTION:

1. Objective: The immediate goal is to evaluate the use of 200 ul of finger prick blood for the isolation of Salmonella typhi by enrichment method.

2. Background: For routine bacteriological isolation of Salmonella typhi blood has been the choice of sample. Although, the better recovery of Salmonella typhi from bone marrow has been documented (Gilman et al., 1975; Robertson et al., 1969), blood culture is preferable because of the painful and tedious technique involved in bone marrow collection. Moreover, in the field situation and in the Bangladesh socio-cultural situation even venous blood is sometime difficult to collect. Considering the need to be able to diagnose typhoid fever in the field we propose a study involving finger prick blood for the culture and isolation of Salmonella typhi from patients.

A protocol was written to use an enrichment method for the isolation of Salmonella using 200 ul of blood taken from finger tip. The ERC reviewed the protocol and suggested to use venous blood and to combine the study with the routine blood culture test where blood is drawn from the vein. Suggestion was accepted and the protocol was modified accordingly. Since it was a pilot study and had limited time period to complete the study, we were able to find only

52 Salmonella suspected patients to be included in the study. A total of 14 patients were confirmed as having Salmonella infection by using Dupont isolator in which 1.5 ml blood was used. Interestingly, the other two methods those were tried such as 200 ul of blood in Dupont Isolator 1.5 with our enrichment technique and conventional 5 ml blood in biphasic blood culture medium. The results were similar i.e. 12 out of 14 were positive in each group. These results have now inspired us to write the present proposal in which every thing will remain unchanged for blood culture method except we will use finger prick blood instead of venous blood. Also, we would like to have 200 patients included in the study for better statistical analysis.

3. Rationale : Based on our previous finding it is logical to do the study using 200 ul of finger prick blood. If the success rate is similar as venous blood, this method can be very useful for field laboratory or malnourished children when it is difficult to draw larger amount of blood.

B. SPECIFIC AIMS:

To develop a simple procedure for diagnosing patients with typhoid fever in the field.

C. MATERIALS AND METHODS:

Two hundred patients under 12 years with symptoms suggestive to typhoid will be studied in Shishu Hospital. Patients having

routine test done in that hospital will have the additional tests performed for this study. Patients who received antibiotics during the previous seven days will be excluded.

Blood: Two hundred microlitres of blood will be collected from the patient by using capillary tubes on arrival into Shishu Hospital after cleaning the finger tip thoroughly with water. Upon collection, blood will be transferred into 5 ml of selenite F broth and after 12 hours of enrichment at 37 C, broth will be streaked onto MacConkey and Bismuth sulphite plates. After overnight incubation at 37 C, all Salmonella suspected colonies will be serologically tested by slide agglutination with specific polyvalent antisera for Salmonella typhi. Other parallel tests will be done as routine test. 6.5 ml of venous blood will be drawn for that purpose. An aliquot of 5 ml will be transferred to conventional biphasic blood culture bottle and the other aliquot of 1.5 ml will be transferred to Dupont Isolator 1.5 for standard Dupont isolation technique.

The 3 parallel tests mentioned above will be compared to each other to find out the finger prick blood that can serve the purpose of blood culture especially in the field situation.

#### SIGNIFICANCE

If the results are encouraging, this may become an acceptable means in the field situation when collection of venous blood is generally not possible at present. Also, it may become useful

for the infant patients since it is sometime impossible to draw even 1.5 ml of blood that is required for Dupont Isolator 1.5.

E. FACILITIES REQUIRED:

No additional facilities will be required as Prof. Akbar will provide the bench space in the Shishu Hospital as it was done in the previous study.

F. COLLABORATIVE ARRANGEMENTS :

Prof. Akbar of Shishu Hospital is a Co-Investigator in this project. This study will be carried out in Shishu Hospital where several typhoid patients are received.

## SECTION III : BUDGET

(For One Year)

<u>Local Staff</u>	<u>Grade</u>	<u>Man month</u>	<u>US\$</u>
P.I. Associate Scientist	NOC	1	900.00
Technician, Shishu Hospital		6	660.00
<u>Travel Plan (International)</u>			
Dr. Anwarul Haq Associate Scientist IICAC Meeting 1989	Dhaka/USA/Dhaka		2,500.00
<u>Supplies &amp; Materials:</u>			
Chemical/Media/Reagent			500.00
Non-stock supplies			2,000.00
Frige			900.00
Transport Dhaka			200.00
Media			1,250.00
Telex			50.00
		US\$	8,960.00 =====

Reviewed by budget office

Brah  
27/6/88



#### REFERENCES

1. Gilman, R.H., M. Termini, M.M. Levine, Pablo Hernandez-Mendoza and R.B. Hornick. 1975. Evaluation of chloramphenicol and ampicillin in Salmonella enteric fever. Lancet. 1211-13.
  2. Robertson, R.P., M.F.A. Wahab, R.O. Roach. New Engl. J. Of. Med. 1968. Relative efficacy of blood, urine, rectal swab, bone marrow and rose-spot cultures for recovery of Salmonella typhi in typhoid fever. 278, 171.
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