tachment 1.

Date 9.9.81

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator K.J. Wilson Trainee Investigator (if any) 503

Application No. 81-039 Supporting Agency (if Non-ICDDR,B) —

Title of Study Growth Rate and Early Introduction of Weaning Food

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)
(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 N.A. 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 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.

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

Trainee

81-039
Rec'd 15/9/81

SECTION I - RESEARCH PROTOCOL

1. Title: Growth Rate and Early Introduction of Weaning Food

2. Principal Investigator: K.J. Wilson

3. Starting Date: November 1981

4. Completion Date: November 1982

5. Total Direct Cost: US $ 5,000.00

6. Scientific Programme Head:

This protocol has been approved by the Nutrition Working Group.

*Signature of Scientific Programme Head: [signature]

Date: 9/9/1981

This signature implies that the Scientific Programme Head takes responsibility for the planning execution and budget for this particular protocol.

7. Abstract Summary:

The protocol is concerned with the testing of a nutrition education strategy using the food available in the home and addresses an issue raised in the Community Health Services Project, Matlab. The nutrition education service will be restricted to an attempt to motivate mothers to introduce solid food to their infants before they would normally do so. The purpose of this early introduction of supplemental weaning food is to estimate its impact on growth in weight and height of infants.

The nutrition status of two cohorts of children of different age groups whose mothers will receive this limited nutrition education, will be followed for one year. Mothers and infants will be matched with a control population for all data. Changes in knowledge and practice of mothers exposed to nutrition education will be assessed at the end of the project.

The data from this project will be used in the preparation of a thesis for the degree of Doctor of Philosophy at Queen Elizabeth College, London University.

9. Review:

(a) Ethical Review Committee: _____

(b) Research Review Committee: _____

(c) Director: _____

(d) BMRC: _____

(e) Controller/Administrator: _____

ABSTRACT SUMMARY

1. Mothers will receive the nutrition education and growth of infants will be monitored.

2. No risk involved.

3. N.A.

4. Subjects will be referred to by number only.

5. Signed consent will be obtained from authorized legal guardian or parent of each infant.

6. Fortnightly interviews with mothers of approximately 20 minutes in length.

7. Subjects will receive nutrition education and their infants will receive health care and growth monitoring.

8. Project requires use of birth records.

SECTION II - RESEARCH PLAN

A. INTRODUCTION:

In most developing countries average growth rate of infants is satisfactory up to about 3 months of age, but then begins to fall off sharply (1). Data showing this fall off in growth comes from longitudinal studies in many countries eg. Uganda, The Gambia and Jamaica (2). In the first two of these countries almost all babies are breast-fed for much longer than 3 months. Growth may falter at that age because of disparity between milk production by the mother and the child's needs but the situation is also complicated by the increased exposure of the child to infection at a time of decreasing passive immunity. It may also be that growth faltering to some degree, is a natural phenomenon (3).

There is some dispute about patterns of growth in the first six months of infancy (4-10) and it may be that some standards for weight increments in the second 3 months of infancy are unnecessarily high reflecting the increased weight gain in bottle fed babies as opposed to breast-fed babies (3). This is particularly so with regard to some UK standards (11).

Whether this fall off in the rate of increase in growth and height after 3 months is a normal physiological phenomenon or not, the fact remains that the decrease is sharper in developing countries such as Bangladesh compared with the developed world. Therefore, growth faltering, to the extent that it exceeds that observed in countries such as the United States, can be seen as detrimental to the nutritional status of infants. The danger may be two-fold; in addition to being more vulnerable to infection at the period of growth faltering (15), the infant is also entering what is generally thought of as the danger period (6-24 months) (15,16) in a less than optimal nutritional state.

Chances of survival through the danger period are well documented as relating to birth weight (12), age and parity of mother (13), and birth interval (14). In a more proximate sense it has been shown in one study at least that mortality of Under 5s is related to weight gain in the post-natal period (21).

This study will investigate whether growth faltering in height and weight is modified by the early introduction of supplemental food.

It is argued that supplementary food is itself so heavily contaminated in many communities, that the infant may be more at risk from malnutrition precipitated by weaning food induced diarrhoea than from the malnutrition brought on by insufficient food. To resolve this controversy we need to know more about the relative contributions of contaminated food and contaminated environment to weanling diarrhoea.

Despite these reservations however, it appears from an extensive literature search (22-26) that only one author (27) feels that malnutrition per se is preferable to the dangers of supplementary feeding.

At four months of age the average intake of breastmilk by the infants of well-nourished, healthy mothers is thought to be in the region of 700 mls per day (4,19). The average value for energy content of breastmilk, again from well-nourished healthy mothers, is 70 kcal/100 mls (18) making a total daily energy intake of 490 kcal at four months. The volume of milk produced by malnourished mothers may not differ as much as the energy content of the milk, due in particular, to a decrease in the fat content of milk.

The average weight of normal Bangladeshi children at four months is probably 5.1 kg (20), the average daily energy requirement for four months old infants is 102 kcal/kg body weight (6,17), the average total requirement for daily intake of energy for Bengali infants should therefore be 520 kcal. By the same reckoning energy intake at 5 months should be 545 kcal

Actual energy intake at four months is therefore 6% deficient increasing to 9% at five months and continuing to rise thereafter.

It is proposed that mothers should supply an additional energy source to infants in the form of a readily available food. In the very poor households in which this study will be carried out, the only available food is rice, flour and vegetables. Dhal, and fish may also be consumed but it is unlikely that such scarce items would be offered to infants. Mothers will therefore be encouraged to feed infants a simple diet of breastmilk with soft rice (jao) or flour (atta) and vegetables when the infant is around six months of age. In this way the energy gap can be bridged for this period of the infant's life at least.

Objectives

The main objective of this project is to investigate whether the early introduction of weaning foods (i.e. before 1 year) in infants, has an effect on their growth rate.

To get a true estimation of the impact on growth rate of the early intake of weaning food, it will be necessary to allow for confounding factors such as morbidity and seasonality. Therefore the effects of morbidity and seasonality on growth will be monitored.

The results of this study will be used in the preparation of a thesis for the degree of Doctor of Philosophy at London University.

B. SPECIFIC AIMS:

1. To estimate changes in growth rate of infants from birth to 18 months by age of introduction of weaning food, allowing for;

   (a) the effect of season on growth rate of infants from birth to 18 months.

   (b) the effect of morbidity on growth rate of infants from birth to 18 months.

2. To estimate change in knowledge and practice in relation to time of introduction and type of weaning food of mothers by exposure to nutrition education process.

3. To document the feasibility of the proposed strategy as a part of the MCH activities in Matlab.

C. METHODS AND PROCEDURE

This study will utilize the facilities of the Community Health Services Project, Matlab and will provide a specific nutrition education service for the MCH component of the integrated project.

(I) A limited survey of knowledge and practice with regard to specific food and health variables will be carried out in two cells (20,000 each) of the MCH-FP area, one cell with intensive MCH services and one without. A sample size of 3,000 will be taken. Interviews for this survey will be carried out as part of the interviews carried out for the fertility control survey and using the same personnel and facilities (See Exhibit 2).

This will provide data on the knowledge and practice of a large population who have been exposed to little if any, nutrition or health education which will be used in designing the form and message of the education process.

(II) The project will involve two cohorts of 75 infants in order to ensure that two cohorts of 50 infants can be followed for one year. The households chosen for this study will all be landless or functionally landless*, labourers and the villages chosen will be equally distant from centres of

*owning less than 1.5 bighas of land.

increased social interaction such as large market villages.

A control group of two cohorts of infants will be matched for SES, mother's age (less than 34 years) and parity (1-4) and having lost not more than 1 child previously. In order to control for the effect of monthly weighing on infants in the control population, six monthly point prevalence surveys will be undertaken on a random sample of 50 infants.

The project will be a one year prospective investigation of the differences in growth rate between 2 study cohorts (from birth and from 6 months) and 2 control cohorts (birth and 6 months). Analysis of demographic data from Matlab shows that, on the basis of the above mentioned criteria of parity, age and socio-economic status, it will only take approximately 6 weeks to accumulate the requisite number of neonates especially as October through January is the peak annual birth period.

The Community Health Workers (CHW) of the Community Health Services Project (CHSP) serving the selected families will be given a short training course in nutrition (see Exhibit 6). The training will include instruction on; growth, malnutrition, the malnutrition infection synergism, suitable weaning foods, dietary requirements of infants, hygienic feeding practices, demonstrations in the preparation of weaning foods and hints on how to carry out the teaching process in the home. The CHWs will be issued with instruction in Bengali emphasising the points to be communicated to mothers and the sequence of communication. Weekly meetings between health assistants, the principal investigator and CHWs will be used to solve problems as they arise.

The education given to mothers will be on the appropriate feeding of infants and in particular the early introduction of suitable weaning foods. Knowledge and practice of mothers in relation to these specific areas of child care, will be taken as a baseline study and again six monthly for one year, using a simple questionnaire (see Exhibit 1).

Anthropometric data (height, weight, skinfold thickness, arm circumference) will be collected monthly on all infants (study and control) by two health assistants with the asistance of the principal investigator. Health assistants will be trained and their accuracy and consistency of measurement checked for arm circumference estimation at the start of the project and again during the study if thought necessary by the principal investigator.

All anthropometric data will be checked bi-monthly by the principal investigator (who will visit every household every two months). In the interests of accuracy, skinfold thickness measurements (tricep) will be collected by the principal investigator only and will therefore be collected bi-monthly.

Using the dietary recall method, the dietary intake of infants will be investigated monthly for one year by the CHWs (see Exhibit 4).* The accuracy of this method will be established by comparing the dietary recall data with data from 12 hour weighed estimations of intake taken in a sub-sample (42 mothers) of the study households. A health assistant will estimate the weight of food ingested by the infant by weighing the container plus food before and after the infant is fed. This process will be repeated over 3 consequtive days. The health assistant will return on the 4th day and ask the mother to recall dietary intake for her infant on days 2 and 3.

Compliance of mothers can be readily assessed from this dietary data. If the mother appears to be feigning complicance out of politeness etc. it should be possible to ascertain from other members of the household or bari, the accuracy of her information. When a mother first introduces semi-solid food to the infant, the CHW will note as far as possible, reasons for compliance and other information (see Exhibit 7).

Morbidity data for all infants in the study will be recorded fortnightly by CHWs using recall methods (see Exhibit 3). Duration and severity of symptoms will be recorded rather than an accurate diagnosis being attempted. Duration and severity of anorexia will be noted.

Basic primary health care will be delivered when necessary within the context of the MCH activities of the CHSP.

D. SIGNIFICANCE

The belief is widely held that the introduction of solid food at around 4-6 months will go some way to eliminating the growth faltering found in entirely breastfed infants, and that consequently nutritional status will be improved. To this end many MCH projects in Bangladesh devote resources to persuading mothers to adopt this practice. To date, however, the impact of growth rate of the introduction of supplemental food has not been estimated and this lack of validation is critical in the development of effective nutrition interventions in Bangladesh.

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*Mothers will be asked to recall the quantity and type of foods eaten by their infant on the day prior to the interview. Quantity meaning number of finger scoops, this being the accepted practice for feeding infants.

Fig. 1a. Growth in weight of study and control infants relative to the international standard (Jelliffe , 1966)

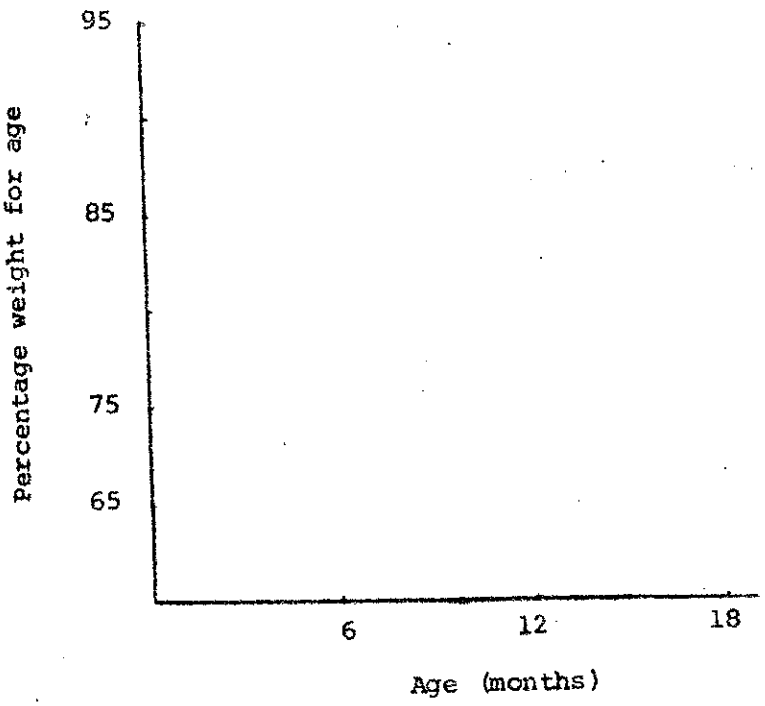


Fig. 1b. Growth in length of study and control infants relative to the international standard (Jelliffe 1966)

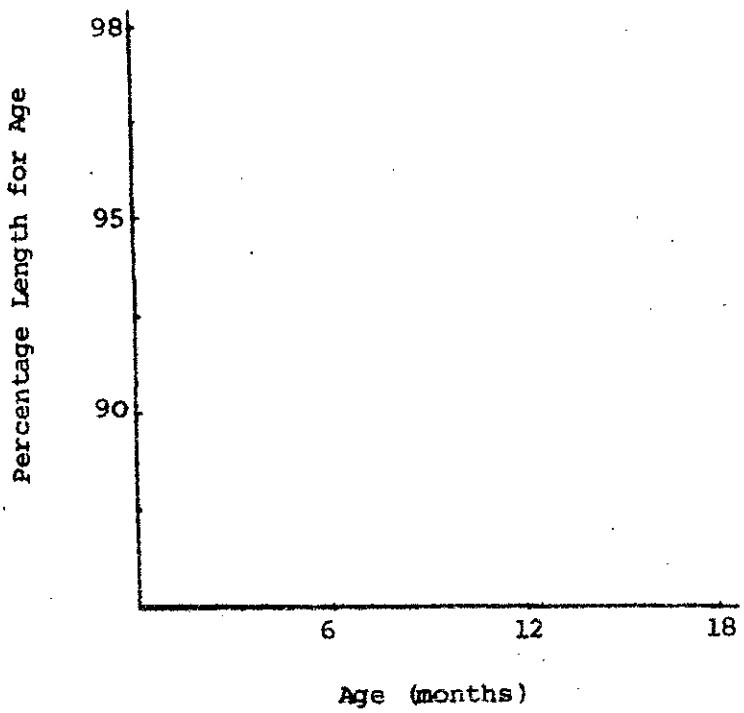


Fig. 1c. Triceps skinfold of study and control infants (Jelliffe, 1966 standard)

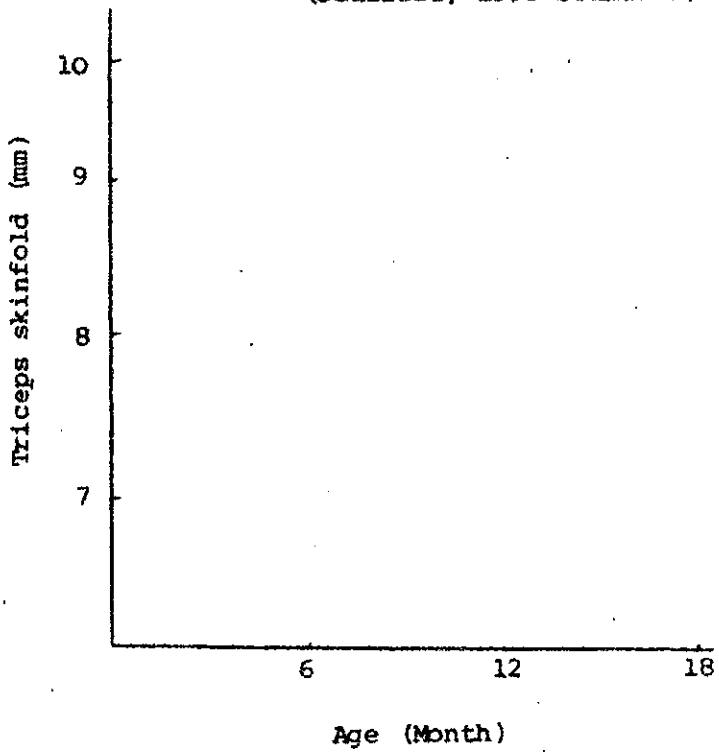


Fig. 1d. Mid. - upper arm muscle circumference of study and control infants (Jelliffe, 1966).

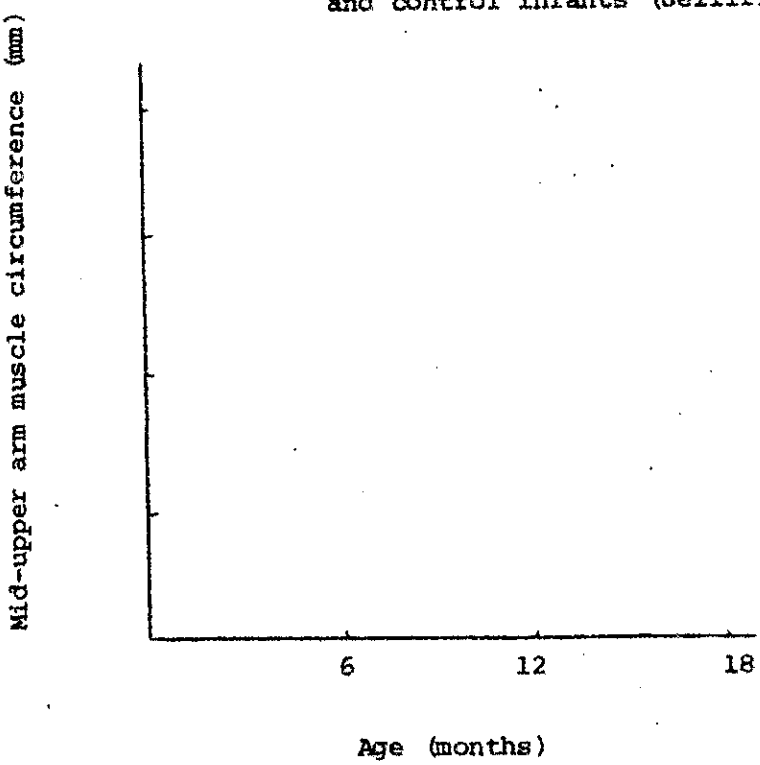


Fig. 2. Age of introduction of home weaning foods of study and control infants.

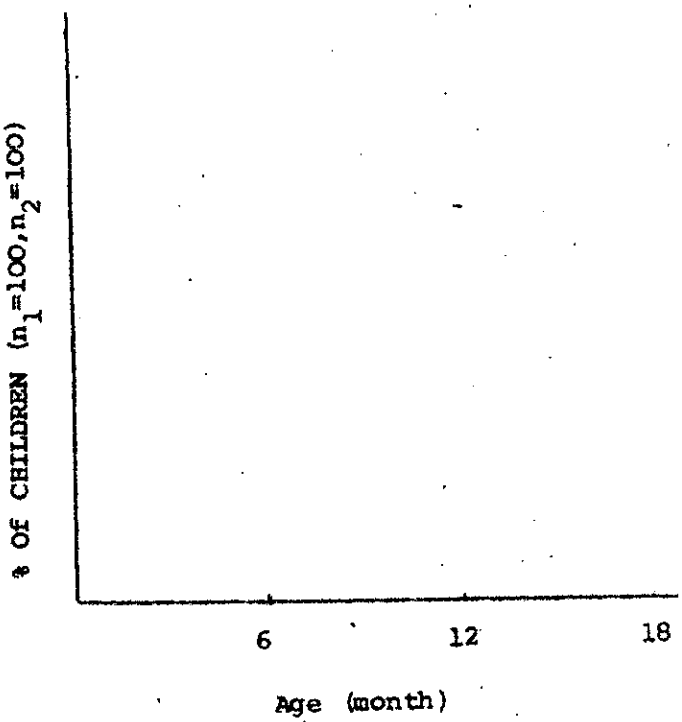
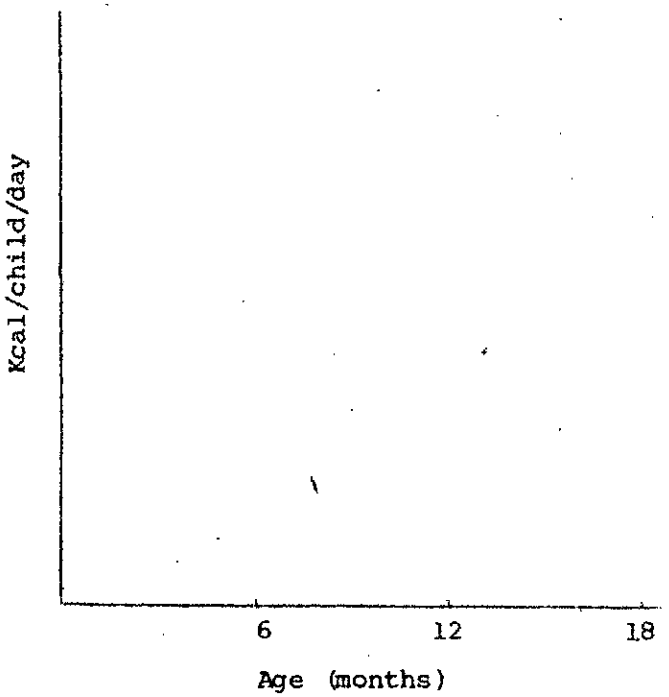


Fig. 3. Mean energy intake of study and control infants, showing deficit from recommended energy requirements.



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SECTION III - BUDGET
A. DETAILED BUDGET

1. PERSONNEL SERVICES

Position	% Effort	No. of days	Annual Salary	Project Requirements Taka	Dollars
Investigator (Wilson)	100	1 year	-	-	-
Senior Field Assistant	50	1 year	Tk. 38,880	19,440	
Health Assistants (2)	100	1 year	27,233	54,466	
Porter/Boatman (2)	100	1 year	10,500	21,000	
Supervisor	5	1 year	44,800	2,240	
			Sub-total:	97,140	

2. Supplies and Materials

Stationary:	Unit Cost	Annual Requirement	
Ballpoint pen	Tk. 6.00	40	240
Clipboard	7.20	20	144
Files (A4)	20.00	20	400
Hole punch	40.00	1	40
			824

3. Equipment

Food scales		2	-
Length board		2	-
Measuring tapes		2	-
Salter scales		2	-

4. Transportation

Speedboats 1 hours run/day	Tk. 105/hour	132 hours	13,860

	Unit Cost	Annual Requirement	Project Requirement	
			Taka	Dollars
5. Printing and Reproduction				
Paper printing	Tk. 0.13	5,000	650	
6. Utilities, Rent and Communication				
Board and rent			4,160	
Computer				
2 coding assistants	1 month	22,529	3,955	
1 data entry	15 days	21,350	889	
1 computer programmer	1 month	34,728	2,894	
			7,738	

B. Summary Budget

Categories		Project Requirements	
		Taka	Dollars
1.	Personnel services	97,140	-
2.	Supplies	824	-
3.	Equipment	-	-
4.	Transportation	13,860	-
5.	Printing and reproduction	650	-
6.	Rent, communication & Utilities	7,738	-
	Total:	120,212	8,000

Conversion rate is Tk. 15.00 to U.S. 1.00

EXHIBIT 1

Selection of Mothers for Study and Control

Name of Village _____ Name of family _____

Family Number (1 2 3 4 5) Ind No. (10 11)

Family Number (6 7 8 9)

Bari Name _____

Bari No. (12 13 14)

day month year (15 16 17 18 19 20)

Age (21 22)

Number of children (23 24)

Education: Father's education (25) Mother's education (26)

Age of youngest (months) (27 28)

Sex: 1 Male
2 Female (29)

Is she still breastfeeding

1 / / No (30)

2 / / Yes

Have any of her children died when under 5. years.

1 / / None (31)

2. / / One

3 / / Two or more

Has any man in the household done any wage labour (i.e. agricultural work on someone else's land for day wages) in the past season. (32)

1 / / Yes 2 / / No

Exhibit 1

Limited survey of knowledge and practice of mothers of children under 5.
Section I of methods and procedure.
Also to be used on study and control population..

1. Age of youngest child [ ][ ]

2. At what age solid food first given [ ][ ]

3. Why at this age : [ ]

   1. Insufficient breastmilk
   2. Sickness of mother
   3. According to CHW instruction
   4. Other _____
   5. Dont know

4. What is the best age to give solid food. [ ][ ]

5. Why at this age : [ ][ ]

   1. Baby needs more food
   2. Good health
   3. Teeth have appeared
   4. Baby reaches for food, appears hungry
   5. Dont know

6. Who told you this, how do you know : [ ][ ]

   1. Husband
   2. CHW
   3. Relative
   4. Neighbours
   5. Others
   6. Dont know

7. Is there any special reason why shak is good for children [ ]

   1. Contains vitamins
   2. Good for eyes
   3. Not specially good for children
   4. Dont know

8. Who told you this, how do you know: ☐

1. Husband
2. CHW
3. Relative
4. Neighbours
5. Others
6. Dont know

9. What foods are good for babies:

1. animal milk ☐
2. powder milk ☐
3. biscuits ☐
4. banana/fruit ☐
5. Glaxo ☐
6. eggs ☐
7. halava sugi ☐
8. halava atta ☐
9. jao ☐
10. fish/meat ☐☐
11. shobji/shak ☐☐
12. potatoes ☐☐
13. other ☐☐

10. Who told you this how do you know: ☐

1. Husband
2. CHW
3. relative
4. neighbour
5. dont know

Exhibit 3

MORBIDITY DATA

Data to be collected fortnightly

_____ Name of CHW

DO NOT WRITE HERE

1. Village ☐☐☐☐

   Bari ☐☐☐

   Family ☐☐☐☐

   Individual ☐☐

2. Date ☐☐☐☐☐☐

3.

	No of Days	Ate less	Ate Nothing
1 high fever			
2 fever			
3 cough			
4 runny nose			
5 diarrhoea (up to 5 times a day)			
6 diarrhoea (over 5 times a day)			
7 diarrhoea with blood			
8 scabies			
9 eye infection			
10 other _____			
_____			

☐☐☐☐☐☐☐☐☐☐

☐☐☐☐☐☐☐☐☐☐

☐☐☐☐☐☐☐☐☐☐

Exhibit 4

FOOD INTAKE

Data to be collected monthly

_____ Name of CHW

DO NOT WRITE HERE

1. Village
   Bari
   Family
   Individual
2. Date

3.

	Dish	Ingredients	Qt	Wt	Cal	Protein
Feed 1						
Feed 2						
Feed 3						
Feed 4						

Breastmilk only

Total :

Exhibit 5 ANTHROPOMETRY Monthly

_____ Name of Health Assistant DO NOT WRITE HERE

1. Village ☐☐☐☐
   Bari ☐☐☐
   Family ☐☐☐☐
   Individual ☐☐
2. Date ☐☐☐☐☐☐

3. Weight _____ ☐☐☐
   Height _____ ☐☐☐
   Arm circ. _____ ☐☐☐

Principal Investigator

Skinfold _____
_____
_____
Average _____ ☐☐☐

Clinical signs: 1 angular stomatis ☐ ☐
2 anaemia ☐
3 night blindness ☐
4 corneal xerosis ☐

Exhibit 6

MANUAL FOR TRAINING CHWs TO TEACH MOTHERS NUTRITION

The training manual is being developed and is not yet completed.

The overall objectives of this training course are to train the workers how to:

- convince mothers and family members of the importance of giving weaning food to infants at the age of six months.
- teach mothers how to prepare weaning food from food available in the house and how to feed and store it hygienically.
- convince mothers to give colostrum to neonates.

A trainer of community workers needs a greater depth of knowledge about the treatment and prevention of diarrhoea, the manual will contain additional information on the subject to increase the trainer's knowledge. It also offers guidelines for effective ways to transmit this knowledge and ideas on how to train others.

The manual will be divided into topics as follows :

- Introduction (vulnerability of children to malnutrition)
- Growth (need for food for growth, monitoring growth)
- Malnutrition/Infection (increased susceptibility to infection in malnutrition
- Dietary needs of infants 0 - 18 months
- Demonstration on preparation of weaning food
- Home visiting, transmitting knowledge, data collection procedure.

Exhibit 7

INTRODUCTION OF SUPPLEMENTARY FOOD

_____ Name of CHW

DO NOT WRITE HERE

1. Village ☐☐☐☐
   bari ☐☐☐
   family ☐☐☐☐
   individual ☐☐
2. Date ☐☐☐☐☐☐

3. When was supplementary started
   one week ago ☐
   two weeks ago ☐

4. Age of child _____ ☐☐

5. Reasons for introduction :

   _____

   _____

   _____

6. What foods given first:

   _____

   _____

7. Why these foods:

   _____

   _____

   _____

   _____

CONSENT FORM

ICDDR,B are doing a study on growth of babies. For this reason we are going to come and weigh your baby every month and to ask you whether he has been ill and what foods he has been eating.

If your baby is ill we will provide care in the home or if necessary in the sub-centre or hospital.

If you do not want to participate or wish at any time to withdraw from the study you will still be taken care of at the sub-centre and in the hospital.

Your signature

_____ Date: _____

_____

Investigator's signature

সম্মতি পত্র

আই. সি. ডি. ডি. আর, বি শিশুদের দৈহিক উন্নতি নিয়ে গবেষণা করিতেছে। এ জন্য প্রতি মাসে আমরা শিশুদের ওজন নিয়ে থাকি এবং শিশু মাতাকে খাদ্যের অভ্যাস ও শারীরিক অসুস্থতা সম্বন্ধে প্রশ্ন করি।

শিশু অসুস্থ হওয়ার সাথে সাথে আমরা তাহাকে হাসপাতালের শিশু পরিচর্যা বিভাগে ভর্তি করি ও যত্ন নিয়ে থাকি।

যদি কেহ এই গবেষণা প্রকল্পে সহযোগিতা না করে অথবা যে কোন সময়ে শিশুকে গবেষণা প্রকল্প থেকে বাদ দেয় তবুও তাহারা হাসপাতাল ও শিশু পরিচর্যা বিভাগের সম্পূর্ণ সহযোগিতা ও যত্ন পাবে।

স্বাক্ষর

তারিখ

ইনভেস্টিগেটর