25 May 1981 Date

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Trespondencestigator Dr. Stan D'Souza	Co-Investigators: Sandra L. Huffman & Abbas Bhuiya
itle of Study Pilot Study on Socio-	Supporting Agency (if Non-1CDDR, B) Project status:
conomic Status and its Association with	(V) New Study
utrition and Morbidity.	() Continuation with change () No change (do not fill out rest of form,
Source of Population:	the following (If Not Applicable write NA). 5. Will signed consent form be required:
(a) 111 subjects (b) Non-ill subjects (c) Minors or persons Yes No	(a) From subjects Yes (No) (b) From parent or guardian
under guardianship Yes No.	(if subjects are minors) Yes (No) 6. Will precautions be taken to protect anonymity of subjects (Yes) No
2hysical risks to the subjects Yes No	7. Check documents being submitted herewith to Committee:
(b) Social Risks Yes (No let) Psychological risks to subjects Yes (No let)	Umbrella proposal - Initially submit an overview (all other requirements will
(d) Discomfort to subjects Yes (No. (e) Invasion of privacy Yes (No. (e))	be submitted with individual studies: Protocol (Required) Abstract Summary (Required)
tion damaging to sub- ject or others Yes No	Statement given or read to subjects on nature of study, risks, types of quest
(a) Use of records, (hosp-	ions to be asked, and right to refuse to participate or withdraw (Required) Informed consent form for subjects
birth or other) (b) Use of fetal tissue or	Informed consent form for parent or guardian Procedure for maintaining confidential
abortus (c.) Use of organs or body fluids Yes No	ity Questionnaire or interview schedule
Are subjects clearly informed about: (a) Nature and purposes of	* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:
(b) Procedures to be followed including	1. A description of the areas to be covered in the questionnaire or
alternatives used (c) Physical risks Yes (No	interview which could be considered either sensitive or which would constitute an invasion of privacy.
(d) Sensitive questions Yes No (e) Benefits to be derived Yes No (f) Right to refuse to	2. Examples of the type of specific questions to be asked in the sensitive areas.
participate or to with- draw from study (g) Confidential handling	 An indication as to when the question naire will be presented to the Cttce.
of data (h) Compensation 6/or treat- ment where there are risks N.A.	for review.
or privacy is involved in	

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

any particular procedure Yes No

Co-Investigator

QU 145,702

(Com. ?

SECTION I - RESEARCH PROTOCOL

1. Title:

Pilot Study on Socio-economic Status and its Association with Nutrition and Morbidity.

Stan D'Souza Principal Investigator: 2.

Sandra L. Huffman & Abbas Bhuiya 3. Co-Investigators:

June 10, 1981 Starting date: 4.

July 9, 1981 Completion date: 5.

US \$3,000 6. Total direct cost:

Scientific Program Head: 7.

This protocol has been approved by the Community Services Research Working Group.

*Signature of Scientific Program Head:

*This signature implies that the Scientific Program Head takes responsibility for the planning, execution and budget for this particular proposal.

Abstract Summary:

This study is the second part of SES and mortality investigation in the five villages of Matlab area to assess the association between socio-economic status, nutrition and morbidity. This information would be helpful in the formulation of programs to meet the health needs of the community. With regard to morbidity an attempt will be made to develop a minimal morbidity list for Matlab area by combining the WHO 'minimal morbidity list' and the one already used in Matlab This will serve as a lay reporting aid to non-medical health workers for reporting morbidity and causes of death.

9.	Review	
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a)	Ethical Review Committee:
b)	Research Review Committee:
	Director:
-	BMRC:
Ť	Controller/Administrator:

ABSTRACT SUMMARY - PARTICULAR ITEMS

- 1. All children less than 5 years of age and women of age 15-44 years will be selected for study since children of that age group are more vulnerable to malnutrition and mother leads to a cycle of malnutrition in the community because of its effect in contributing to low birth weight of infants.
- 2. No risks; not applicable.
- 3. Not applicable.
- 4. Data will be analysed and published in aggregate and there is no possibility of identifying individuals.
- 5. A verbal consent form will be approved by the head of household before starting the work.
- 6. Interview and anthropometric measurements will be conducted at the respondent's house and questions on morbidity will be asked and it will take half an hour time.
- 7. No direct benefits to individuals, will provide a better understanding of the relationship between morbidity, nutritional status and socio-economic status which may be an aid to the planners for a better health planning.
- 8. Use of SES records of the households.

Statement about Confidentiality

Verbal consent will be obtained from the head of households. Implied consent will be assumed for other family members (see Appendix I).

Identifying information (name, census number) appears on the questionnaire forms (see Appendix IIb). Becuase it is necessary to link events using this information which cannot be delected. However, the staff who have access to these questionnaire is trained and aware of their confidential nature.

After the data is linked, all analysis is done using aggregate information. There is no way that individuals can be identified.

SECTION II - RESEARCH PLAN

A. INTRODUCTION

This limited study represents the second part of a socioeconomic investigation in five villages of the Matlab area. This Pilot Study focuses on the socio-economic status and its association / with nutrition and morbidity. Data collection on the first part of the study has been completed and is now being tabulated. The principal purpose of the present investigation is to assess which socio-economic factors correlate most closely with nutrition and health status. This information would be helpful in the formulation of programs to meet the health needs of the community. In order to address those in greatest need of health services, simple indicators to delineate which children experience high rates of diseases from those that are ill less often would help programs set priorities for service. Community health surveys which could obtain this information are costly and time consuming. Information on a few select socio-economic factors is easier to obtain, information would facilitate the development of those inputs related to nutritional status through the use of socio-economic indicators focusing on children likely to be malnourished. With regard to morbidity there is interest on a world-wide basis on the problems of 'lay reporting of health information' (1). It is not possible especially in the rural areas of developing countries to obtain medical validation of diseases or even for causes of death. A fundamental need has been felt for training health workers--paramedics--who would be

capable of diagnosing, from a set of simply recognised symptoms, particular diseases. WHO has set out a list called 'minimal morbidity list' where some diseases can be recognised by non-medical personnel. This list is found in Appendix 1.

Pilot runs were conducted in the State of Gujarat to examine the suitability of the WHO prepared lists. These runs were conducted for three months. The data related to 4200 cases of morbidity. The evaluation of the use demonstrated the feasibility of adopting a list. It was found to be of great advantage for the personnel if they were familiar with the symptoms of common diseases. (2).

The approach of lay reporting can only give probable causes of morbidity. It is not conceived as a substitute for diagnosis given by a testing physician. However, the data can be utilised for better planning. Major groups of diseases indicated their relative importance.

Field trials of a pilot nature were also carried out in Burma, Maldives, Sri Lanka, Thailand as well as in several areas of the Western Pacific region.

The result of these trials had demonstrated that international lists when adapted to suit local needs can be used to obtain crude diagnosis of death or diseases (3). As a result of the field trials the lists were modified to the one published by the WHO in 1978 mentioned earlier.

This study is intended to assess whether this particular list, in addition to those already utilised in the Matlab area (Appendix 2) could be consolidated into a single list which could then be utilised throughout the area under surveillance.

B, SPECIFIC AIMS

- 1. Selection of SES indicators that correspond to nutritional and health status in order to select out the characteristics of families that are at risk of being malnourished and having high rates of diseases.
- 2. Development of 'minimal morbidity lists' which can be utilised in the Matlab area by May reporters' -- health assistants.

C. MATERIALS AND METHODS

As described in Part I of this Pilot Study protocol, 5 villages will be selected for study. Over the past 10 years these villages have been included in other studies collecting nutritional data. The past correlation between malnutrition and SES can be assessed, and then compared to the present situation. In addition, there has been little previous work on the association between morbidity and SES. The current pilot study will also allow an examination of this association. The specific methods for data collection and analysis are described below.

Subjects

Because preschool children are the most vulnerable to malnutrition, all children aged less than 5 years will be included from the study villages.

In addition, because of the particularly vulnerable state of women in Bangladesh in relation to intrafamily food distribution, frequent pregnancies, and cultural restriction on diet, they often experience low levels of nutritional status. Poor nutrition in the mother leads to a cycle of malnutrition

in the community because of its effect in contributing to low birth weight of infants. Therefore women residing in these villages aged 15-44 will be included for study as well.

SES data from the five villages is now being tabulated on the S-34 in Dacca.

The list of subjects for this present study—children under 5 and mothers aged 15-44—will thus be obtained. At present an estimate of 4500 respondents has been made. Based on completion of 30 schedules per day, 5 teams (2 persons each) will require 30 days to complete the job. The budget has been based on these assumptions.

Measurement of Nutritional Status

The following measures of anthropometry will be used as indicators of nutritional status: weight, height, and arm circumference.

Weight

The measurement of weight allows an assessment of current nutritional status defined as body mass. During periods of nutritional deficiency, muscle and fat deposition is reduced. When comparisons are made to reference standards of weight-for-fieight, one is able to assess the level of wasting in children, or acute malnutrition. Weight measurements will be made in a beam balance scale which will be calibrated in the field before each weighing. They will also be checked for accuracy each morning and evening to ensure reliability.

Height

Height is a measure of linear growth. During long periods of nutritional deprivation, growth is retarded and the child becomes stunted. Comparisons of height levels in relation to reference standards of height-for-age allows an assessment of stunting, or chronic malnutrition. Height will be measured using a

stadiometer. Standing height will be taken for women and children over the height of 100 cm. Lying lengths will be taken for children less than 100 cm.

Arm Circumference

Arm circumference is often used as an indicator of body mass. It is easier to take in field conditions than weight or height since large bulky equipment is not needed. It will be collected in this study in order to assess whether it could serve as easily available indicator for nutritional status that could be obtained while the census data is being collected. Thus the time and training needed for these measurements will be carefully recorded. Arm circumference will be taken with an oil cloth tape in the midpoint of the left upper arm.

Morbidity

A questionnaire to be administered to the women and the mothers of the children will be used to elicit information on morbidity experience.

This will include information on the prevalence of illness during the last 24 hours, last 2 weeks, and during the previous year. The list of diseases will be elaborated on the basis of pretests done in a village separate from the 5 study villages using those in Appendix 1 and Appendix 2 respectively. preliminary code book will be prepared.

Tables for Analysis

The following, tables will be prepared for the analysis. This will be done for the previous study results on mutrition, and previous census information on SES. In addition, the current mutritional health status will be compared to the current socio-economic variables.

1. Nutrition of children

For each age, and sex, weight for height, weight for age, arm circumference for age, and height for age will be tabulated by the socio-economic factors obtained in part 1 of the study.

2. Nutrition of women

Weight, height, and arm circumference of the women will be tabulated by the same socio-economic variables.

3, Morbidity

The prevalence of the specified illnesses for the specified time will be correlated by the same socio-economic variables.

D. FACILITIES REQUIRED

The logistic support of the three branches data management, computer and the Matlab field station will be utilised. Details of personnel utilisation are to be found in the budget.

E, COLLABORATIVE ARRANGEMENT

Dr. Sandra Huffman, from Johns Hopkins University will be a co-investigator of the study.

SECTION III - BUDGET.

A. Detailed Budget

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the state of the s		No.of	Annua1	Requi	uirements	
Position	%Effort	days	Salary	Taka	Dollar	
Field Surveillance Branch				,		
10 Health Assistants	190	30.	22,529	26,000	**	
Data Management Branch	•	•	•			
1 Data Processing Asstt. 1 Coding Assistant	100 100	45 15	25,020 22,529	4,330 1,130	1974	
Computer Services	•					
1 Analyst Programmer(National)1 Data Entry Technician	50 100	15 10	48,776 27,105	1,407	-	
Sub-total		•		34, 080		

None

	CUPPLIES AND MATERIALS					
2,	SUPPLIES AND MATERIALS	% Effort	No.of days	Annual Salary	Require Taka	Dollar
	Stationary		•		1,500	-
3,	EQUIPMENT					·
	None		`			
4,	PATIENT HOSPITALIZATION			•		
	None					
5,	OUTPATIENT CARE				, -	•
	None	<u>:</u>		. •	·	
6,	ICDDR, B TRANSPORT					•
-	Dacca-Matlab-Dacca 4 trips Matlab Speedboat (one boat one hour daily for 30 days)		•		1,420 5,716 7,136	, ,
7.	TRAVEL AND TRANSPORTATION OF PERSONS					·
	None	,				
8.	LOCAL TRAVEL	-		•		
	None		•			
9.	INTERNATIONAL TRAVEL	· · · · ·				
	None					•
10	. TRANSPORTATION OF THINGS			•		

		% Effort	No, of days	Annual Salary	Requirements Taka Dollar
11.	RENT, COMMUNICATION AND UTILITIES				
12.	Communication PRINTING AND REPRODUCTION				1,500
	Questionnaires, cyclostyling (5000 copies) Other printing and repro-	·			1,020 -
13.	duction material OTHER CONTRACTUAL SERVICES				2,500 3,520
14.	None CONSTRUCTION, RENOVATION, ALTERATION				

None

MISCELLANEOUS COMPONENTS

15.

B. BUDGET SUMMARY

CATEGORY	TAKAS		DOLLARS
		•	
1. Personnel	34,080		*
2, Supplies	1,500		*
3-5 Nil items	•		*
6. ICDDR,B Transport	7,136		**
7-8 Nil items			••
9. Communication	1,500		
10. Printing/Reproduction	3,520		**
11-13 Nil items	-	•	₹.
Total	47,736		**
Total in Dollars \$:	3,000*		

^{*}Calculated at Kk, 15, 90/\$1,00

APPENDIX - A

Verbal Consent Statement

The International Centre for Diarrhoeal Disease Research, Bangladesh (formerly Cholera Research Laboratory) is planning to collect informations on weight, height, arm circumference and morbidity of children less than 5 years of age and women of age group 15-44 years. Our female workers will measure height, weight and arm circumference of the children and women. They will also ask some questions on morbidity of the children and women for the last 24 hours, 2 weeks and during previous year. All informations given will be treated as confidential. Please note that no one will be paid. One may at any time refuse to participate. If you have any questions we will try to answer them. Do you have any questions? Do you agree to participate?

(Appendix A) Bengali Version

জৌপ্রিক সম্পতি পথ

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APPENDIX I

Minimal Morbidity List

~	Description	Detailed List No.	Possible Diagnosis
1	Fever with skin eruptions	010-012	Measles, Chickenpox, Smallpox
2 .	Fever with neck rigidity, vomiting, skin rash	024	Meningitis
3	High fever, intermittent, with chills and prostration	030, 031	Malaria
4	Fever, unqualified	039	
5	Yellow skin, yellow whites of eyes	046	Jaundice
6	Skin sores and ulcerations, unqualified	049	
7	Diarrhoea and vomiting, massive dehydration, watery stools	050 .	Cholera
8	Diarrhoea, abdominal pain, mucopurulen and bloody stools	060	Amoebic dysentery
9	Diarrhoea, unqualified	069	
10	Abdominal pain, rigidity of abdominal wall	070	Acute abdomen
11	Other abdominal apin or swelling	071, 072	
12	Chronic cough with loss of weight, blood in sputum, slight fever	080, 081	Tuberculosis
13	Acute cough, fever, chest pain, shortness of breath	082	Pneumonia
14	Nose and throat discomfort, watery discharge, cough, fever	090	Common cold, Upper respiratory infection
15	Breathing difficulty, shortness of breath, chest pain, swollen ankles	100	Heart disease

16	Burning pain during urination, discharge of pus from urethra (male)	113	Gonorrhoea
\ 17	Sore eyes and other eye complaints	12	
18.	Toothache and other mouth problems	130-133	
1.5	Ear pain, discharge	135	
	locked jaw, muscular spasms, history of open wound or childbirth	141	Tetanus
r î.	Convulsions, with unconsciousness	147	Epilepsy
₹2	Paralysis, unqualified	148	
23	Unconsciousness, coma, unqualified	149	
24	Pregnancy with complications	151	Complicated pregnancy
25	Abortion	152	Abortion
26	Childbirth with complications	154	Complicated childbirth
27	Puerperium with complications	155	Complicated puerperium
28	Injured during birth by passage or manipulation	162	Birth injury
29	Small or premature baby	163	Immaturity
30	Weakness, loss of weight, anaemia, oedema, history of inadequate diet	170, 171	Malnutrition
31	Pain and swelling in joints or muscles	175	Arthritis, Rheumatism
32	Serious injuries	18	
33	Mild injuries	19	
34	Other specified causes of morbidity		

(iii)

Othe	er reasons for contact with the health servi	ice:-
35	Injection, vaccination	S11
36	Dressing of wounds	S13
37	Normal delivery	S 14
38	Other procedures	S10, S12, S15
39	Maternal and child health consultation	S16
40	Family planning consultation	S1 7
41	Other consultation	S18
42	Other service	S19
Exte	rnal cause of injury:-	
43	Bites or stings of venomous animals	E10
44	Burns	E11
45	Falls	E13
46	Poisoning	E14
47	Transport (traffic) accidents	E15
48	Other violence	E12, E16-E19

APPENDIX IIb

Diarrhea/Growth Study - Classification of Illness

Form Space D	No diarrhea	=	0
	Diarrhea - no dehydration	=	1
	Diarrhea - mild dehydration	==	2
	Diarrhea - mod. dehydration	==	3
	Diarrhea - severe dehydration	=	4
	Dysentery - no dehydration	=	5
	Dysentery - with dehydration	=	6
	Vomiting - no diarrhea	=	7
	Unknown	=	9
Form Space Dx	Meas1es	_	01
Torm opace bx	Mumps		
	•		02
	Chickenpox	=	03
	"Viral" exanthem unknown etiology	=	04
	Scabies	=	05
	Impetigo	=	06
	Cellulitis	2 2	07
	Eczema	=	08
	Miscellaneous skin lesions	=	10
	URT Infection	=	11
	Conjunctivitis	=	12
	Otitis	=	13
	Whooping cough	=	14
	Tonsillitis	#	15
	Stomatitis	=	16

Diptheria	=	17
Pneumonia	=	18
Bronchitis/croup	=	19
Asthma	=	20
Tuberculosis	=	21
Hepatitis	=	22
Meningitis	=	23
Tetanus	=	24
Malaria	=	25
Typhoid fever	=	26
Urinary tract infection	=	27
Unknown	222	99