

REVIEW BOARD ON THE USE OF HUMAN VOLUNTEERS
CRL

Date: 1/2/78

Principal Investigator Dr. M. U. Khan Trainee investigator(if any) NIL

Application No 78-019 Supporting Agency(if Non-CRL) _____

Title of study ANALYSIS OF GROWTH AND DEVELOPMENT DATA OF MEHERAN, MATLAB. Project status:
(☒) New Study (analysis of collected data)
() 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 NA
 - b) Non-ill subjects Yes No NA
 - c) Minors or persons under guardianship Yes No NA
 2. Does the study involve:
 - a) Physical risks to the subjects Yes No NA
 - b) Social risks Yes No NA
 - c) Psychological risks to subjects Yes No NA
 - d) Discomfort to subjects Yes No NA
 - e) Invasion of Privacy Yes No NA
 - f) Disclosure of information possibly damaging to subject or others Yes No NA
 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 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
 5. Will signed consent form be required:
 - a) From subjects Yes No NA
 - b) From parent or guardian (if subjects are minors) Yes No NA
 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 Board for review.

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

M. U. Khan
Principal Investigator

NIL
Trainee

78-019
Recd 14/7/78

SECTION I - RESEARCH PROTOCOL

1. Title : Analysis of growth and development data of Meheran
2. Principal Investigator : Dr. Moslemuddin Khan
3. Starting date : August 01, 1978
4. Completion date : July 31, 1979
5. Direct cost : \$ 7300
6. Abstract Summary :

The collection of data for growth and development studies from the village Meheran of Comilla for the period 1975 - 77 had been completed in December, 1977. There has been no such data collected in Bangladesh from rural children on longitudinal basis. There is no data on the standard growth of Bangladesh rural children also. We now plan to analyse, code, punch and computerise these data for establishing A) Standard growth patterns of rural children, B) Influence of various social factors on growth, C) Morbidity pattern and its influence on nutrition and growth D) Dietary pattern E) Relation of infection and malnutrition and the F) Age of dentition of rural children and the affect of various factors on dentition.

7. Review :
 - a. Research involving human subject : _____
 - b. Research Committee : _____
 - c. Director : _____
 - d. BMRC : _____
 - e. Controller/Administrator : _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION :

1. Objective : There is scarcity of data on the growth and development and morbidity pattern of Bangladesh children. We require to prepare our national growth standard and disease pattern of children for comparison with other countries. The socio-economic conditions and illnesses believed to be associated with acute and chronic under nourishment predisposing weight loss and retardation of growth also need to be examined. The relationship between mal-nutrition, infection and the influence on growth require to be identified. The age of dentition and related factors are to be established. Whether counting no. of teeth the approximate age of children can be determined needs exploration.
2. Background : Most countries of the world have their own national standard of growth and development of children. This is needed for comparison and assessment of our growth and nutritional status with other countries. In Guatemala it has been shown (Martorell, R. et al. 1975) that the normal growth pattern compared to norms of developed countries are different. Many factors are responsible for these differences (Mata L.J. et al). In analysing our preliminary data we have seen that although the birth weight and height are quite close to standard of developed countries these fall back from the age of 4th month. Diarrhea is said to affect growth (Martorell et al, 1975). The incidences of diarrhea and other illness in Bangladesh children are also quite high. Whether or not these illnesses have any influence on plateauing of growth curves needs exploration. 31% of Bangladesh children (1-2yrs) are acutely undernourished (Nutr. Sur of Rural Bangladesh, 1975-76). We want to re-examine this from our longitudinal data. For estimation of age ossification of wrist and hand had been used (Charles. Y. et al. 1973). Teeth has been used for this purpose by Delgado, H. et al (1975). We can examine this from our own data. Malnutrition increases infection (Mata, J. L.) and infection predisposes malnutrition. We can also examine this from our existing data.
3. Rationale : We have already collected the data with the above objectives. We now need to analyse the data. These informations will give us an idea about the growth and development, morbidity

pattern and age of dentition of rural children and the factors related with growth and dentition. In national health planning programme attempts may be made to utilise these data and to correct the factors responsible for weight loss and retardation of childhood growth and development. It is therefore, extremely essential to analyse the already collected data, establish the rural norms and pinpoint the related factors responsible for growth retardation, malnutrition and infection.

B. SPECIFIC AIMS

1. To find out the growth norms of rural children in respect of Ht., Wt., circumferences of chest, head and arm.
2. To findout illness or dietary pattern associated with poor growth of Bangladesh children :
 - a. How morbidity and diet pattern effects the velocity of growth at different age of children.
 - b. How family income, housing and occupation effects the growth.
3. To findout age of dentition and its relation with other factors.
4. To findout general morbidity and mortality pattern of infants based on diet, birth wt., seasonality etc.
5. Diarrheal diseases and malnutrition which comes first.

C. METHODS OF PROCEDURE :

The data has been already collected. A village (Meheran) was selected in Matlab Surveillance area away from any urban influence. For this purpose a central children clinic was established. This was daily attended by a paramedic. He was

assisted by two village Dais. A Physician attended the clinic once weekly. Seriously ill patients were admitted in Matlab field hospital. A supervisors guided the health assistant frequently. The parents were explained about the purpose and given the option of recruiting their children in the study. The children were measured at birth (within 5 days of birth) and once monthly upto 12 months and then one quarterly. We included some children whose dates of birth were already recorded. The illness data were recorded in the free clinic and also collected by biweekly visits. History of eruption and extraction of teeth were recorded regularly. Dietary and socio-economic histories were obtained. Ht., Wt., circumferences of head, chest and arm and hemoglobin percent were recorded in forms. Medicine for diarrheal and minor illness of children were given.

Now, the growth data will be analysed with other informations and arranged for coding by two field assistants. They will first check for inconsistencies and completeness of all data. All information will be transferred to Master sheets and then coded in the printed code sheets.

The Statistical Branch will punch the data on IBM cards and then transfer it to computer tape. After programming tabulations will be done by the Statistical branch.

The analysis will done according to the following simple frame work :

1. Standard growth of rural children, (quarterly percentile by age and sex of Ht., Wt., chest, head and arm).
2. Morbidity and morbidity pattern of children (incidence of diseases by age, sex, season and family size).
3. Influence of diet, diarrhea, other illness on growth (using wt., before and after illnesses and quarterly percentile wt. and change of diets).

4. Relation of malnutrition with illness and affects on dentition and growth.
5. Normal age of dentition and prediction of age (by estimating no. of teeth at different age).
6. Influence of diet, socio-economy, illness on dentition (comparing diet, income and illness)
7. Change of 46% of children during growth & illness.

Then suitable manuscripts will be prepared and published through CRL reports and also through national and international journals.

D. SIGNIFICANCE

The national growth standard for children of Bangladesh is not available. The morbidity and dentition age are also not available. The growth of Bengalee children are below the level of developed and many developing countries. The analysis may pin point some factors related with retarded growth and the Govt. or any Agency may consider correction of such factor in national planning. This will be an extremely valuable piece of information.

E. FACILITIES REQUIRED

No new facilities are need. The existing facilities are enough for analysing this data. The additional facilities will be use of computer for analysis. No field work is needed for this analysis.

F. COLLABORATIVE ARRANGEMENT

No collaborative work will be involved in this study.

REFERENCES

1. Reynaldo Martorell et al. Acute Morbidity and Physical Growth in Rural Guatemalan Children. Am. J. diseases of Children - Vol. 129, November, 1975.
2. J. Mata et al. Infection and infectious diseases in a malnourished population : A long term prospective field study. XIII Symposium Sweden Nutrition Foundation.
3. Institute of Nutrition and food Science; University of Dacca. Nutrition Survey of Rural Bangladesh 1975-76; pp 102 & 110.
4. Charles Yarbrough et al. Determining the biological age of the pre-school child from hand wrist Radiograph. Investigative Radiography, V-8 # 4 July - August 1973.
5. Hernan Delgado et al. Nutritional status and the timing of deciduous tooth eruption. Am. J. Clinical Nutrition # 28, March 1975, PP 216 - 224.
6. Khan, M. et al. CRL Technical report, 1976.

SECTION III - BUDGET

A. DETAILED BUDGET

1. PERSONNEL SERVICES :

<u>N A M E</u>	<u>Position</u>	<u>% time used</u>	<u>Period</u>	<u>Taka</u>	<u>Dollar</u>	<u>Incremental Costs</u>	
						<u>Taka</u>	<u>Dollar</u>
Dr. M. U. Khan	Investigator	25%	12 month	19,000	-	Nil	Nil
Field Assistant 2	For coding	100%	6 "	13,000	-	Nil	Nil
Punch Operator 2		100%	1 week	600	-	Nil	Nil
Programmer 1		100%	1 "	600	-	Nil	Nil
Computer cost		16 hrs. @600		9,600	-	Nil	Nil
Total Tk.				44,600	-	-	-

2. SUPPLIES AND MATERIALS

	<u>T A K A</u>	<u>DOLLAR</u>	<u>Incremental Cost</u>	
			<u>T A K A</u>	<u>DOLLAR</u>
Stationaries	2,000		Nil	Nil
Stencils		20.0	Nil	Nil
Forms etc.	500		Nil	Nil
IBM Cards 5 packets		80.0	Nil	Nil
Computer Tape		30.0	Nil	Nil
Total Tk.	2,500	\$ 130.0	-	-

		Incremental Cost	
		TAKA	DOLLAR
3.	<u>EQUIPMENT</u>		
	No additional equipment is needed.	Nil	Nil
4.	<u>PATIENT HOSPITALISATION</u>		
	No hospitalisation is needed	Nil	Nil
5.	<u>OUTPATIENT CARE</u>		
	Not involved	Nil	Nil
6.	<u>CRL TRANSPORT</u>		
	Transport for using computer 100m x 3 = Tk. 300		
	Time 10 x 6 = Tk. 60		
	Matlab trip 300 x 5 = Tk. 1500		
	Total Tk. Tk. 1,860	1,860	
7.	<u>TRAVEL AND TRANSPORTATION OF PERSONS</u>		
	This may arise only in case of presentation of data locally or outside Tk. 2,000 \$ 2,000		
	Tk. 2,000 \$ 2,000	2,000	2,000
8.	<u>TRANSPORTATION OF THINGS</u>		
	Not involved		
9.	<u>RENT, COMMUNICATION & UTILITIES</u>		
	Tk. 1,000		
	Total Tk. 1,000	Nil	

Incremental
Cost
TAKA DOLL.

10. PRINTING & PUBLICATION

Tk. 5,000 \$ 100

Total Tk. 5,000 \$ 100

5,000 100

11. OTHER CONTRACTUAL SERVICE

Not needed.

12. CONSTRUCTION, RENOVATION, ALTERATION

Not involved.

B. BUDGET SUMMARY

			<u>INCRIMENTAL COST</u>	
	<u>T A K A</u>	<u>DOLLAR</u>	<u>T A K A</u>	<u>DOLLAR</u>
1. Personnel Services	38,600	-	Nil	Nil
2. Supplies & Material	2,500	90	Nil	Nil
3. Equipment	-	-	Nil	Nil
4. Out Patient care	-	-	Nil	Nil
5. CRL Transport	1,860	-	1,800	-
6. Travel and Transportation of	2,000	2000	2,000	2000
7. Transportation of things	-	-	Nil	Nil
8. Rent, Communication & Utilities	1,000	-	Nil	Nil
9. Printing and Reproduction	5,000	100	5,000	100
10. Other contractual service	-	-		
11. Construction, Renovation and Alteration -	-	-		
Total Tk.	50,960	\$ 2190	8,800	2100
Overhead charges @ 30%	15,238	657		
Ground total Tk.	66,248	\$ 2847		
Ground total \$	7300			

ABSTRACT SUMMARY

Purpose : There are scarcity of growth and development data and the morbidity and mortality pattern of infant and children. For these purposes we have already collected data from the village Meheran during the period 1975-77. We now want to analyse the data with the following aims : To establish

1. The growth norms of rural Bangladesh children,
2. Factors associated with poor growths of children,
3. General morbidity and dietary pattern of children and infant,
4. Relationship of diarrheal diseases and malnutrition and
5. Age of dentition and factors influencing eruption of milk teeth.

Methods: The data has already been collected on longitudinal basis by a singlehand. For this purpose a village clinic was established for taking measurement and health care of children. The children were visited twice weekly by home visit and also in the clinic during usual regular visits. All information were obtained from the mothers. The weight was measured in kg. and height and circumferences of chest, head and arm were measured in cm. The measurements were taken monthly upto 12 months of age and then quarterly.

Now the collected data will be scrutinised and transferred to a Master sheet. This will be then transferred to standard code sheets by F.A.S. Then the Statistical branch will punch the data on IBM cards and transfer them to computer tape. A programmer will analyse the data in the computer according to our requirements.

1. The data had been collected and no human subject is necessary for the purpose.
2. Not applicable now; there was no risk.
3. Not applicable.
4. The data has been kept confidential and no specific information from a particular person has been or will be disclosed. After use the raw data will be destroyed.
5. Signed consent was obtained before obtaining the data. Now no consent is needed.
6. Not applicable now.
7. The children and the society were highly benefited. I treated the children, hospitalised them when needed, immunised the mother and children against Tetanus.
8. Not applied now; Fingertip blood was collected for of Haemoglobin.