

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

Principal Investigator Dr. Stan D'Souza

Co-Investigator: Mr. Abbas U. Bhuiya 224

Application No. 80-047(P)

Trainee Investigator (if any) _____

Title of Study Pilot Study on

Supporting Agency (if Non-ICDDR,B) _____

Socio-Economic and Mortality Differentials

Project status:

in 5 Villages.

- 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.

I 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.

[Signature]
 Principal Investigator

[Signature]
 Co-Investigator

80-047(P)

Rec'd.

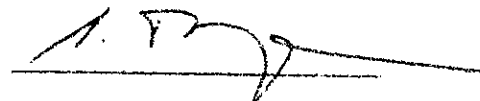
29.12.80.

SECTION I - RESEARCH PROTOCOL

1. Title: Pilot Study on Socio-economic and Mortality Differentials
2. Principal Investigator: Dr. Stan D'Souza
3. Co-Investigator: Mr. Abbas U. Bhuiya
4. Starting Date: 15 January 1981
5. Completion Date: 15 April 1981
6. Total Direct Cost: US \$ 2,518.00
7. Scientific Programme Head:

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

*Signature of Scientific Programme Head:



Date: 22 December 1980

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

8. Abstract Summary:

Around the world it has been documented that mortality and socioeconomic status of the household are inversely correlated. By using 1974 SES information from Matlab D'Souza et al. (1980) also found similar inverse relationship. A minor investigation regarding the relevancy of 1974 SES by Huffman et al. (1976) in an ICDDR,B internal note indicated that SES of the households have considerably changed within a two-year period. An updating of Matlab SES data is urgently felt. Before starting the big task of complete SES enumeration in the whole study area a pilot study is essentially needed for many obvious reasons. It would be carried out in five villages for which besides SES we have other relevant information for the last ten years. An attempt will also be made to study the socioeconomic differentials in mortality by different age group and sex.

9. Reviews:

- (a) Ethical Review Committee: _____
- (b) Research Review Committee: _____
- (c) Director: _____
- (d) BMRC: _____

ABSTRACT SUMMARY - PARTICULAR ITEMS

1. Not applicable.
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 interviewing.
6. Interview will take place at respondents house and questions on socio-economic variables will be asked and it will take half an hour.
7. No direct benefits to individual; will provide a better understanding of the relationship between mortality and socioeconomic status which may be an aid to the planners for a better health planning.
8. Use of death records only, and previous census and Dss records.

Religion : _____ Date Completed : _____

No.	Dwelling No.	Name	Age	Sex	Marital Status	Relation to Head	Date of Birth	Education	Read/Write		Occupation			
									P	A	Primary		Secondary	
											I	O	I	O

	Land Yield	Taka	Maunds	Unk
Cash	_____	_____	_____	_____
Paddy	_____	_____	_____	_____
Kaon	_____	_____	_____	_____
Wheat	_____	_____	_____	_____
Potato	_____	_____	_____	_____
Swt. Pot.	_____	_____	_____	_____
Jute	_____	_____	_____	_____

Receive Remittance? Yes No
 Own radio? Yes No
 Own any watch? Yes No
 Own hurricane? Yes No
 Own lep (quilt)? Yes No

Number of cows:
 Number of boats:
 Kosha Diasha Baro

Sources of water during Winter Season
 Oct.-Jan. (Aswin - Ch-Magh 15)

	River	Canal	Tank	Ditch	T.W.	Other	Unk.
Drink							
Cook							
Bathe							
Wash							

Use fixed latrine? Yes No
 Latrine within 15 yds. from a used water source? Yes No
 Majority usually use pot for washing after defecation? Yes No

Roof		Walls			Dimensions (feet)	
Tin <input type="checkbox"/>	Other <input type="checkbox"/>	Tin <input type="checkbox"/>	Tin-mixed <input type="checkbox"/>	Other <input type="checkbox"/>	Length	Breadth
Tin <input type="checkbox"/>	Other <input type="checkbox"/>	Tin <input type="checkbox"/>	Tin-mixed <input type="checkbox"/>	Other <input type="checkbox"/>	Length	Breadth
Tin <input type="checkbox"/>	Other <input type="checkbox"/>	Tin <input type="checkbox"/>	Tin-mixed <input type="checkbox"/>	Other <input type="checkbox"/>	Length	Breadth
Tin <input type="checkbox"/>	Other <input type="checkbox"/>	Tin <input type="checkbox"/>	Tin-mixed <input type="checkbox"/>	Other <input type="checkbox"/>	Length	Breadth

Statement about Confidentiality

Verbal consent will be obtained from at least one adult subject in each household -- those who will be answering the questions. Implied consent will be assumed for other family members. (See Appendix A).

Identifying information (name, census number) appears on the questionnaire forms (see Appendix B). Because it is necessary to link events using this information which cannot be deleted. However, the staff who have access to these questionnaires 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.

Pilot Protocol on Socio-economic
and Mortality Differentials in
5 Villages

A. INTRODUCTION

The DSS protocol No. 80-035 for Matlab covers the large-scale data collection in the two areas relating largely to the registration of vital events for the four year period starting in September 1980. The 1974 census indicated in the protocol included collection of SES data on a variety of characteristics for the entire population. Earlier collection of SES data on a few items was carried out in 1968 for the old trial area and in 1970 for the new trial area. These data sets form an important resource that can throw light on various issues related to health, mortality and morbidity. Infant mortality rates remain high in less-developed countries. Within these countries as well as in affluent ones, demographers and medical professionals have become increasingly aware of the fact that health care is not reaching the various classes of society in an egalitarian manner. Mortality rates tend to be higher in "lower" classes of society. A recent WHO-ESCAP sponsored conference in Mexico (1979) on the socio-economic determinants of mortality has focused concern in this area. In third-world countries, reliable data do not exist to study the problem of mortality differentials. Indirect estimation procedures.

are resorted to, based on retrospective surveys. The Matlab data set--with special reference to the 1974 census--has provided important information on these differentials. A study has been presented at a WHO-ESCAP Conference in Manila in December 1980 (D'Souza 1980).

The ICDDR,B has made an official request for UNFPA regional funds in a project entitled - Matlab Demographic and Operational Research and Training (Project No. INT/79/P29). This project was committed by the UNFPA to ICDDR,B at the interim international committee meeting in Geneva in February 1979, was submitted after approval by the Director and Management Committee to the UNFPA in March 1979, and revised in June 1979. At the Board of Trustees meeting in July 1979, the Trustees approved and accepted the commitment of funds. Under this project the ICDDR,B contracted to do research on various items including "Policy and Programme applications of medical and socioeconomic causes of fertility and mortality." UNFPA approval of this project has now been granted (Oct. 1980).

Some of the applications of socioeconomic differentials in mortality for the health systems have been well developed by Antonovsky (1979) who states "it is incumbent upon us to urge the establishment of a systematic, continuous monitoring programme to assemble appropriate data". He points out that socioeconomic differentials in mortality mean that success has been achieved in one section of the community

which is not available to other segments.

As regard the criteria for socioeconomic classification, a paper by Bradley and Johnston (1979) reviews the situation for several countries. The following are considered to have special relevance to mortality studies:

- a) Occupation and status in employment
- b) Income
- c) Education
- d) Industry
- e) Housing Condition
- f) Urban and rural residence
- g) National and ethnic groups

However, the authors note that obtaining such data is difficult.

Kitagawa and Havser (1973) consider education as the most satisfactory of the several indices of socioeconomic status. Education defined by years of schooling is generally reliably reported. In the case of India, Vaidyanathan (1972) has reported mortality differentials by geographical location, rural-urban habitat, religion and caste, occupation, education, type of housing and lighting, landholding and income. SES data were collected in the 1974 Census. The "education of mother" proved to be the index showing the highest statistical significance with regard to mortality differentials (D'Souza, 1980).

In India, Vaidyanathan (1972) has collected data from various surveys showing an inverse relationship between occupational class and mortality. Owners and tenant cultivators have lower mortality than agricultural labourers. White-collar workers have lower mortality rates than blue-collar workers. The UN Mysore Population Study (1961) uses the type of housing and type of lighting as a proxy for socio-economic status in urban areas and landholding in rural areas. Mortality differentials are as described above, with labourers and tenants having an infant mortality rate 59 percent above the rural rate. In the urban area of Bangalore City, the infant mortality rate for the population living in huts or mud houses with thatched roofs and for those without electric lighting was about 11 percent higher than the rate for the whole city population.

In Nigerian data, Caldwell has shown that education, especially that of the mother, is correlated negatively with child mortality rates (Caldwell, 1979). Preston has studied the changing relation between mortality and economic development (Preston, 1975). The Mexico Conference (1979) set of papers include background papers for regions such as Latin America (Behm), Asia and the Pacific (Hashmi) and tropical Africa (Gaisie).

2. Bangladesh

Since Independence in 1971, Bangladesh has suffered two severe crisis periods, one linked to the liberation struggle and the other to the

1974 famine. Death rates have been higher during these periods, particularly among poorer groups (Chowdhury and Chen 1977). The 1975 crude death rate among landless families was three times that of families with 3 or more acres (McCord 1980).

The Bangladesh Retrospective Survey on Fertility and Mortality (1974) has documented mortality differentials in childhood by socioeconomic status. Children of women who live in houses with walls of brick had a higher chance of survival than children whose mothers live in houses of mud. Infant and child mortality decreased with the educational level of both husband and wife. These data are based on indirect estimation procedures, which have their own particular limitations. Vital registration is practically non-existent in Bangladesh and hence the main data sources on mortality differentials have been obtained from small area surveys. Comanigonj thana has been the scene of innovative health interventions, and survey data on mortality rates for a 10% sample exist (Langsten 1976).

Using the Matlab data set, D'Souza and Chen (1979) have focused on sex biases of mortality differentials. Earlier work on the same subject has been recorded in the Matlab area (Ruzicka and Chowdhury 1978). Occupation has been correlated with mortality differentials in the Matlab area (Chowdhury and Aziz 1974). Becker (1978) studied relationships between seasonality data of deaths with SES.

Chen et al. (1979) have shown that children under 5 constituted 53.1 percent of all deaths in the period 1975-77. Among infants the most significant cause of deaths was tetanus. Tetanus neonatorum accounted for 26.2 percent of all infant deaths. A significant shift in causes of death occurs for children under 1-4 years. 43.9 percent of deaths were due to diarrheal diseases. Measles was the next cause of death with 13 percent. The paper associated under-5 mortality with socioeconomic and nutrition status; children residing in crowded housing (<242 sq. ft.) had nearly a two-fold higher mortality rates than children residing in less crowded housing (>242 sq.ft.). Children who were below the 63% cut off of the Harvard weight-for-age standard or below 70% of the Harvard weight-for-height standard experience about three-fold higher rates of mortality in comparison to their better-nourished counterparts. D'Souza et al. (1980) have documented mortality differentials and SES characteristics for the 1974 census.

Although malnutrition is known to increase the risk of mortality, past studies have found conflicting results when assessing the relationship between nutrition and socioeconomic status. The national survey of rural Bangladesh, 1975-1976 (Ahmed, 1977) noted significant positive correlations in food and nutrient intake, by income level of the family and landholding but did not observe such an association

with the family education score. Studies among rural women in Matlab noted only minimal correlations between maternal nutritional status (weight, height or arm circumference) and either educational level (comparing, women with no education to those with some education) or a scoring of family wealth based on the ownership of certain household goods (Huffman, 1977). However, data from a small number of families for whom information on landholding was available, indicated that women from landowning families (2 acres) had higher weights than those from landless families (Chen et al, 1979).

In addition to a benefit to finding an association between SES and nutrition, it would also be helpful to be able to correlate morbidity and socioeconomic status. Those groups at higher risk to illness could be selected for more intensified efforts, either in terms of provision of health services, vaccination programs, or health education. At present, we have no such indicator that will detect individuals at higher risk to disease. A parallel study will be set up to collect data specific to nutritional and morbidity variables. In fact the selection of villages for this study have been based on the parallel study requirements. While SES and fertility is extremely important, (Rafiqul H. Chowdhury, 1977) in view of the fact that various other protocols are addressed to fertility issues, no provision is being made

for a study at present.

The choice of villages will assist longitudinal interpretation of nutritional status especially of children over a ten year period.

A parallel limited study is being prepared with this end in view.

The introduction of morbidity variables in the parallel study will assist the design of more detailed studies on mortality directed at specific age groups.

B. SPECIFIC AIMS

1. Update of SES Characteristics in selected villages. A small survey has indicated that the 1974 SES patterns may have changed since the census was taken (Huffman et al, 1976).
2. The limited survey would serve as a pilot for a later SES census for the whole DSS area. The selection of variables, questionnaire development, costs and time involved will thus be assessed more accurately.
3. Analysis plans would attempt to link the SES characteristics of the selected villages over a ten year period. Mortality differentials would be studied.

C. METHODS AND MATERIALS

Occupational data were collected for the new trial area in 1968. In 1970, a few SES items were collected for the old trial area (occupation, education of head only, landholding and crops). In the 1974 census SES items--occupation and education were collected for the individual. At

data collection since 1970. These villages will be selected for this pilot study. Table III gives some characteristics of these villages:

The data collection will be done in two phases:

1) Time period: January 1981

Items: SES

The list is found in Appendix 3

The present population of the 5 villages is about 12,000 consisting of approximately 2000 households. Using an estimate of 30 minutes per interview 125 man days will be required to do the field work.

The budget has been shown to reflect 15 working days.

2) Time period: March 1981

Items: Anthropometric measures and morbidity data

For these villages anthropometric measures will be taken for all children under age 5, and for the mothers of these children--since these are the two most vulnerable population groups in terms of poor nutritional status and risk of mortality. In addition, information on morbidity for these subjects will be collected for the period of the preceding two weeks.

Details of this study will be set up in a separate limited study protocol.

The following tables will be prepared for the analysis for the year 1970-73, related to 1970 SES data, 1974 through 1977 linked to the 1974 SES data, 1978-1980 linked to 1980 data for relevant items for the 5 villages:

1. Mortality rates by age, sex and education of household head
2. Mortality rates by age, sex and education of mother
3. Mortality rates by age, sex and highest education in the family
4. Mortality rates by age, sex and religion
5. Mortality rates by age, sex and occupation of household head
6. Mortality rates by age, sex and occupation of individual
7. Mortality rates by age, sex and area of dwellings in household
8. Mortality rates by age, sex and family size
9. Mortality rates by age, sex and number of boats owned by the household
10. Mortality rates by age, sex and number of cows owned by the household
11. Mortality rates by age, sex and articles possessed by the family
12. Mortality rates by age, sex and sources of drinking water
13. Mortality rates by age, sex and use of fixed latrine
14. Mortality rates by education of household head and occupation
15. Mortality rates by education of household head and area of dwellings
16. Mortality rates by education of household head and number of cows owned
17. Mortality rates by education of household head and use of fixed latrine

The SES profile of the five villages at three points in time 1970, 1974 and 1980 will be compared using an index "education of head of household". The tables will assist in the confirmation of earlier results indicating mortality differentials and SES from the 1974 data. An assessment of the time for the questionnaire to be filled in, costs and logistic problems will be documented as well as reliability of information obtained. The field work should be terminated within a three week period. The tabulation of the results and some analysis should be terminated by the end of March 1981. This will provide the required insight necessary for Phase II of the study. Dr. Sandra Huffman will be associated with the second phase.

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SECTION III
DETAILED BUDGET

1. PERSONNEL SERVICES

<u>Position</u>	<u>% Effort</u>	<u>No. of days</u>	<u>Annual Salary</u>	<u>Requirements</u>	
				<u>TAKA</u>	<u>DOLLARS</u>
1 Research Associate	100	30	Tk. 48,776.00	5,682	-
<u>Field Surveillance Branch</u>					
1 Field Research Officer Gr-I	10	15	Tk. 48,776.00	281	-
10 Health Assistants (F.A)	100	15	Tk. 22,529.00	13,000	-
Sub-total					
<u>Data Management Branch</u>					
1 Statistical Officer Gr-I	10	30	Tk. 48,776.00	563	-
2 Coding Assistants	100	5	Tk. 22,529.00	866	-
Sub-total					
<u>Computer Services</u>					
1 Programmer(National)	50	15	Tk. 48,776.00	1,407	-
2 Data Entry Technician Gr-I	100	10	Tk. 27,105.00	2,085	-
Sub-total				<u>23,884</u>	

2. <u>SUPPLIES AND MATERIALS</u>	<u>% Effort</u>	No. of days	Annual Salary	Project Requirements	
				<u>TAKA</u>	<u>DOLLARS</u>
Stationary 4 Disketts (2D)				1,500	- 64
3. <u>EQUIPMENT</u>					
None					
4. <u>PATIENT HOSPITALISATION</u>					
None					
5. <u>OUTPATIENT CARE</u>					
None					
6. <u>ICDDR, B TRANSPORT</u>					
Dacca-Matlab-Dacca 4 trips				1,420	
Matlab speedboat (one boat two hours daily for 15 days)				5,716	
				<u>7,136</u>	
7. <u>TRAVEL AND TRANSPORTATION OF PERSONS</u>					
None					
<u>LOCAL TRAVEL</u>					
None					
<u>INTERNATIONAL TRAVEL</u>					
None					

	<u>% Effort</u>	<u>No. of days</u>	<u>Annual Salary</u>	<u>Project Requirement</u>	
				<u>TAKA</u>	<u>DOLLARS</u>
8. <u>TRANSPORTATION OF THINGS</u>					
9. <u>RENT, COMMUNICATION AND UTILITIES</u>					
Communications				1,500	
10. <u>PRINTING AND REPRODUCTION</u>					
Questionnaire cyclostyling (2,500 copies)				1,260	
Other printing and Repro- duction				2,750	
Sub-total				<u>4,010</u>	
11. <u>OTHER CONTRACTUAL SERVICES</u>					
None					
12. <u>RECONSTRUCTION, RENOVATION, ALTERATION</u>					
None					
13. <u>MISCELLANEOUS COMPONENTS</u>					

B. BUDGET SUMMARY

<u>CATEGORY</u>	<u>TAKAS</u>	<u>DOLLARS</u>
1. Personnel	23,884	-
2. Supplies	1,500	64
3-5 Nil items	-	-
6. ICDDR,B Transport	7,136	-
7-8 Nil items	-	-
9. Rent/Communication	1,500	-
10. Printing/Reproduction	4,010	-
11-12 Nil items	-	-
13. Miscellaneous	-	-
Total	<u>38,030</u>	<u>64</u>
Total (in Dollars)	\$ 2454*	64
Grand Total (in dollars)	\$ 2518	

*Calculated at Tk. 15.50/\$ 1.00

Table 1

SES data collection by year of census

<u>Census year</u>		<u>OTA</u>	<u>NTA</u>
1966		No SES data	No census
1968		No census	Occupation of individuals
1970		Occupation and Education of head and ever married individual	No census
		Landholding	
		Crop yield/ Income of land leasers	
1974	Individual	- Education - Occupation	
	Family	- House structure House-space Land yield (5%)	
		Receive remittance possession of radio; watch hurricane, quilt, cow, boat, source of water, latrine	
1980	Same as 1974		

Table II

Year	Study	Type of subjects	Age	Villages
1968	Census/Some SES	All	All	NTA
1970	Census/Some SES	All	All	OTA
1970	Quak Stik	Children	1 - 9	21 (B, C, H, S, U, W V3, V5, V6, V10 V12, V22, V24, V25, V27, V28, V29, V30, V35, VB3, DO)
1974	Census/SES	All	All	All
1976	Postpartum	Lactating mothers	15-44	80 (Control villages in contraceptive Distribution Program)
	Amenorrhea	Children	1 - 2	
1978/ 1979	Oral Rehydration	Children	1 - 4	
	- Labon gur			9(S, V18, V19, V20, V22, V52, V55, V83, VB12)
	- Packet			11(M, N, O, V10, V28, V31, V39, V59, V62, V88, D101)
	- Control			S(A, J, U, V8, V51, VB9, VB10).

Table III

Some characteristics of selected pilot study villages

Village	No. of subjects in study		
	Total population '79	Percent Muslim	Distance for hospital
S HS	1024	39.4	7 miles
U	6342	80.1	Within 1 mile
V 10 HS	1261	100.0	2 miles
V 24 HS	2212	92.3	6 miles
V 28 HS	1095	72.0	7 miles

Verbal Consent Statement

The International Centre for Diarrhoeal Disease Research, Bangladesh (formerly Cholera Research Laboratory) is planning to collect information on socio-economic status of households of Matlab DSS area. We will collect information on education, occupation and ownership of household members. You will be asked some questions relating to the above variables and it will be treated as confidential. Please note that you will not be paid. You may, at any time, refuse to answer questions. If you have any questions we will try to answer them.

Do you have any questions now?

Do you agree to participate?

ঐতিহাসিক সমস্যাগুলি পত্র

আন্তর্জাতিক উদ্যোগের সবেশনা কেন্দ্র (প্রাথমিক কলেজ বিদ্যালয় ব্যবহারে)
স্বতন্ত্র পরিবারের আর্থ-আসন্নায়িক অবস্থার উপর জ্যেষ্ঠ অংশীদার
পরিচালনা করছে। আন্তর্জাতিক পরিবারের সদস্যদের শিক্ষা, সেবা ও বিশ্ব
সম্পত্তির উপর কিছু প্রকল্প করুন এবং প্রকল্পে আর্থ-ধর্মের অর্থ নাগালে
পারে। প্রকল্পে আপনার দেয়া যাবতীয় জ্যেষ্ঠনী জ্ঞান রাখা হবে।
প্রত্যেক আপনাকে কোন "টাকা পয়সা" দেয়া হবে না। আপনি ইচ্ছে
করলে যে কোন সমস্যা প্রকল্পে জ্ঞান দেয়া বন্ধ করতে পারবেন। প্রকল্পে
আপনার কোন প্রকল্প থাকলে আন্তর্জাতিক জ্ঞান দিতে চেষ্টা করুন।
আপনার কোন প্রকল্প আছে কি?
আপনি কি আন্তর্জাতিক সহযোগিতা করতে রাজী আছেন?