

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Dr. A.N. Alam

Trainee Investigator (if any) \_\_\_\_\_

Application No. 83-002

Supporting Agency (if Non-ICDDR,B) \_\_\_\_\_

Title of Study Nutritional Anaemia in

Project status:

Rural Bangladesh

- 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:
- (a) Ill subjects  Yes  No
  - (b) Non-ill subjects  Yes  No NA
  - (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 abortus  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 Committee:
- 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 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 complete 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 Committee for review.

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

[Signature]  
Principal Investigator

\_\_\_\_\_  
Trainee

83-002  
20/1/83

SECTION I - RESEARCH PROTOCOL

1. Title Nutritional Anaemia in Rural Bangladesh
2. Principal Investigator: Dr. Ahmed Nurul Alam
3. Principal Co-  
Investigator: Dr. Paul Goff
  
- Co-Investigators: Dr. A.H. Baqui  
Mr. A.M. Sardar  
Dr. N.M. Abdal  
Dr. M. Mujibur Rahaman
4. Starting Date: March 1983
5. Completion Date: February 1984
6. Total Direct Cost: US \$ 15,362
7. Scientific Programme Head:

This protocol has been approved by the Nutrition Working Group

Signature of Scientific Programme Head:

M. M. Rahaman

Date:

9/1/1983

8. Abstract Summary :

A prospective field study to determine the type, severity and prevalence of nutritional anaemia in rural Bangladesh is planned. Five groups of anaemic patients will be identified from the initial prevalence study: (1) children under six between 6 months to 6 years, (2) children between 6 and 13 years,

(3) women in the childbearing age (4) pregnant and/or lactating women and (5) adult males. Each group will comprise of fifty patients. All anaemic patients will be offered the opportunity to undergo a standardized battery of tests designed to determine the nutritional causes of their anaemia.

This study will help to determine the extent and the specific aetiology of anaemia in a randomly selected population. Future community - wide interventions to correct the identified problem could also be planned. Follow-up study is anticipated that will evaluate anaemia in diarrhoeal disease with a specific goal of comparing the types and prevalence of anaemia in general population with those with diarrhoea.

9. Reviews:

(a) Research involving human subjects: \_\_\_\_\_

(b) Research Committee: \_\_\_\_\_

(c) Director: \_\_\_\_\_

(d) BMRC: \_\_\_\_\_

(e) Controller/Administrator: \_\_\_\_\_

## SECTION II - RESEARCH PLAN

### A. INTRODUCTION:

1. Objective: The aim of this study is to determine the type, severity and prevalence of nutritional anaemia in a rural community of Bangladesh.
2. Background: Nutritional anaemia is a global problem affecting all age groups and levels of society. People in rich and poor countries alike suffer from these deficiencies. Anaemia can be defined as a condition in which values for haemoglobin, haematocrit or number of red cells per cubic millimeter are below established "normal" values. In nutritional anaemia, the reduction in haemoglobin levels is due to inadequate dietary supply of essential haemopoietic nutrients. These are most commonly iron and folic acid (1). Other causes occurring less frequently include protein deprivation and deficiencies of vitamin B<sub>12</sub>, vitamin A, copper and perhaps vitamin C. Other deficiency states exist that may affect haematopoiesis - the relationship of which has not been clearly proven. It is estimated that 500 million to 1 billion individuals in the world are affected by this type of anaemia.

Premature infants, preschool children, pregnant women and lactating mothers are particular vulnerable to nutritional anaemia (1). Studies in women in the third trimester of pregnancy and not receiving supplements have shown prevalences of anaemia (haemoglobin less than 11 G/100 ml) of 38.5% in Latin America, 57-80% in India, 82% in Burma and 84% in Thailand (2). In a nutrition survey of rural Bangladesh in 1975-76, anaemia WHO guidelines was found to be present in 7 out of every 10 persons (70%) (3). Eighty two percent children between 0-4 years, 75% school children, 62% of adult males and 50-70% of women in child bearing age were found to be anaemic. In a prospective study on nutritional determinants of natural fertility at Matlab, more than 75% pregnant women were found to be anaemic (Hct < 33) (Personal communication - Dr. A. Chowdhury). Poor buying capacity due to poverty, ignorance of dietetic principles, poor nutrient absorption particularly that of iron from our staple food, rice and cereals, frequent respiratory and gastrointestinal infections including diarrhoeal illness, parasitic infestation - all may play contributory role in the development of nutritional anaemia in Bangladesh.

Most nutritional anaemias in a healthy population are due to iron deficiency. Folate deficiency is likely to be the next most important cause, especially in pregnant women. Vitamin B<sub>12</sub> deficiency is rarely a significant cause of anaemia even in population subsisting largely on a vegetarian diet. Severe protein deficiency in children may contribute to the anaemia as seen in kwashiorkor (4). Deficiencies of other vitamins (eg. vit. C) and some trace elements, such as, copper, zinc etc. may also produce anaemia, but there is no definite evidence to suggest that these are of public health importance.

### Nutrient Balance

An adequately nourished healthy individual is in a state of nutritional balance, in which the amount of any given nutrient absorbed from the diet is equal to the amount of nutrient broken down in metabolic process and/or the amount lost from the body. This balance, if distributed by one or a variety of factors, such as, increased losses, increased requirements, decreased intake in the diet, decreased absorption or decreased utilization etc. relative or absolute deficiency of nutrient occurs. Anaemia results in when such deficiency is sufficiently severe. This concept applies to all the nutritional causes of anaemia.

### Iron Balance:

Iron is considered to be a one way element, that is, it enters the body and it is retained and recycled - yet iron deficiency is a frequent problem. Total body iron in a healthy adult male is about 4-5 G of which 70% (about 3 G) is circulating in erythrocyte haemoglobin. About 25% of the body iron is stored in the liver parenchyma and the macrophages of reticuloendothelial system complexed with protein to form ferritin and haemosiderin. A relatively small amount is found in R.E. cells of the bone marrow, where it acts as a reserve supply for erythropoiesis. The remainder of the body iron is incorporated in myoglobin and in iron-containing enzymes. Only about 4 mg of total body iron (0.1%), bound to transferrin, is circulating in the plasma.

The total daily loss of iron is about 1 mg, mostly into the intestinal tract and from the skin. This equals the amount of iron absorbed daily. Apart from the obligatory

losses, women of child bearing age lose additional iron due to menstruation (direct loss), pregnancy (increased requirements of the foetus, placenta and increased maternal red cell mass) and lactation (iron secretion in the breast milk). The total iron requirement for a pregnancy is about 1000 mg - these requirements are concentrated in the second half of pregnancy. During lactation about 0.2 mg of iron/day is required in addition to the basic requirement. The WHO has recommended the daily requirements of iron i.e., the amount that must be absorbed to maintain homeostasis to be as follows (table I) (5,6).

Table 1

Group	Iron absorption requirement (mg)
Infants 5 to 12 months	0.7
Children 1 to 12 years	1.0
Boys, 13 to 16 years	1.8
Girls 13 to 16 years	2.4
Menstruating women	2.8
Men	0.9
Pregnancy, first half	0.8
Pregnancy, second half	3.0
Lactation	2.4

Losses other than those mentioned above occur as a result of bleeding. Hookworm infestation has long been incriminated in the pathogenesis of tropical iron deficiency. Layrisse and Roche in a study on Venezuelan rural population were able to demonstrate that with egg counts of over 2000/G faeces, there was a significant correlation between the severity of the infestation and the degree of anaemia (7).

Iron malabsorption also contributes to iron lack. As a result of different populations studies, WHO in 1959 suggested that a daily intake of iron of 10 mg/day for men, 12 mg/day for women and 15 mg/day for women during the second half of pregnancy was sufficient (8). It soon became evident that iron deficiency anaemia was still prevalent in tropical countries even though the studies revealed daily iron intake to be as high as 30 mg/day (9,10,11). The explanation for this phenomenon is that iron in diets is not readily available. Incorporating radioactively labelled iron into food, studies of iron absorption from a wide variety of food stuffs were carried out. Mean iron absorption for vegetables ranged from 1% for rice to 6% for soyabeans, and for animal foods, from 2% for ferritin to 22% for veal muscle (12, 13). Studies carried out in Burma have shown that non-haeme iron absorption from Southeast Asian basal meal of rice, vegetables, and spices containing 7.6 mg of total iron was only 1.4% (14). Addition of 40 G of fish to the basal meal increased absorption to 6.4% in men and 11.9% in women. Similar observations were made by Hallberg et al in Thailand (15). It was also observed that presence of meat (12) or addition of ascorbic acid (16, 17) in the diet increased the absorption of iron, whereas phytates (18), eggs (19) and coconut milk (20) inhibited iron absorption from other foods. Therefore while the absorption of iron is related to iron status of the body and individual with reduced body iron can absorb iron more efficiently, in these tropical countries the iron is less available and therefore cannot be absorbed.

The main source of dietary iron in rural Bangladesh is from rice and the rural poor eat less of fish and meat. This iron, as mentioned above, is poorly absorbed and this fact may explain high prevalence of iron deficiency here.

#### Folate Balance

Folates are present in most foods - liver, green vegetables, yeast, nuts, chocolates etc. are rich in folates (21,22). Marked losses of folate activity occur during prolonged cooking especially in large volumes of water (21,22). Total body stores of folate in a healthy adult can meet the normal body requirements for upto 4 to 5 months and if dietary intake of folate is reduced to minimum the signs of megaloblastic anaemia do not appear until after 19 weeks (23). Total body stores in normal humans

varies from 6-10 mg, liver being the main storage site. Large amounts of folates and their breakdown products are lost in the urine (24,25). Folates excreted into bile in high concentration are reabsorbed by the gut (26,27). Recommended daily intake of folate expressed as total folate (i.e. the amount measurable by Lactobacillus casei assay after treatment with conjugase) as suggested by WHO are shown in the following table (Table II) (5).

Table - II

Group	Folate requirement (mg)
0 - 6 months	40 - 50
7 - 12 months	120
1 - 2 year	200
13 year and over	400
Pregnant women	800
Lactating women	600

As most food folates are polyglutamates, they are to be hydrolyzed to monoglutamate form before transport across the intestinal cell can occur (28) and folic acid be absorbed in the proximal small intestine. The bioavailability of folates in various foods has not been widely studied. The folates in bananas, beans, yeast etc. are better absorbed than those in lettuce, cabbage, wheat germ and orange juice (29) and glucose enhances the intestinal uptake of monoglutamate folate (30). Folate deficiency can occur for a number of reasons, such as, decreased dietary intake, malabsorption, increased demands as in pregnancy, during lactation and during infancy and early childhood, during therapy with methotrexate aminopterin phenylhydantoin, barbiturates etc.

Vitamin B<sub>12</sub> Balance

Vitamin B<sub>12</sub> deficiencies leading to typical megaloblastic anaemia are rather rare. Total body stores are enough (estimated in adults in U.K. to range from 1 to 5 mg) to



prevent development of haematological changes for a period of 2 to 8 years (31). Non-vegetarian diets allow enough vit. B<sub>12</sub> intake. South Indians living on purely vegetarian diet rarely develop B<sub>12</sub> deficiency anaemia although theoretically their diet should not provide enough vit. B<sub>12</sub> intake. As a result it appears that vitamin B<sub>12</sub> deficiency is much less likely in Bangladesh. Protein deficiency (such as in Kwashiorkor) may play a major role in the development of anaemia in Bangladesh. Copper and other vitamin deficiencies such as that of vitamin C, riboflavin, vitamin A, vitamin B<sub>6</sub>, etc. may play contributory role in the development of anaemia, but none of them has been incriminated as the sole cause of anaemia in the literature.

Presence of anaemia adversely affects the overall health of the population. Milder degree of anaemia resulted in decreased work output and proper treatment increased the productivity of anaemic workers. Severe anaemia limits the maximum work output by imposing a ceiling on oxygen transport of blood to the tissues. However, the severity of clinical features is dependent not only on the degree of anaemia, but on the rapidity of its development. Similarly mild anaemia in pregnancy may be associated with premature delivery, lower birth weight, placental hypertrophy and increased maternal oestriol excretion. Severe anaemia in pregnant women increases the risk of premature delivery and foetal and maternal morbidity and mortality (32). In vitro demonstration of decreased phagocytic activity of leucocytes, impairment of lymphocyte transformation, decreased level of granulocytic enzyme myeloperoxidase that may affect host resistance to bacterial diseases suggested that anaemic subjects might be more prone to develop infection. One study found a higher incidence of respiratory infection in children with iron deficiency anaemia. However, subsequent studies failed to demonstrate similar observations.

Frequent attacks of diarrhoea and parasitic load may bring about pathological changes in the small intestinal mucosa which may be responsible for impaired absorption of available iron in Bangladeshi food and of other micronutrients like copper, zinc etc. Severe iron deficiency anaemia may be associated with hypochlorhydria or even histamine fast achlorhydria and anorexia. This in turn may increase the susceptibility to gastrointestinal infection and diarrhoeal diseases by allowing pathogens through ingested food and water to pass on to small intestine.

## Assessment of Anaemia

Anaemia is a potential public health problem in Bangladesh in need of immediate action. WHO, understanding the magnitude of the problem, had supported collaborative studies in several countries to ascertain the prevalence of deficiency states and anaemia in different population groups. Majority of these studies were carried out in urban population and were not truly representative of the whole community. Standard haematological tests, e.g. haemoglobin level, packed red cell volume (PCV, haematocrit), red and white cell counts, mean corpuscular haemoglobin concentration (MCHC), mean corpuscular volume (MCV), serum iron, serum iron, serum unsaturated iron binding capacity (TIBC), serum folate, vitamin B<sub>12</sub> and albumin etc were evaluated in most studies. As mentioned before, definition of anaemia based on haemoglobin binds results in large number of false negative and false positive findings. Accuracy of detecting iron deficiency in population surveys can be substantially improved by employing a battery of laboratory measurements of the iron status. Serum iron, iron binding capacity along with transferrin saturation and red cell protoporphyrin were widely used as sensitive and specific parameters to determine the iron status. Along with investigation of anaemia, the WHO also sponsored collaborative studies to try to obtain information on the extent and distribution of iron stores in different communities. In the past, iron stores have been measured by repeated phlebotomy, iron absorption studies or, by histological examination of bone marrow smears or liver specimens. More recently, immunoradiometric methods have been developed for the measurement of serum ferritin. Several studies suggest that such estimations may prove to be the single most effective and sensitive tool for evaluating the iron status of different population groups as serum ferritin measurements correlate closely with body iron stores in healthy individuals (33,34).

### Specific Aims:

The primary aim of this study will be to determine the prevalence and the causes of anaemia in Bangladesh. To achieve this goal, the following tests will be performed:

- (1) Screening haematocrit and haemoglobin estimation will be done on blood obtained from a finger stick.
- (2) Cell indices, MCV, MCH, MCHC, blood smears, estimation of serum protein, serum iron, iron binding

capacity, serum ferritin, vitamin B<sub>12</sub>, folic acid and red cell folate will be done on venous blood in patients found to be anaemic. Screening for Malarial parasite will also be done.

- (3) Measurements of vitamin A, vitamin C and copper will also be done in the anaemic subjects.
- (4) Examination of stool for the presence of ova/cyst of parasites and the number of eggs present per gram of stool.

Table - III

Anaemic Levels

	<u>Hematocrit</u> <u>Below*</u>	<u>Hb. (G/100 ml)</u> <u>Below **</u>
Children between 6 months & six years	33	11
Children between 6 & 13 years	36	12
Women in childbearing age (including 1st & 2nd trimester)	36	12
Pregnant and/or lactating women (including 3rd. trimester)	33	11
Adult males	38	13

\* All patients below these standards who agree will be evaluated for the nutritional causes (35,36).

\*\* WHO standards for anaemia (37).

### C. METHODS AND PROCEDURE

The purpose of this study is to determine the prevalence and causes of anaemia in Bangladesh. To find the prevalence 5 groups of patients, 50 in each group will be studied: children under 6, children between 6 and 13, women in the childbearing age, pregnant and/or lactating women and adult males. Anaemia will be established by finding an hematocrit below standard levels (Table III). The percent of each population determined to be anaemic will be the prevalence of anaemia for that population.

The study will be conducted in four randomly selected villages of Matlab DSS - comparison area. Four hundred households from these villages will be selected randomly using random number table. All members in these households will be examined for HCT to cover approximately 2000 population which will allow us to identify about 1000 anaemic subjects. The screening haematocrit will be done on blood obtained from a finger stick and the microhaematocrit method will be used. More severe patients with HCT 10% or more below the WHO guidelines (Table III) will be entered consecutively for the aetiology study in the order that they are identified as anaemic until 50 patients in each group are studied. The selected patients will then be brought to Matlab treatment centre for an overnight stay and collection of blood and stool samples for detailed examination. A questionnaire regarding their personal and medical history will also be administered.

#### Testing Procedure:

In the aetiology study, estimations will be performed on venous blood. Standard haematologic methods will be used. The haemoglobin will be estimated using the cyanomethemoglobin method. The red cell and white cell counts will be performed using a ZBI model coulter counter. Cell indicated the mean corpuscular volume (MCV), mean corpuscular haemoglobin concentration (MCHC), will be calculated from the haematocrit, haemoglobin and red cell counts using the standard formulae. Blood smears on all anaemic patients will be reviewed by an experienced haematologist with special emphasis on cell size, shape, hypersegmentation and other morphological characteristics and malarial parasites. This study of the smears will be made without knowledge of other haematologic and chemistry results.

Serum protein will be measured using the technique of Henry et al (38). The iron and iron binding capacity will be determined using the technique of Henry (39). The ferritin is to be estimated by the method described by Miles (40). This and folic acid, red cell folate and B<sub>12</sub> levels will be measured, using kits supplied by Bio-Rad Laboratories (Caxton Way, Watford, Hertfordshire, England (41,42)). The measurements of vitamin A (43), vitamin C (44) and copper will be done by using spectrofluorometer and atomic absorption spectrophotometer.

About 5-6 ml of blood will be needed to accomplish these tests in adults. In preschool children omission of less critical tests for this age group. (eg vit. B<sub>12</sub>, serum ferritin, vit. C, copper etc.) will allow adequate testing with only 3 ml. of blood. Stool will be collected and examined for the presence of ova/cyst of parasites. Kato (45) thick smear technique will be used to count the number of eggs present per gram of stool.

### Interpretation of Results

Using this battery of tests, nutritional anaemias should be readily diagnosed. Protein calorie deprivation alone will cause a normocytic normochromic anaemia with associated decreases in serum proteins and the iron binding capacity. In these cases the ferritin level should remain normal unless there is iron deficiency associated with protein calorie deprivation. Iron deficiency, itself, will be diagnosed by the typical changes in cell indices, the blood smear, and the blood iron studies. With iron lack, the red cell become smaller with resulting drops in appropriate red cell measure. Also, decreases in the serum level of iron and ferritin further confirm that the body's stores have been depleted. Clinical history along with iron studies will help to sort out those cases of anaemia secondary to infection and chronic inflammatory disease.

The other nutritional causes of anaemia will be identified using several indicators. Vitamin B<sub>12</sub> and folic acid deficiency cause enlarged cells because of disrupted nuclear maturation. The enlargement is reflected in increased mean corpuscular volume (MCV). Furthermore, on examination of the peripheral smear, other diagnostic changes in the red cells and shift cells are often apparent. The serum levels of vitamin B<sub>12</sub> and folic acid the red cell folate remain the most accurate measures of these deficiencies and will be evaluated on all patients.

The contribution to the anaemia of copper and vitamin A deficiency will be evaluated by direct measurement of their

serum levels. Since deficiency of these factors alone cause a subtle anaemia, and since only patients with a greater than 10% drop in their blood level will be in the study, isolated vitamin A or copper deficiency is not expected to be found. Deficiency in these factors contribute to the development of severe nutritional anaemias. Iron lack, deficiencies of vitamin B<sub>12</sub> and folic acid clearly will be the major determinants of pathological process. During the course of the study all identified problems in the study patients will be treated or referred for treatment.

D. SIGNIFICANT AND RATIONALE

Anaemia is a major public health problem. As many as 49% of diarrhoeal patients admitted to ICDDR,B (Dhaka station) in the last six months (June to November, 1982) in whom HCT was done were found to be anaemic according to WHO criteria. In order to do a comprehensive study of anaemia in these patients, it was first necessary to obtain baseline data which is currently unavailable. The present study will help us to (1) determine the extent of this problem in Bangladesh and (11) identify the group having the highest prevalence. It is expected that this will allow us to compare the prevalence and types of anaemia in general population with a group of patients with diarrhoea and to plan interventions to correct the identified problems, such as, food fortification, therapeutic supplementation, parasite control, family counselling, nutrition education etc. It is also hoped that this study will uncover the patterns of anaemia which are amenable to a community wide intervention.

E. FACILITIES REQUIRED

Matlab treatment centre and its clinical pathology laboratory will be utilized for overnight stay of the patients, estimation of HCT and examination of stool. ICDDR,B biochemistry laboratory will provide the facilities for haematologic estimations. No animal sources or new equipment will be required.

F. COLLABORATIVE ARRANGEMENTS:

None

SECTION III - BUDGET

A. DETAILED BUDGET

1. Personnel Services

<u>Name</u>	<u>Position</u>	<u>% of Effort</u>	<u>Annual Salary Tk.</u>	<u>Dollar</u>
Dr. A.N. Alam	Principal Investigator	40	67,939	
Dr. Paul Goff	Principal Co-Investigator	-	-	
Dr. A.H. Baqui	Co-Investigator	20 (1yr)	13,180	
Dr. N.M. Abdal	"	20 (1yr)	6,900	
Mr. A.M. Sarder	"	20 (1yr)	15,686	
Dr. M.M. Rahaman	Consultant	-		
		Tk.	<u>103,705</u>	

2. Supplies and Materials

A. Biochemical tests for 250 patients (Haemoglobin, WBC, RBC, Iron, Ferritin, TIBC, Folate, Red cell folate, vit B<sub>12</sub>, Ascorbic acid and Serum Protein). \$ 9234

B. HCT estimation 3x 2000 = 6000

C. Stool exam (ova/cyst and egg count) 4x300 = 1200

Training and technician = 500

3. Equipment: N I L

4. Hospitalisation cost (270 patients days) 27xTk. 150/day = 40,500

5. Outpatient care: N I L

6. ICDDR,B transport: Speedboat run (200 hrs.) = 21,000

7. Transport of materials	=	4,000	
8. Rent, communication, utilities:		N I L	
9. Printing and Reproduction		10,000	
10. Construction:		N I L	
11. Medicines		2,000	
		<hr/>	<hr/>
Tk.	188,905		\$ 9234

( \$ 1 = Tk. 201 = \$ 9445

Total = \$ 9,445 + \$ 9,234 = \$ 18,679

10% overhead cost = \$ 1868

Grand Total = \$20,547

Total incremental cost = \$20,547 - \$ 5,185

= \$ 15,362



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### ABSTRACT SUMMARY

1. Two hundred and fifty identified anaemic patients in 5 equal groups of (1) children between 6 m to 6 yrs. (2) children between 6 and 13 yrs, (3) women in the childbearing age, (4) pregnant and/or lactating women and (5) adult males will be recruited from Matlab DSS-comparison area for the present study.
2. There is no potential risk involved in the study.
3. Not applicable.
4. All records will be kept strictly confidential. They will remain with the principal investigator. If data is put on computer tapes, study patients will be referred to by number only.
5. Informed consent (signed or thumb impression) from patients or their guardians will be obtained prior to the study. There is no procedure in this study which may unmark the privacy of the subject.
6. Interview will be taken only related to their medical and personal history and is needed only to assess their status of anaemia. Five minutes will be enough to gather such history.
7. This study will help to determine the prevalence, extent and types of anaemia. The identified patients will benefit from the specific treatment of the nutritional deficiency causing their anaemia. Society will benefit from future correct community-wide interventions of this major public health problem.
8. The study will require 5-6 ml. of blood in adults and 3 ml in children below 6 years of age. The blood and stool samples will be collected after the overnight stay in the hospital.

## স্মৃতি পত্র

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আনুষ্ঠানিক উপরায়ত্ব গবেষণা কেন্দ্র: তাইরিয়ার চিকিৎসার সাথে সাথে পুষ্টি সংক্রান্ত সমস্যা নিয়ে গবেষণা করে আসছে। রক্ত শূন্যতা বাংলাদেশের একটি বড় ধরনের জনস্বাস্থ্য সমস্যা যার জন্য আশু সমাধান প্রয়োজন। আমরা বিভিন্ন বয়সে রক্ত শূন্যতার প্রকোপ সম্বন্ধে একটি গবেষণা করতে চাই। আমরা চাই সমাজের বৃহত্তর সুার্থে আপনি/আপনার মিনু এই গবেষণায় অংশগ্রহণ করুন। আপনি যদি রাজী থাকেন তাহলে -

১) আপনাকে এক স্মারিতর জন্য হঠাৎ চিকিৎসা কেন্দ্রে থাকতে হবে।

২) রক্ত শূন্যতার অবস্থা সম্বন্ধে জানার জন্য আমরা আপনাকে মিত্রা (হইতে) সামান্য রক্ত প্রাপ্ত বস্তুর বেলায় ৫ মি.মি এবং মিনুদের বেলায় ৩ মি.মি) এবং দল পরীক্ষার জন্য বেড়া হবে।

৩) পরদিন সকালে আপনাকে ঠিকই পিন্ডে বাড়ী পাঠিয়ে দেয়া হবে।

আপনি যদি রাজী থাকেন তাহলে দ্রুত সাক্ষর করুন কিংবা বাব হাডের বন্দোবস্তের ছাপ দিন।

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গবেষকের সাক্ষর

তারিখ-----

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রোগী/অভিভাবকের সাক্ষর-কিংবা টিপসহি:

তারিখ-----

QUESTIONNAIRE

Patient Number \_\_\_\_\_ Date \_\_\_\_\_

Occupation  Primary  Secondary

Age  Between 6 m to 6 yrs.  Children between 6 and 13

Women in childbearing age (upto 2nd trimester)  Pregnant and/or lactating women (3rd trimester) included

Adult males

If female, pregnant?  yes  No  Date of last menstrual period

No of pregnancies

No of children  1  2  3  4  over 5

Ages of children \_\_\_\_\_

Education (Mother's) \_\_\_\_\_ Household \_\_\_\_\_

Medical History

Recent illness within 3 months requiring medication

Yes  No

If yes, hospitalisation required?  yes  No

Type of illness  Diarrhoeal disease

Respiratory infection

Other, if known

Current medication \_\_\_\_\_

Nutritional Status

Height       Weight       Skinfold thickness (in mm)

Number of family members \_\_\_\_\_

Quality of house:  full tin      $\frac{1}{2}$  tin and  $\frac{1}{2}$  bamboo     Thatched

Annual income from other sources \_\_\_\_\_

CONSENT FORM

The ICDDR,B is carrying out research in fields of nutrition along with management of diarrhoea. Anaemia is a major public health problem of Bangladesh needing immediate attention. We propose to do a study whereby the extent and the severity of nutritional anaemia in different age groups will be ascertained. We like you/your children to participate in the study for the well being of the society. If you decide to participate in our study, you can expect that.

- (1) You will stay in Matlab treatment centre for one night only.
- (2) A sample of blood (5-6 ml in adults and 3 ml in children below 6 yrs of age) and stool will be collected to determine the status of anaemia.
- (3) Next morning, you will be discharged with medicine (eg. vitamin/iron tablets).

If you wish to voluntarily participate in this study, then please sign your name or give left thumb impression below.

\_\_\_\_\_  
Signature of the Investigator

\_\_\_\_\_  
Signature or LTI of the patient/  
Guardian

Date: \_\_\_\_\_

Date: \_\_\_\_\_



Prevalence of Anemia

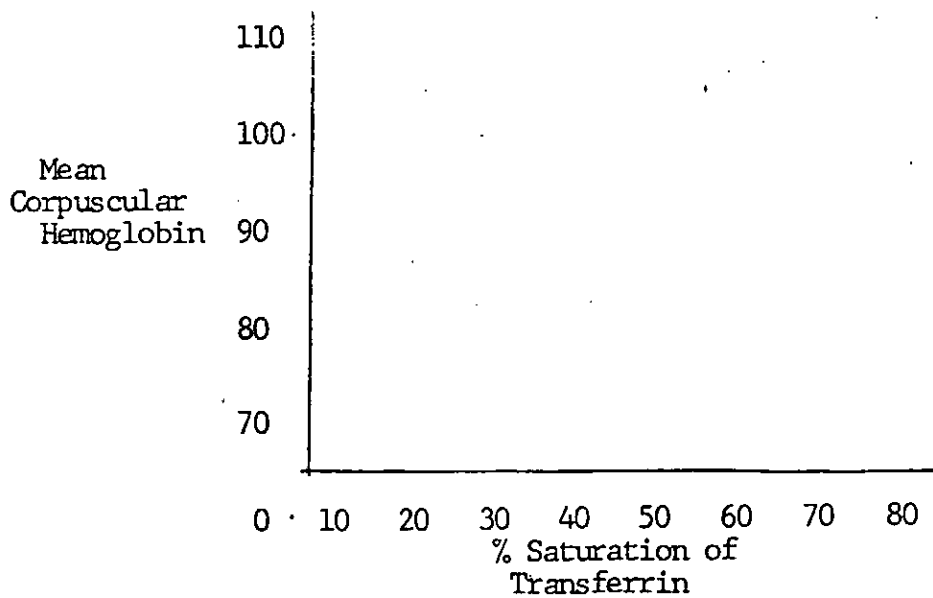
<u>Group</u>	<u>Number Anemic/</u>	<u>Number Studied</u>	<u>% Anemic</u>
I			
II			
III			
IV			
V			
<del>VI</del>			

Iron Studies

<u>Group</u>	<u>Ferritin # under 12/ Total Studied</u>	<u>Per cent Saturation of Transferrin #under 10%/# studied</u>
I		
II		
III		
IV		
V		
<del>VI</del>		

<u>Group</u>	Causes of Anemia			
	<u>Iron Deficiency</u> <u>Number/ %</u>	<u>Folic Acid</u> <u>Number/%</u>	<u>B<sub>12</sub></u>	<u>Other</u>
I				
II				
III				
IV				
V				
<del>VI</del>				

Correlation between MCV and Saturation of Transferrin



Folic Acid Levels

<u>Group</u>	<u>#under 4/ Total Studied</u>	<u>% with deficiency</u>
I		
II		
III		
IV		
V		
<del>VI</del>		

Other Vitamin Levels

<u>Group</u>	<u>Vit. B<sub>12</sub></u>	<u>Vitamin C</u>	<u>Vitamin A</u>
I			
II			
III			
IV			
V			
<del>VI</del>			