

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator 1) Dr. GABRIEL E. Sella Trainee Investigator (if any) _____
2) Dr. MQK Talukder

Application No. 85-030 Supporting Agency (if Non-ICDDR,B) _____

Title of Study: "EFFECT OF ZINC SUPPLEMENTATION ON PREGNANCY, INFANT GROWTH AND IMMUNE DEFENSE CAPACITY" 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:
 - (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 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 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 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 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)

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

Dr. MQK Talukder
Principal Investigator
(MQK Talukder)

Trainee

85-030

19/9/85

SECTION-I : R E S E A R C H P R O T O C O L

1. TITLE : EFFECT OF ZINC SUPPLEMENTATION ON PREGNANCY, INFANT GROWTH AND IMMUNE DEFENSE CAPACITY.
2. PRINCIPAL INVESTIGATORS : DR. GABRIEL EUGEN SELLA
DR. M.Q-K-TALUKDER
- CO-INVESTIGATORS : DR. AYESHA MOLLA
DR. DILIP KUMAR DAS
3. STARTING DATE : Mid. November 1985
4. COMPLETION DATE : Mid. November 1987
5. TOTAL BUDGET : US \$ 48,019.00
6. SCIENTIFIC PROGRAMME : (THIS PROTOCOL HAS BEEN APPROVED BY THE NUTRITION WORKING GROUP).
- PROGRAMME HEAD : M. G. Rabau
(Signature of the Program Head)
- Date: 12/9/1985

SECTION 1 - RESEARCH PROTOCOL

7. Abstract Summary:

Bangladesh population is at high risk of zinc deficiency because of the low level of the nutrient in the soil (42), the inadequate food intake containing zinc and also because of the prevalence of protein energy-malnutrition and diarrhoeal diseases. As such zinc deficiency is thought to be highly prevalent among pregnant women of low socio economic status and their infants.

This study aims to optimize the effects of zinc supplementation on the outcome of pregnancy and on the growth and immune defense capacity in infants.

100 pregnant women at high risk of zinc deficiency will be selected in the Dhamrai area. After the confirmation of the zinc deficient status, they will be assigned in a random double-blind fashion to one of two groups. Both groups will receive vitamin-minerals supplement according to recommended dietary allowance (RDA). In addition, women in one of the groups will receive zinc supplements according to RDA. The supplements will continue throughout the periods of pregnancy and first 12 months of lactation. The infants of the participants will be like-wise supplemented in the same way as their mothers, for the first 12 months of life. All the participants will receive at no cost the usual health services as presently offered by the Institute of Child Health and Research IPCMR quipe at Dhamrai.

The following data will be collected : dietary intake, infectious disease prevalence/incidence, anthropometric and bio-chemical data.

The expected effects of zinc on pregnancy and lactation are : (a) better metabolic utilisation of the usual food intake as evidenced by improved weight gain and maintenance (b) easier child birth, as evidenced by a shorter period of parturition, (c) better birth weight and (d) better breast milk production containing a large zinc concentration.

The expected effects of zinc supplementation on the infants are :

- (a) improved growth, as expressed by anthropometric values and
- (b) a lower incidence of infectious diseases, especially diarrhoea.

SECTION II - RESEARCH PLAN

A. INTRODUCTION

A.1 Objectives :

1. Supplementation of zinc to women at high risk for zinc deficiency during pregnancy and lactation. Such supplementation aims at optimizing the gestational period, outcome of pregnancy, better utilization of the existing diet and lactational performance.
2. Supplementation of zinc to the infants at high risk for zinc deficiency through the age of one year, the year encompassing the highest childhood mortality rate. Such supplementation aims at optimizing the growth and development of the infants.
3. To assess the effect of such supplementation on the development and function of the immune mechanism in infancy.

A.2 Background :

The high infant mortality rate in Bangladesh is a function of several complex factors. Of great relevance among these are malnutrition and the high incidence and prevalence of infections and infectious diseases, especially of diarrhoeal symptomatology.

It would be highly imaginative and perhaps naive to encourage a simple solution, a panacea, to this enormous child health problem. The fact that no simple solution exists, however, should not detract from seeking an innovative approach which may lead well on the way to better growth, development and decrease in incidence of infectious disease in the infants at risk. Such an approach is proposed in the present project. It involves the dietary supplementation of zinc, an essential nutrient to the subjects at high risk for its deficiency. A successful testing of this supplementation in field conditions would result in placing a significant "piece of the puzzle" where it is due. The benefits would outweigh the cost by far, and that in several dimensions, zinc, the nutritional element to be supplemented, costs very little, needs no coldchain, doesnot deteriorate, has no expiry date,

can be stored anywhere, produces no side effects, and is virtually nontoxic
physiologic dosage - 1
Toxic dosage -200 . Successful testing would signify the recognition of
 zinc as a main booster to the metabolic utilisation of the usual diet and as a
 major booster to the cell-mediated immune capacity. Thus, it is hypothesized that
 normal growth, such as directed by the genetic potential, would be optimized under
 the circumstances of risk for deficiency by a non-caloric, non-toxic, essential
 nutrient whose retail market-cost for the life-span needs is less than US \$ 2.00.

Zinc, an essential nutritional element, is paramount to the function of over 90
 enzymes, of vitamin A, of reproduction related hormones, and of growth related
 hormones (Insulin, GH, T4)^{3,9,13,15,16,17,22}. Recently, its role in cell-mediated
 immunological function has been recognized and new knowledge is being accumulated
 in earnest. ^{4,5,6.}

Pure zinc deficiency, due to a metabolic dysfunction, has been identified as acro-
 dermatitis enteropathica. The affected patients have been known to be easy, conti-
 nuous pray to secondary mucocutaneous infections of bacterial and fungal aetiology,
 infectious conditions which often led to severe disability and death until the
 benefits of the zinc treatment were recognized and applied.⁷

Nutritional zinc deficiency reaches subclinical or clinical relevance wherever
 the intake of animal protein is deficient and whenever the water and vegetable
 foods are derived from soil that is zinc depleted.^{2,8,18.}

Poverty and malnutrition being widespread in Bangladesh, there is evidence that
 zinc deficiency may be highly prevalent in the community in this country.⁴³

Nutritionally derived zinc deficiency is expressed within a broad range of sympto-
 matology at the sub-clinical and clinical levels. It may be expressed, though not
 necessarily concurrently and to the same extent by short stature (akin to pitui-
 tary dwarfism)⁸, hypogonadal function (lack of libido, sex hormone deficiencies
 and clinical disturbances, high miscarriage rates) congenital abnormalities(ascer-
 tained abnormalities in experimental animals),^{9,10} vision dysfunction (night blind-
 ness)³² smell and taste dysfunctions (hyposmia, hypogeusia),^{24,25} and skin, hair,
 and nails dysfunctions (mucocutaneous dermatoses, alopecia, paronychia).²⁴ Zinc
 deficiency has been associated with anergy and cellmediated immunity dysfunctions,
 conditions rendered easily reversible by the addition of zinc to the dietary
 intake. ^{38,39,30,41}

Experimentally induced zinc deficiency is evidenced in a short period of time by anorexia, poor physical growth, delayed (or non-existent) sexual development, abnormal hormonal output, thymic hypotrophy (or atrophy) disappearance from circulation of T and B - lymphocytes and low circulatory levels of RBP-retinol, to mention but some of the findings.^{23,27} Pregnancy is at best precarious in conditions of experimental zinc deficiency, with high rates of abortion, congenital defects in the live offspring and universally observed very low birth weight.

Experimental zinc deficiency in humans, mainly in the form of iatrogenic dietary omission due to lack of knowledge, becomes evident clinically in a very short period of time (1 week) and appears in the form of anorexia, mucocutaneous lesions and decreased numbers of T-lymphocytes etc. The symptoms are reversed in a matter of days by the addition of zinc to the diet. Chronic iatrogenic deficiency has not been reported, but it is clinically evidenced by severe muco-cutaneous lesions, and lack of growth in children²³, (Dr. George Graham, Personal Communication). In general it has been shown that "induced" zinc deficiency can be reversed by the addition of the element^{23,8,22,24,31}.

Zinc Metabolism :

A short review of zinc metabolism reveals the following : (a) Most of the bio-available zinc is absorbed in the enterocytes at the duodenal level after it is transported there by a pancreatic ligand, picolinic acid ; (b) it is transported from the mucosal to the serosal site by a metallothionein, which it itself induces; (c) is transported to the entero-hepatic circulation via transferrin ; (d) it is bound in liver and released to the blood stream in the form of zinc-albumin and zinc alpha 2-macro-globulin compounds, which encompass 60% and 35% of the total serum zinc respectively ; the remainder 5% is composed of Zn-aminoacid compounds. Plasma zinc is transferred to the tissues, e.g. enzymes, hormones as presumably needed; the homeostatic mechanisms of tissue transfer are incompletely understood, except for one : the transfer of zinc from the plasma to the liver as one of the body's acute responses to infectious agents. A leukocytic substance, L.E.M.(Leukocytic endogenous mediator), released as an acute phase-reactant against bacterial/viral attack, induces the re-entry of plasma zinc to the liver where it is stored and employed in the synthesis of acute-phase defense substances such as caeruloplasmin. Subsequent to the acute phase, the plasma zinc levels increase slowly in a matter of days ; (f) once in the tissues, e.g. 30% in the muscle and 20% in the

skin, zinc is very slowly released or exchanged, having a tissue half-life of 250 days ; (g) zinc is excreted mainly in the feces (95%) and very little in the urine except in renal pathologic conditions ; one portal of excretion that merits particular attention is that of perspiration, which depends upon ambient temperature or high metabolic state (e.g. high fever) the other portal of exit is that of sperm in the male (i.e. ejaculation at a rate of 3-4 times/day would easily exceed the normal nutritional intake, since sperm, rather, the prostatic fluid concentrates actively zinc from the plasma at a rate of 10 to 1); (h) finally, zinc, in plasma and the eye is an active component of vitamin A metabolism ; intestinal zinc passage is enhanced by concurrent intake of vitamin A ; zinc contributes to the synthesis of retinol binding protein ; the rate of release of holo-retinol binding protein (i.e. RBP + retinol) to the plasma is partly a direct and specific function of the zinc level ; zinc, in the form of cofactor of retinol dehydrogenase in the retina is paramount to the function of retinol in the photo-optic cycle ; zinc deficiency specifically conditions night blindness, even in the presence of adequate retinol concentration.

It should be understood that this short review of zinc metabolism is only meant as a memory-refresher within the context of this background section and does not render full justice to what is presently known about the metabolism of this essential nutritional element. 3,4,12,18,19

A.3 Rationale :

2 Recent evidence points to the fact that zinc deficiency may be highly prevalent in several areas in Bangladesh in view of (1) the poor Zn-concentration in the soil and crops and (2) the low intake of animal-protein in the diet. Infants would be prime targets and they also exhibit a very high mortality rate. It is hypothesized that Zn supplementation (e.g. in syrup solution) to their diet would improve significantly the metabolic efficiency of food utilization and will boost the immune defenses, thus helping to diminish the incidence of infectious disease in the first year of life. To confirm the hypothesis, a double-blind, longitudinal study is necessary and is projected to cover the fetal period and first year of life, periods which are paramount to cellular growth and development, including those of the immune system.

B. SPECIFIC AIMS

To optimize the effects of zinc supplementation on the growth and immune defense capacity in infants at high risk in Bangladesh.

C. METHODS & PROCEDURES

C.1 Study Village :

The research study shall be done, in Dhamrai which is 26 miles north of Dhaka. Dhamrai is an Upa-Zilla with a central semiurban look, electrified market-place (and Upa-Zilla administration) ; but the surrounding areas are typical villages. For the last three years a child health clinic once weekly is being run by the staff and the postgraduate students of the department of Child Health, IPCMR. (Now, the Institute of Child Health and Research). Eight villages had been taken into the study to examine the health and nutritional status of the children population. There are 5083 people in these 8 village of which 2218 are under the age of 15 years. There are 280 under the age of 1 year and 1000 women are of child bearing age of which 140 are pregnant.

Most of the people are landless, occupation being day labourers, fisherman, brass workers, boatmen etc. The average per capita income is US \$ 120 which is the national average in the country. Their dietary habits are mostly rice and leghums. Consumption of vegetables, fruits and animal proteins is very poor. 100% of the mothers put their children to breast on the third or fourth day of life. There is evidence of lactational failure in many of the women. Bottle feeding is common. Additional food supplementation (weaning) is delayed till around two years of age. 80% of the children under 15 years suffer from malnutrition^{47,48}. Incidence of chronic diarrhoea was found to be 3 times more common than acute diarrhoea in children attending the outpatient clinic⁴⁷. The average weight of the mothers was recorded as 41 kg., which reflects a poor nutritional status. There are 4 local volunteer health workers helping on part time basis with the running of the clinic and the research projects presently being carried out.

C.2 Patients Selection

C.2.1 Sampling Frame

The sampling frame for selection of participants in the supplementation program will comprise 8 villages in the Dhamrai area. One hundred pregnant women (see section C.2.2.) will be sought as participants.

C.2.2 Eligibility

Eligibility criteria for participation in the supplementation program will include :

- (a) Pregnancy in the first term at the time of entrance in the study ;
- (b) Agreement to allow the health workers to question them about infectious disease symptomatology regarding themselves and their infants.
- (c) Age : any woman who is pregnant, primi or multiparas ;
- (d) Serum Zn level $< 75 \mu\text{g}/\text{dl}$;
- (e) At high-risk for Zn deficiency according to dietary intake patterns ;
- (f) Agreement a priori to allow anthropometric measurements on themselves and their babies ;
- (g) Agreement a priori to allow milk and blood studies on themselves.

C.3. Recruitment of Participants:

All first-term pregnant women in the Dhamrai will be invited for a free check-up at the clinic held by Dr. Talukder. At that time, they will be informed of the purpose and conditions of the study as well as of the benefits to be derived. Upon agreement in principle to participate, the following procedure will take place :

- (a) Questionnaire on (1) dietary preference of different common foods including those high in Zn content (2) 24-hrs. dietary recall.
- (b) Blood sampling for detection of anemia (haemoglobin, haematocrit) as well as for albumin, total protein, retinol binding protein (RBP) and zinc ;
- (c) Demographic, socio-economic questionnaire ;

- (d) Upon finding those eligible according to the established criteria(see C.2), they will be invited formally to participate and given the consent form to sign. At that time and at subsequent time they will receive all the informations they may require ;
- (e) Upon entrance in the program they will undergo anthropometric measurements and will allow for sampling of the drinking water and usual food consumed in the household (for Zn studies purposes).

C.4. Allocation to Zn + or Zn-Supplementation:

The allocation will be done by geographic (proximity, neighborhood) clustering, such that one community health worker may service a cluster of 25 participants and not confuse at any time the zinc containing bottle from the other one. The clustering and allocation will continue until the desired number of participants are reached such that 50% will belong at any time to one of the supplementation groups.

As such we would end up with 4 clusters of 25 participants, to be serviced by 4 community health workers. Each health worker will receive a supply of syrup containing vitamins, minerals + Zinc and will distribute it on alternate days to her group for the duration of the study.

The allocation of the Zinc + zinc - groups will be done by random assignment as soon as the "clustering" will become feasible and the future participants will be asked them to sign the consent forms. The health workers will not know if the service participants assigned to one or another of the groups.

C.5 Supplementation Regimen and Monitoring :

Nutritional Supplementation Procedure

- C.5.1 After the completion of the preparatory phase (consent, blood work, dietary questionnaire, food sampling, anthropometry, demographic, socioeconomic questionnaire) each participant will be visited on alternate days by the community health worker (H.W) assigned to her for the duration of the study. At that time the H.W. will give the participant the supplement (by pipetting the syrup into her mouth) and will do likewise for the participants existing children

(upon the participant's wish). The supplements will be different in concentration according to RDA for pregnancy, lactation and infancy.

During each visit the H.W. will inquire about the participant's (and her infant's) state of health with regards to infectious disease symptomatology according to a check-list. Upon finding any symptomatology she would urge the participant to visit the weekly clinic, which would offer free service to the participants and their progeny for the duration of the study. The H.W. will also remind the participants and ensure their compliance to visit the clinic at the scheduled times (see C.5.2). The work of the H.W. will be monitored by a supervisor to whom the H.W. will report weekly. At that time she will deliver the filled check-lists and report otherwise all relevant information on each participant, including that of compliance with the scheduled visits to the clinic.

The supervisor will inspect monthly each H.W.'s work by an unscheduled visit on her "territory". She will take note of any relevant health or supplementation compliance problems and report it weekly to the visiting investigator. She will also compile a statistical list on each participant/infant with the aid of the H.W.'s and that of the clinic file. She will deliver the list (in triplicate) to the investigators monthly for the duration of the study.

The monitoring will be done by the investigators upon weekly visits.

At that time they will take note of any problems and solve them. The health monitoring will also be done by the clinic and appropriate reporting will be given to Dr. Talukder weekly.

Each participant is free to disengage from the study at any time. At the end of 12 months post-partum, each participants' supplementation will terminate both for her and the infant.

C.5.2 SCHEDULE & FOLLOW-UP AT THE CLINIC

Mother :	Pregnancy	Post delivery (lactation)		
	First Term	First Week	26 Weeks	52 Weeks
	- Anthropometry	- Anthropometry		
	- Demographic SES Questionnaire	- Dietary studies	Same	Same
Infant	- Dietary	- Blood studies		
	- Food sampling	- Milk studies		
	- Blood studies			
Infant :	_____	- Anthropometry	Anthropometry	Anthropometry
		- Blood studies	Dietary St.	Dietary Studies.
			Blood St.	Blood St.

The supplementation in all cases will be done according RDA values.

C.6. Field Procedures

C.6.1 Field Questionnaires

Standardised questionnaires are :

- demography, socio-economic status
- dietary frequency pattern
- 24 hrs. recall

will be composed in Bengali and filled up by a team member of the clinic at the time of the participant's entrance into the study and at three scheduled other times (see C.5.2).

C.6.2 Health Workers Check-list

A list reflecting common infectious disease symptomatology will be noted alternate days visits by the H.W. for the duration of the study.

C.6.3 Supervisor's Check-list

This list will comprise descriptive statistics deriving from (1) the weekly H.W. check-list reports and (2) the data on file in the clinic on each participant/infant. The complete list will have coding space and will be coded accordingly by the supervisor. The coded list will be provided monthly to the investigators.

C.6.4 Anthropometry

The anthropometric measurements will consists of

- height (to the nearest 1 cm)
- weight (to the nearest 20 gms) on a calibrated scale
- left mid arm circumference to the nearest 0.1 cm.

The anthropometry will be performed independently by two members of the health team and the final results will consist of the averaged figures.

C.6.5 The health workers will perform the food-water sampling after adequate training received from the supervisor.

C.6.6 The blood/milk studies

The blood will be drawn by venepuncture (5ml for the mother, 1 ml for the infant) by a health team member, according to the schedule. The strictest care will be taken to draw the blood into zinc-free containers.

The needles used will be sent alongside the filled container to ICDDR'B in sterile plastic envelopes well identified (by number corresponding to the participant's name) according to schedule. The milk (after careful cleaning of the nipple) will be expressed in a zinc free container and sent in the manner described above.

C.6.7 The supervisor will ensure that the participants will follow their schedules. She will ensure that her list contains the data derived from C.6.1 - C.6.6 for each participant and forward the data coded to the investigators monthly.

C.7 Supplementation and benefits to the participants

The participants will receive appropriate RDA supplements of vitamins and minerals throughout two essential periods of her life, i.e. pregnancy and lactation. Fifty percent of the participants will receive in addition the zinc RDA supplement, in this proposed study. The same benefits may be extended upon the expressed desire to the participant's other progeny. The participants and all their children will receive free medical care for the 10 most common ailments, for the duration of the study.

D. Data collection and Analysis

D.1 The data to be analysed will be comprised of :

D.1.1 Anthropometric data (height, weight, mid-arm-circumference, for the mother/baby of 4 (mother) and 3 (baby) points in time, thus allowing for the construction of longitudinal growth curves.

D.1.2 Blood studies (haemoglobin, haematocrit, albumin, total protein, R.B.P. and zinc for the mother and her baby at 4 (mother) and 3 (baby) points in time, thus allowing for the construction of longitudinal time curves.

D.1.3 Dietary Studies Data

- (a) Food pregnancy questionnaires
- (b) 24 hrs. recall questionnaires
to be obtained at 4 points in time from the mothers.
- (c) Dietary questionnaires re : the weaning foods at the beginning of the period of feeding the infants weaning foods and at the termination of the study.

The dietary studies data will allow for construction of longitudinal trends, for establishing dietary patterns and semiquantitative analyses of nutrient and energy intake.

D.1.4 Household Food/Water Samples Data

- (a) Samples of food/water taken in zinc/free test-tubes will be analysed for zinc content 4 times.
- (b) Samples of the weaning food will be taken and analysed for zinc content in the first week of feeding weaning food and at the end of the study.

The zinc content of the samples will be determined periodically and trend curves will be constructed.

D.1.5 Breast milk studies data (Total protein, albumin, R.B.P. and zinc) will be collected at 3 different time periods. Longitudinal trends will be constructed for each element considered.

D.1.6 Demographic - Socio-economic status will be obtained from the participants at the scheduled times.

D.2 Statistical Analysis

Summary of variables -

Independent variables : SES
 Mother's age
 Mother's parity
 Food habit

Dependant variables : Delivery complications
Birth weight
Anthropometry of mother
Anthropometry of children
Incidence of illness

The acquired data from the individual cards shall be tabulated according to the stratification and variables accounted for.

Curves of (a) anthropometric values and (b) incidence of illness shall be constructed.

Comparison of delivery complication in Zn + and Zn - group will be constructed by χ^2 test.

With regards to the anthropometric and incidence of illness, student's t-tests shall be done for the two groups.

Multivariate analysis will be done to examine the net effect of zinc supplementation while controlling for other factors (of independent variables).

All the results shall be presented in simple and concise tabulations, specific for the variables presented. It is not possible to establish a priori the number of tables, histograms or graphs that shall result at the final statistical outcome.

E. Significance

The study will confirm the zinc deficient status of the pregnant mother and of infants in a community. Zinc supplementation as a single intervention program is expected to demonstrate better pregnancy outcome, better birth weight and better infant growth and immune defense capacity. The study shall add new knowledge to biological science. The result of the study may suggest for better national economy through supplementation program to the soil, expecting higher crop yields. Zinc supplementation program in the community may prove to be cost effective in terms of pregnancy outcome, infant growth and immune defence capacity.

WEEKLY ILLNESS/INFECTIOUS DISEASES RECORD

Mother's Name -

Mother's Number -

Childs Name -

Childs Number -

Visit No.	Date	Fever	Cold	Cough	Diarrhoea (No.)	Diarrhoea with blood.	Rash Other Samptoms	Therapy Home Care	Comment
Child									
Mother									

B U D G E T

1. Personal Services

Name	% of effort.		Project requirements:
a. Dr. Gabriel Eugen Sella	10%		nothing required.
b. Prof. M.Q-K Talukder	20%		
c. Dr. Ayesha Molla	10%		
d. Dr. Dilip Kumar Das	100%	\$ 3600 X 2	\$ 7,200.00
e. Field workers (4)	75%	2400 X 2	4,800.00
f. Study clerk (1)	25%	180 X 2	360.00
		<hr/> Sub-Total	\$ 12,360.00

2. Stationery & supplies -

a. Cork & test tubes (1600) size 16 X 125 mm		\$ 13.44
b. Butterfly needle (1000)		500.00
c. Disposable syringe (1000)		1,340.00
d. Stationery		200.00
		<hr/> Sub-Total
		\$ 2,053.44

3. Equipment None

4. Patient hospitalisation None

5. Transportation

PG (Dhaka) - Dhamrai - Dhaka

PG - ICDDR'B - Dhamrai - ICDDR'B - PG \$ 100 X 12 X 2 \$ 2,400.00

6. Laboratory tests -

a. Serum Zn ⁺⁺	- 800 test	= \$ 2.89 X 800	= \$.2312.00
b. Serum Albumin	- 700 "	\$.1.81 X 700	\$.1267.00
c. Serum Total protein	700 "	\$.0.46 X 700	\$ 322.00
d. Serum R.B.P.	700 "	\$.10.33 X 700	\$.7231.00
e. Urine for pregnancy test	200 "	\$.3.27 X 200	\$.654.00
f. Milk total protein	300 "	\$.7.29 X 300	\$.2187.00
*g. Milk zinc	300 "	\$.8.67 X 300	\$.2601.00
*h. Milk albumin	300 "	\$.5.43 X 300	\$.1629.00
*i. Milk RBP	300 "	\$.11.37 X 300	\$.3411.00
j. Food zinc	700 "	\$.8.67 X 700	\$.6069.00
k. Water zinc	700 "	\$.2.89 X 700	\$.2023.00
		<hr/>	
		Sub-Total	\$ 29,706.00

*Methods needed to be set. Tentative costs are given

7. Analysis & publications -

a. Computer analysis		\$.500.00	
b. 4 papers publication 250.00 x 4		\$.1000.00	
		<hr/>	
		Sub-Total	\$.1500.00

BUDGET SUMMARY

1. Personal services	\$.12,360.00
2. Stationery & supplies	\$.2,053.00
3. Transportation	\$.2,400.00
4. Laboratory tests	\$.29,706.00
5. Analysis & publications	\$.1,500.00
	<hr/>
TOTAL	\$.48,019.00

SUPPLEMENTATION OF MINERALS-VITAMINS STUDY

CONSENT FORM

I understand that the Institute of Child Health and Research (ICHR), IPQMR and the ICDDRDB, Dhaka are carrying out a community research to determine the impact of minerals and vitamins supplementation on infant growth and ability to defend against infectious diseases.

I understand that by receiving this supplementation I improve my chances for a normal pregnancy, delivery, lactation and for having an infant in a better condition of health than otherwise. I understand that supplementation to my infant for the first year of life will further improve his/her chances for normal growth and better defense against infectious disease.

I understand to donate freely ^{four}~~three~~ samples of blood and of milk during the period of the study.

I understand and I agree to the taking of ^{three}~~two~~ small samples of blood from my infant at the beginning and end of the study.

I understand and allow for the measurement of height, weight and ^{midarm circumference}~~tricipital skin fold~~ ~~three times~~ for myself and for my infant during the period of the study.

I understand and agree to answer a questionnaire about my diet and any infant's weaning diet ^{four times}~~twice~~ during the study.

I understand and agree to allow for taking small samples of household drinking water and usual food ^{four times}~~twice~~ during the study.

I understand that a community health worker will deliver and supervise the in-taking of the food supplements every other day for the duration of the study. I understand and agree to answer during each visit questions referring to infectious disease symptoms ~~referring to infectious disease symptoms~~ with regards to myself and my infant as well as other children I have in the household.

I understand that for the duration of the study I and all my children will enjoy free medical services for common ailments such as provided once-a-week by the clinic led by the ICHR in Dhamrai.

I understand that I always preserve the right to withdraw myself and/or my infant from the study at any time. I also understand that if I do withdraw, I may not be allowed to return to the study.

I agree that all of the above are clear, I have asked the person who has given me the form all the questions I had for further clarification and I have the right to ask any further questions at any time. I consent therefore, in my name and that of my infant to be included in the food supplementation study.

Signature of Supervisor

Signature of Participant
left thumb impression.

Signature of Investigator

Date _____

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