

REVIEW BOARD ON THE USE OF HUMAN SUBJECTS, ICDDR,B.

22

Principal Investigator Dr. M. U. Khan

Trainee Investigator (if any) _____

Application No. 80-019

Supporting Agency (if Non-ICDDR,B) _____

Title of Study Analysis of growth and development data of Meheran

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).

1. Source of Population:

- (a) Ill subjects ☒ Yes ☐ No
 (b) Non-ill subjects ☒ Yes ☐ No
 (c) Minors or persons under guardianship ☒ Yes ☐ No

2. 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 ☒

3. 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 ☒

4. 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 Board:

- 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 Board for review.

N.B. The field part of this study had already been completed obtaining written consent. The data will be now analysed.

We agree to obtain approval of the Review Board on the Use of Human Subjects for any changes involving the rights and welfare of subjects before making such change.

Principal Investigator

Trainee

A-33755

80-019
Recd 14/5/80.

SECTION I - RESEARCH PROTOCOL

1. Title : Analysis of growth and development data of Meheran.
2. Principal Investigator : Dr. Moslemuddin Khan
3. Starting Date : June 2, 1980
4. Completion Date : December 31, 1980
5. Total Direct Cost : \$ 15,050.00
6. Scientific Program Head :

This protocol has been approved by the Disease Transmission
Working Group.

Signature of Scientific Program Head : [Signature]

Date : 5/5/80

7. Abstract Summary :

The data collected on anthropometry, illness, diet, dentition etc.

from Meheran children between birth to 10 years of age during 1975-77

needs to be analysed. This is an unique set of data collected on longitudinal

basis from a village of Comilla. The analysis of the data will provide

answers to the following questions:

1. Seasonal variation of growth of children.
2. Seasonality of certain illness of infants like diarrhoea, respiratory infection, skin disease, measles etc.
3. Relationship of diarrhoea and other infection with weight and hight and some other anthropometry.
4. Prevalence of acute malnutrition in this group of children.

5. Variation of Hb% and its relation with growth and season.
6. Difference in growth and growth rate between children born of mothers with high and low body weight.
7. Period-breast feeding can maintain nutritional status.
8. Period of deciduous teeth eruption and its relation with growth.
9. General growth curve of birth cohort of Meheran children.

The data needs to be processed, punched and transferred to computer teps and analysed to answer the above questions.

8. Reviews :

- a. Research Involving Human Subjects : _____
- b. Research Review Committee : _____
- c. Director : _____
- d. BMRC : _____
- e. Controller/Administrator : _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objective : For assessing and comparing the nutritional status of Bangali children with other countries there is no longitudinal growth and development data in Bangladesh children available at present. This study will provide or growth and developmental paramiter of a typical rural village. In addition, the study will provide us with information on the seasonality of growth variation, seasonality of diarrhoea and other common infections in children, Hb% and its relation with nutrition, prevellance of acute malnutrition, efficacy of breast feeding and the time of supplementation of food to children and interaction of infection and malnutrition, dentition as an indicator of survival or death etc. These will serve as valuable information for health and nutrition planners of Bangladesh and the region.

Background : Nutrition survey of Rural Bangladesh(1) had revealed that about one third of all households consumeless than 80% of the calorie requirements and 20% of the children were both wasted and staunted. Under the age of 5 about 25% of the children have severe or 3rd degree malnutrition. In Latine American only 3% of

under 5 children have severe malnutrition(2). We in Bangladesh, do not know whether this severe malnutrition begins from infancy. A study was necessary to examine this problem in a rural situation and follow growth pattern from birth. Martorell et al(3) has shown that normal growth pattern in developing countries are different from the norms of developed countries. Mata et al(4) found that there are many factors responsible for this difference.

Martorell(3) demonstrated that growth in Guatemalan children was affected severely by diarrhoea. Other investigators(5) have suggested that interaction of infection and malnutrition is the leading cause of morbidity and mortality in developing nations. Mata(4) suggested that malnutrition increases infection and infection predisposes malnutrition. We can examine this from our own data. Further more, the duration of maintenance of normal nutrition of breast fed babies can be assessed from our data. Breast feeding is said to protect from infection(6). Although breast feeding is quite prevalent in rural areas there is not dearth of infection and malnutrition in young children in Bangladesh. We can examine the causes of such vicious cycle from our data already collected. Malnourished children are said to have depressed cell mediated immunity(7). We can examine nutritional status of children.

affected with measles. Nutritional status at birth and subsequently is said to influence development of milk teeth(8). From our data data we can examine the seasonality of growth velocity and interaction of infections like diarrhoea, respiratory illness, measles skin diseases and avitaminosis.

3. Rationale : We have collected the data with the stated objectives. The data if analysed will give us an anthropometric parameter of rural children, pattern of illness in infancy and the factors responsible for differences in growth and development in rural Bangladesh children. As the field part of the activity is over analysis will take less than a year and no extra employment will be needed and the cost will be quite modest. The data produced will be of immense value to the health and nutrition planners of the country. Therefore, the analysis of data seem to be extremely important.

B. SPECIFIC AIMS

To examine :

1. If there is any seasonal variation of growth of children.
2. Pattern of common illness of children by season.
3. Prevalence of malnutrition in Meheran children.

4. General growth curve of birth cohort of Meheran children.
5. Relationship between infection (diarrhoea, measles) growth and malnutrition by time dependant regrestion analysis.
6. Hb% and its relation with age, growth and its seasonal variation.
7. Effect of mother's weight on birth weight and subsequent growth of children.
8. Time of eruption of milk teeth and its relation with growth.
9. Effect of SES on growth and infection.
10. Difference of the growth pattern between living and dead children.

METHODS OF PROCEDURE

The village Meheran of Matlab was selected for the purpose of this study. This village was under the surveillance of (CRL) ICDDR, B since 1966 and the dates of birth of all the children born since then have been recorded. The occupation of the inhabitants of the village are primarily fishing and agriculture. There are also some petty businessmen, Govt. and private service holders. The female folk are absolutely engaged in household activities which includes preparation of food, child raring, cleaning the house, facing domestic water, cleaning dirty lines and helping the final processing of agricultural harvest. The population was nearly 2000 and the people were cooperative.

For the purpose of this study a central clinic was established in the village. A trained paramedic assisted by two female aides from the village worked in the clinic. The paramedic was trained to take anthropometric measurements and to prescribe medicine for diarrhoea, skin diseases, worms and some other minor ailments. A physician attended the clinic weekly. Severely ill study cases were referred to Matlab hospital. A Field Supervisor and the Investigator frequently supervised the works.

The parents were explained the purpose and requirement of the study and they were given the option of recruiting their infants to the study. The study children were treated for minor ailments in the clinic. The date of clinic visit was informed to the parents and if they forgot to bring them on the scheduled date the aides brought them to the clinic from home. The study children could attend the clinic on any day for illness. The maximum distance of the household of a child was within half a mile from the clinic.

The study was commenced with some pre-school children whose dates of births were already known. Parents of all new borns were encouraged to include their children in the study. The expectant mothers were followed from beforehand. The new born children

were measured within 5 days of birth. Then they were measured every months upto 12 months of age and then every 3 months. Anthropometric measurements were taken for weight(Kg.) hight, circumferences of mid arm of left hand, chest and head and cranlococcy's length(cm). Estimation of Haemoglobin percent, eruption of teeth, duration of breast feeding, types of supplements were all recorded. All records of illness were recorded in the individual files from the clinic record. The detail history of illness were however, collected by biweekly home visits. The history of illness were also transferred to the individual files of every child. The housing condition, income and some other SES of parents were collected from every family at the begining and at the end of the study. A summary sheet of data collection is given in appendix. A. The data were collected from 1975 to 1977. Nearly 200 children from birth and about 200 children with higher age were included in the study.

Plan of analysis

The data will be transferred to code sheet and will be punched according to the card plan given in appendix B. It will be then transferred to computer tape for cleaning and for following analysis :

1. Time dependant regression analysis for all kinds of infection in relation to maternal behaviour, infant nutrition, and socioeconomic status will be done.

2. Seasonal velocity of growth. The gain in weight by months will be computed and will be classified for different months of the year for different age group (0-5, 6-11, 12-23, ~~24-59~~ 24-59 and 60+) and will be compared by season and age.
3. Pattern of common illnesses by age and seasons will be demonstrated.
4. Seasonality of growth rate and diarrhoeal disease will be demonstrated for different age.
5. Prevalence of malnourished children for different season by age will be found.
6. The relationship between growth rate and diarrhoeal disease for different age group will be investigated and the interaction of other infection and malnutrition will be investigated comparing the velocity of growth of infected and non-infected children and also comparing the rate of infection between children with low and high growth rate.
7. Growth pattern of different anthropometry of this population will be drawn and compared with reference growth curve.

8. The effect of breast milk on growth curve will be estimated after age 2 years comparing the growth curves of the children who continued breast milk with that of non-continuing group.
9. Children with high and low birth weight (< 2500 gm) will be seperated and their growth pattern will be compared.
10. The relationship between mother nutritional status (weight) and growth rate of children will be investigated.
11. Eruption of teeth will be tabulated by 'age and compared with other standard and its relation with hight and weight gain.
12. Effect of SES on growth of children will be investigated.

D. SIGNIFICANCE

This study will reveal growth pattern and difference of Meheran children with the Harvard standard. The percentages of severely malnourished children in this population, the efficacy of breast feeding in maintaining normal growth, the pattern of childhood common illnesses, the effect of mother's weight in birth weight and subsequent weight of children, the time of eruption of deciduous teeth, the effect of SES on growth and the relation of infection and malnutrition etc. will be revealed from this study. Most of these information are not available at present for Bangladesh children.

E. FACILITIES REQUIRED

No new facilities or new field work is needed for this study.

However, the assistance of Mr. R. Bairagi consultant and the use of computer will be needed for analysis. The present staff of the Statistical Branch will do the work.

F. COLLABORATIVE ARRANGEMENT

No collaborative arrangement is needed.

REFERENCES

1. Nutrition Survey of Rural Bangladesh 1975-76, INFS, University of Dacca, 1977.
2. Editorial Lancet, April 28, 1979, P-911.
3. Martorell R. et al. Acute morbidity and physical growth in rural Guatemalan children. Am. J. dis. children V: 129, Nov. 1975.
4. Tahir, C.E. DeSweemer, C. Nutrition and Infection; Food, Nutrition and Health. World review Nutr. Diet. 16: 203-225, 1973.
5. Neuman, C. G. Interaction of malnutrition and infection. Arch Intern. Med. V: 137, Oct. 1977, P-1364.
6. Drake, S. G. Human milk versus cows milk. J. Human nutrition. 30: 233-238, 1976.
7. Dosseter, J. Whittle, H. C. Greenwood, B. M. B. M. J. June 24, 1977, p. 1633.
8. Delgado, H. Habicht, J. P. et al. Nutritional status and timing of deciduous tooth eruption. Am. J. Clin. Nutr. 28: March, 1975. pp. 216-224.

SECTION III - BUDGET

A. DETAILED BUDGET

1. PERSONNEL SERVICES

<u>NAME</u>	<u>POSITION</u>	<u>% TIME USED</u>	<u>PERIOD</u>	<u>PROJECT REQUIREMENT</u>	
				<u>TAKA</u>	<u>DOLLAR</u>
Dr. M. U. Khan	Scientist	25%	12 m		1600.00
Mr. R. Bairagi	Consultant (part time)	20%	12 m	2,400	170.00
Cod. Asstt. 2	-	100%	3 m		750.00
Statistical Asstt. 1	-	50%	6 m		550.00
Punching Operator 2		100%	$\frac{1}{2}$ m		70.00
Programmer 1		20%	3 m		200.00
Typist 1		15%	1 m		30.00
Sub total				-	\$ 3370.00

SUPPLIES AND MATERIALS

<u>Item</u>	<u>Costs</u>	
	<u>Taka</u>	<u>Dollar</u>
Stationaries(including xeroxing)	3,000	-
Stencils (75)	300	-
Forms etc.	500	-
IBM cards (4000)	-	100
Computer tape	-	20
Sub total	Tk. 3800	\$ 120

3. EQUIPMENTS

No additional or new equipment is needed

4. PATIENT HOSPITALISATION

No hospitalisation is needed

5. OUTPATIENT CARE

Nil

6. ICDDR TRANSPORT

Transport for using computer Tk. 300.00 -

" time Tk. 60.00 -

Matlab trip 5 X 400 Tk. 2,000.00 -

Sub total Tk. 2,360.00 -

7. TRAVEL AND TRANSPORTATION OF PERSONS

Local for presentation of findings Tk. 2,000.00 -

International - 2,500.00

Sub total Tk. 2,000.00 \$ 2,500.00

8. TRANSPORTATION OF THINGS

Not involved

9. RENT, COMMUNICATION & UTILITIES

Tk. 1,600.00

Sub total Tk. 1,600.00 -

10. PRINTING AND PUBLICATION

Tk. 2,000.00

-

Sub total Tk. 2,000.00

-

11. OTHER CONTRACTUAL SERVICE

10% salary of Mr. Bairagi

Computer time 600 x 12 hours Tk. 72,000.00

-

Sub total Tk. 72,000.00

-

12. CONSTRUCTION, RENOVATION, ALTERATION

Not needed.

B. BUDGET SUMMARY

	<u>C A T E G O R Y</u>	<u>TAKA</u>	<u>DOLLAR</u>
1.	Personnel	-	3370.00
2.	Supplies	3800.00	120.00
3.	Equipment	-	-
4.	Hospitalisation	-	-
5.	Outpatient	-	-
6.	ICDDR Transport	2360.00	-
7.	Travel of persons	2000.00	2500.00
8.	Transportation of things	-	-
9.	Rent/Communication	1600.00	-
10.	Printing	2000.00	-
11.	Contractual Service	72000.00	-
12.	Construction	-	-

Total - Tk. 83760.00 \$ 5990.00

or \$ 5584.00 + \$ 5990.00

= 11574.00

overhead @ 30% 3473.00

grand total = \$ 15047.00

APPENDIX B

CARD PLAN : Growth Pattern of Infants and Children.

<u>ITEM</u>	<u>COLUMN</u>	<u>CODE</u>
Card #	1	1
Study #	2-4	
Census #		
Village No.	5-6	
Family No.	7-9	
Individual No.	12-14	
Date of births :		
Day	15-16	3 = 03, 11 = 11
Months	17-18	6 = 06, 12 = 12
Year	19-20	70 = 70
Sex	21	Male = 1, Female = 2
No. of delivery	22	
No. of living issue	23	
Delivery normal	24	Yes = 1, No. = 2
Delivery instrumental	25	Yes = 1, No. = 2
Any defect at births	26	Yes = 1, No. = 2
Delivered at hospital	27	Hosp. = 1, Home = 2
Delivery assisted by	28	Yes = 1, No. = 2
No. of family member	30-31	
No. of rooms	32	
Dwelling	33	Building=1, Tinsed=2,
Has a kitchen	34	Yes=1, No.=2
Latrine used	35	Sanitary=1, open pot=2, Indiscriminate=3,
Sources of drinking water	36	Tubewell=1, Pond=2, Canal=3, Other=4
Sources of washing water	37	"
Total monthly income	38-41	350 = 0350
Major source of income	42	Cultivation=1, fishing=2, Service=3, Business=4, Day labour=5, Other=6.
Duration of maintenance from agriculture	43	

<u>ITEM</u>	<u>COLUMN</u>	<u>CODE</u>
Duration of maintenance from fishing	44	
Total . . .	45	Yes=1, No.=2
Mothers weight	46-48	39.400 = 394
Mothers height	49-52	170.4 = 1704
Father's weight	53-55	39.400 = 394
Father's height	56-59	170.4 = 1704
Introduction at age(months)		
Cow milk	60-61	
Rice powder)		
Ata liquid)	62-63	
Rice gruel)		
Rice	64-65	
Bread	66-67	
Fish	68-69	
Egg	70-71	
Vegitables	72-73	
Meat	74-75	
Dal	76-77	
Banana/Fruits	78-79	
Card #	1	2
Study #	2-4	
Case #	5-7	
Sex	8	Male=1, Female=2
Age(months)teeth irrupted	9-10	
At birth		
Weight	11-13	34.40 = 394
Height	14-17	56.6 = 0566
crownc length	18-20	40.5 = 405
Circumference of head	21-23	50.8 = 308
" chest	24-26	30.3 = 303
" arm	27-29	9.2 = 092
Hb	30-32	8.2 = 082

<u>ITEM</u>	<u>COLUMN</u>	<u>C O D E</u>
Disease	33	No disease=0, diarrhoea=1, Caugh=2, Measles=3 Influenza=4, Other fever=5 Avitaminosis=6, Skin disease=7 Worms=8, Any other disease=9.
at 1 month	34-56	Same in 11 through 33
at 2 month	57-79	"
Code #		
Code #	1	3
Study #	2-4	
Case #	5-7	
Sex	8	Male =1, Female=2
at 3 month	9-31	Same as in 11 through 32 of Card #2
at 4 month	32-54	"
at 5 month	55-77	"
Card #	1	4
Study #	2-4	
Case #	5-7	
Sex	8	Male=1, Female=2
at 6 month	9-31	Same as in 11 through 33 of card 2
at 7 month	32-54	"
at 8 month	55-77	"
Card #	1	5
Study #	2-4	
Case #	5-7	
Sex	8	Male=1, Female=2
at 9 month	9-31	Same as in 11 through 33 of card No. 2
at 10 month	32-64	"
at 11 month	55-77	"

<u>ITEM</u>	<u>COLUMN</u>	<u>C O D E</u>
Card #	1	6
Study #	2-4	
Case #	5-7	
Sex	8	Male=1, Female=2
at 12th month	9-31	Same as in 11 through 33 of card no. 2
1-3 month	32-54	"
1-6 month	55-77	"
Card #	1	7
Study #	2-4	
Case #	5-7	
Sex	8	Male=1, Female=2
at 1-9 month	9-31	Same as in 11 through 32 of card no. 2
2-0 month	32-54	"
2-3 month	55-77	"
Card #	1	8
Study #	2-4	
Case #	5-7	
Sex	8	Male = 1, Female = 2
at 2-6 month	9-31	Same as in 11 through 32 of card no. 2
2-9 month	32-54	"
3-0 month	55-77	"
Card #	1	9
Study #	2-4	
Case #	5-7	
Sex	8	Male=1, Female=2
At 5-3 months	9-31	Same as in 11 through 32 of card no. 2
3-6 month	32-54	"
3-9 month	55-77	"

<u>ITEM</u>	<u>COLUMN</u>	<u>C O D E</u>
Card #	1-2	10
Study #	3-5	
Case #	6-8	
Sex	9	Male=1, Female=2
At 4-0 month	10-32	Same as earlier
4-3 months	33-55	"
4-6 months	56-78	"
Card #	1-2	11
Study #	3-5	
Case #	6-8	
Sex	9	Male=1, Female=2
At 4-9 month	10-32	Same as earlier
5-0 months	33-55	"
5-3 months	56-78	"
Card #	1-2	12
Study #	3-5	
Case #	6-8	
Sex	9	
At 5-6 months	10-32	Same as earlier
5-9 months	33-55	"
6-0 months	56-78	"
Card #	1-2	13
Study #	3-5	
Case #	6-8	
Sex	9	Male=1, Female=2
At 6-3 month	10-32	Same as earlier
6-6 month	33-55	"
6-9 month	56-78	"
Card #	1-2	14
Study #	3-5	
Case #	6-8	
Sex	9	Male = 1, Female=2
At 7-0 month	10-32	Same as earlier
7-3 month	33-55	"
7-6 month	56-78	"

<u>ITEM</u>	<u>COLUMN</u>	<u>C O D E</u>
Card #	1-2	15
Study #	3-5	
Case #	6-8	
Sex	9	Male=1, Female=2
At 7-9 months	10-32	Same as earlier
8-0 month	33-55	"
8-3 month	56-78	"
Card #	1-2	16
Study #	3-5	
Case #	6-8	
Sex	9	Male=1, Female=2
At 8-6 month	10-32	Same as earlier
8-9 month	33-55	"
9-0 month	56-78	"
Card #	1-2	17
Study #	3-5	
Case #	6-8	
Sex	9	Male=1, Female=2
At 9-3 month	10-32	Same as earlier
9-6 month	33-55	"
9-9 month	56-78	"
Card #	1-2	18
Study #	3-5	
Case #	6-8	
Sex	9	Male=1, Female=2
At 10-0 month	10-32	Same as earlier
10-3 month	33-55	"
10-6 month	56-78	"

ABSTRACT SUMMARY

The field part of the anthropometric study on growth and development of Meheran children had been completed earlier. Though periodical analysis and preliminary reporting have been done the data set has not been yet analysed completely. The information contains anthropometric measurements, illness records, dentition record, qualitative dietary record, breast feeding record, socioeconomic records etc. From this data we propose to analyse : seasonal variation of growth, seasonality of illness, interaction between diarrhoea and nutrition, other infection and nutrition, prevalence of malnutrition, seasonal variation of Haemoglobin percentage, growth velocity of children of mothers with different body weight, breast feeding pattern, age of eruption of milk teeth, general growth curve of Meheran children and their relation with socioeconomic facts etc.

1. The object is to obtain information on growth of children and the factors associated with it. Therefore, the population have to be infant and children. The data has been collected from a rural area to represent the majority of Bangladesh children. The consent was obtained from the parents.
2. The procedures do not involve risks of any kind either physical, mental or social.

3. As no risk is involved protection against risk does not arise.
4. The analysis of already collected data will not reveal anyone's name. The data has been kept confidentially in the custody of the investigator and there is no possibility of any kind of leakage of any information. The data does not contain any confidential information.
5. The informed signed consents of the mother or the fathers were obtained at the inception of the study. The study was explained to them at their own premises at the time of proposal. Everybody had the option to withdraw.
 - a. Signed consent was obtained
 - b. No information was withheld from the study subjects or their parents.
 - c. No risk was involved or no privacy was encroached upon.
6. The interviewed was on the no. of family members, socioeconomic status, housing, diet of children, illness etc. About $\frac{1}{2}$ hour's time was needed in the first interview. It was taken in their own premises.
7. The study subject were treated for all mild illnesses and all diarrhoeal illnesses without any charge. They received multivitamines

and also immunisation against Tetanus, Diphtheria and Pertussis right in their own homes without charge. These benefits definitely ought weigh the little inconveniences of the parents and children.

8. The activity requires the use of records on anthropometry and illness generated by this laboratory only.