Attachment-1.

86

REVIEW BOARD ON THE USE OF HUMAN VOLUNTEERS

CRL 77-014

Date 1/8/77

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

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

Title of study Shigella Morbidity, Interfamilial spread and Intervention Studies.

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 possibly 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
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 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

Trainee

Please return 2 copies of entire protocol to Chairman, Review Board on Use of Human Subjects

Attachment 1a

INFORMATION TO INCLUDE IN ABSTRACT SUMMARY

The Board will not consider any application which does not include an abstract summary. The abstract should summarize the purpose of the study, the methods and procedures to be used, by addressing each of the following items. If an item is not applicable, please note accordingly:

1. Describe the requirements for a subject population and explain the rationale for using in this population special groups such as children, or groups whose ability to give voluntary informed consent may be in question.

2. Describe and assess any potential risks - physical, psychological, social, legal or other - and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.

3. Describe procedures for protecting against or minimizing potential risks and an assessment of their likely effectiveness.

4. Include a description of the methods for safeguarding confidentiality or protecting anonymity.

5. When there are potential risks to the subject, or the privacy of the individual may be involved, the investigator is required to obtain a signed informed consent statement from the subject. For minors, informed consent must be obtained from the authorized legal guardian or parent of the subject. Describe consent procedures to be followed including how and where informed consent will be obtained.

   (a) If signed consent will not be obtained, explain why this requirement should be waived and provide an alternative procedure.

   (b) If information is to be withheld from a subject, justify this course of action.

6. If study involves an interview, describe where and in what context the interview will take place. State approximate length of time required for the interview.

7. Assess the potential benefits to be gained by the individual subject as well as the benefits which may accrue to society in general as a result of the planned work. Indicate how the benefits outweigh the risks.

8. State if the activity requires the use of records (hospital, medical, birth, death or other), organs, tissues, body fluids, the fetus or the abortus.

The statement to the subject should include information specified in items 2,3,4 and 7, as well as indicating the approximate time required for participation in the activi

Rcd. Aug. 16, 77
77-014

ABSTRACT SUMMARY

SHIGELLA MORBIDITY, INTERFAMILIAL SPREAD AND INTERVENTION STUDIES

Dr. M.U. Khan

The incidence of Shigellosis both in urban and rural areas has increased many folds within a short period of time. The case fatality and the subsequent infection rates are higher than cholera. This is one of the most important medical problems in Bangladesh at present. We propose to study this problem with emphasis on its morbidity for better understanding in early diagnosis, pattern of interfamilial spread and whether intervention is possible either by hygienic habits or by use of drugs.

The cases will be selected for a 10 day study randomly and the study will be initiated on the 1st day of admission of the index in CRL. Rectal swab will be cultured for 10 days, illness and socioeconomic history obtained and 1st and 10th day finger tip blood will be collected from the index and contacts of the index cases. Water samples will be collected for culture using millipore filtration. The families will be grouped into 4 groups : 1) Antibiotic prophylaxis group 2) Health Education & provision of soap group 3) Control group and 4) non-shigella control group. Antibiotic treatment will be for 3 and 5 days. About 50 families in each group will be studied. Culture and blood testing will be done using standard technique.

1. The population will be from all ages, sex and religion from the metropolitan area of the Dacca city.
2. No major risk is involved in this study. The pricking sensation for obtaining a drop of fingertip blood will be a minor physical injury. The obtaining of Rectal Swab is without any risk. Children may psychologically refuse in certain cases.
3. For minimising the pricking pain sharp, thin and sterilised sera sharp blade will be used. The children will be eased by giving them candy and balloons.
4. The purpose of the study will be explained to the subjects or guardians of the subjects right in their own premises. A consent form will be signed by them for every case. They will be at liberty to refuse or withdraw at any time of the study. Their refusal or withdrawal will not bar them from obtaining hospital treatment in any way.
5. The interview will be initially with the attendant of the admitted patient. He will be taken to the family by the team and our purpose will be explained to them. If he agrees to co-operate with CRL then the final forms will be filled up and a consent obtained from them. This interview may take about 15-30 minuites.
6. The sick people will receive treatment in CRL. The milder cases not admitted will also receive treatment. The antibiotic group will receive preventive treatment and the health education group will learn the hygienic practices and also get soap during the period of study. For serious diarrheal cases of all groups free treatment will be available. If the spread can be prevented the immediate neighbourhood will be saved from the disease. These will outweigh the minor risks.
7. The study needs to record the age, sex and number of the members of the family and some information about the water use pattern and domestic practices. None of these are confidential in nature. Drawing of fingertip blood will involve no risk at all.

SECTION I - RESEARCH PROTOCOL

1) Title: Shigella Morbidity, Intrafamilial Spread and Intervention Studies.

2) Principal Investigator: Dr. Moslemuddin Khan

3) Starting Date: August 1, 1977

4) Completion Date: August 1, 1978

5) Total Direct Cost: $ 20,020 (first year)

6) Abstract Summary:

The incidence of shigellosis both in urban and rural areas has increased several fold. The case fatality and subsequent infection rates are higher than cholera. We plan to study this problem epidemiologically with special emphasis on morbidity, intrafamilial spread and whether intervention by drug and health education can control the intrafamilial spread. The presumptive shigella cases would be identified and the family visited on the first day of admission. The shigella obtained will be subgrouped and tested for sensitivity. The families will be censused and rectal swabs obtained and cultured from family members for 10 days. Water samples will be obtained for culture. Socio-economic history will be obtained. The shigella families will be grouped into 1) Antibiotic Prophylaxis group, 2) Health education with provision of soap group, 3) Control group and 4) Non-shigella control group. Antibiotic treatment will be for 3 days and 5 days. If no shigella is isolated from the index case the family will be in non-shigella control group. Severe cases from the families will be hospitalized. Mild cases will be treated with placebo. Types and quantity of water used will be recorded daily. At least 50 families from each group will be considered as minimum. This study will document the morbidity of cases not brought to hospital, the pattern of intrafamilial spread, the effectiveness of antibiotic intervention in families.

7) Review:

a) Research Involving Human Subjects: _____

b) Research Committee: _____

c) Director: _____

d) BMRC: _____

e) Controller/Administrator: _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objective: Shigellosis is one of the most important public health problems now in Bangladesh. The morbidity and mortality are worse than cholera even under institutional treatment. The intrafamilial infection is very common. All family contacts would prefer to avert an attack. But as there is no definite way of protection against it, it would be worthwhile to examine whether intrafamilial spread of shigellosis could be intervened or controlled by either imparting health education with provision of soap or by use of drugs in urban and semi-urban areas of Dacca City.

2. Background: Frequency of shigellosis in Bangladesh increased since Liberation War of 1971. The Sh. flex and Sh. Shiga are the most common types. The case fatality rate is 5-10 times higher than cholera. Many strains have developed resistance to conventional antibiotics. In 1968 less than 5% of all diarrhea of a Dacca community was associated with Shigella (Khan, M, and Mosley, W.H., E.P. Med. Jour., V:XII No. 2, 1968). In 1970 out of all CRL admissions shigella was

associated with 0.6% of cases whereas in 1973 over 14% were associated with shigella (Khan, M, and Curlin G., Bangladesh Med. Jour. V:3, No. 2, October 1974). When the St. Martins Island was affected with Shiga Bacillus dysentery the overall attack rate was over 32% and fatality rate was 6.4% (Khan, M. et. al. South East Asian Jour. Trop. Med. and Pub. Health, V:6, No.2, June 1975). The attack rate in the age group 1-4 was nearly 57% and the case fatality rate was over 41%. Dr. Gangarosa et.al. (J. Infect. Dis. V:122, No.3, September, 1970) had shown that the attack rates in Guatemalan village was 36.5% for male and 30.5% for female for 1969. Cesar A. Mendizabal-Morris et.al. (Am. J. Trop. Med. Hyg. V:20, No. 6, November 1971) had shown that in Guatemala the case fatality rates in untreated cases were 8.4% in villages and 10-15% in acute hospitalized cases. The fatality rate under CRL facilities is around 4% at present. Rahaman, M.M. et. al. (Jr. Infect. Dis. V:132, No. 1, July 1975) has suggested water to be a vehicle of transmission. Rosenberg M.L. thinks it is transmitted by water and person to person contact (Am. Jour & Epid. V:104, No. 5, 1976) Khan M, et. al. suggested that in certain

situations this may act as vehicle of transmission. Levine M.M. et. al. (Am. Jr. Epid. V: 104, No. 1, 1976.) has shown that live oral vaccine against Sh. sonnei is effective in controlling Sh. sonnei. But this strain is minimum in Bangladesh.

These studies suggest about 50% of the subsequent cases in a family in an endemic area stem from intra-familial spread. The mode of spread, rate of morbidity by age and sex, symptometology of unhospitalized cases and whether the spread can be intervened in situation as prevailing in Bangladesh have not been documented. Dr. McCormack has shown that intrafamilial spread of cholera cases can be intervened by the use of Antibiotics (WHO Bull. V:38, 1968, P. 787-792).

Therefore, it is important to study this problem to specify the pattern of spread of infection among the members of the affected families, identify symptometology and possible control measure for prevention of spread within the family contacts.

3. Rationale: Shigellosis causes a high degree of morbidity, mortality and a colossal loss of working hours. Multiple cases from a family or a community are frequently reported. For poor families or communities as in Dacca, shigellosis is a cause of great concern; but there is no known efficient preventive procedure. It has been found that intra-familial spread of cholera can be checked by tetracycline prophylaxis. Therefore, an intervention study is desirable in an area like Dacca where shigellosis is occuring all the year round.

B. SPECIFIC AIMS

We want to answer the following questions:

1. What is the rate of intrafamilial secondary cases and what age and sex groups have the highest secondary attack rate?

2. Does source of water, quantity of water, availability of soap and education effect the secondary attack rate?

3. Is ampicillin effective in preventing secondary cases of shigellosis?

4. Is passive haemagglutination test a useful epidemiologic method for detection of infection?

C. METHODS OF PROCEDURE

Confirmation of shigellosis is not obtained until 3rd day of admission. Presumptive cases will be picked up on the first day from the indoor admission on random basis. The index case taken up for study should have 1) a family, 2) live within metropolitan area, 3) be cooperative and 4) the illness should be of short duration. Follow-up families will be divided into 4 groups: A) Antibiotic therapy group, B) Health Education & Soap Group, C) Control Group and D) Non-shigella Group. Matching of age and sex will be attempted between the cases and controls. The groups will be determined using regular cyclic order - A.B.C.D. The illness forms will be filled in the hospital interviewing either the adult attendant in the cases of infants and children or the adult patients directly. The family census forms and the socio-economic forms will be filled in the premises of the index. A team of one trained male and one female field assistant will visit the families, take R.S., water samples, finger-tip

blood, record information on illness, impart health education, supply soap and medicine and verify and measure the domestic water from the storage jars as the case may be. Rectal swabs will be cultured using McConkey's and S.S. plates for at least 10 days. Water will be cultured after millipore filtrations. None will be included in the analysis if his R.S. has not been cultured at least for 3 days or a single positive R.S. has not been obtained. The R.S. will be plated in the field and deposited with the microbiology branch as soon as possible. Passive haemagglutination technique will be used for estimation of titer against specific serotype. The culture results will be incorporated in the form when available. The sympto-metology of diarrheal or dysenteric illness if any would be recorded daily in the forms.

Antibiotics will be supplied to the Group A on the first day before obtaining culture results. If the R.S. of the index is found to be negative for shigella the family will be treated as control. If it turns out that the drug is not sensitive (5th day) to the isolate obtained the family will be followed.

History of penicillin reaction will be obtained from the contacts. Two capsules of ampicillin will be administered by the CRL staff in the morning to every adult and one capsule/syrup will be given to the children. Equal dose for each contact will be left in the house for evening use. On the following morning the CRL will verify whether previous night's dose had been taken and whether there is any skin rash before administering them the next dose. The use of the drug will be: 1 gm daily in two divided doses for 3 or 5 days. Alternate families will receive 3 or 5 days treatment. In case of reaction the drug will be withdrawn and antihistamine given. In severe cases the pateint will be hospitalized.

Group B will not receive any antibiotic. For mild diarrheal illness placebo or oralyte will be supplied to them. Severe cases will be sent to CRL. Aspirin and minor medicine may be supplied. They will receive one ball of washing soap and one cake of bathing soap weekly for the period of study only. The staff will advise them for cleaning the utensils, clothes, bedsheets and the environment as far as possible. They will advise them to use excess of water for washing

purposes. Hands should be definitely washed with soap after defecation, cleaning night soil of children and clothes and before taking any food. They will advise them to wash utensils, vegetables and food with tap or tubewell water and keep the food covered and consumed freshly prepared food. They will encourage them to take the children to distance places or latrine for defecation. In case of passing of stool in the room or premises they will be advised to clean it as thoroughly and early as possible. They should protect the food from flies. The staff will watch whether the soap is used properly. The water storage jars should be properly cleaned daily and the water should be protected from children and from dipping of dirty mugs and cups. They should be encouraged to use tap or tubewell water for bathing and washing. The use of canal, river, pond or ditch water should be prohibited. The children should be fed by the mothers only and she should wash her hands and utensils with soap before feeding. No left over food should be taken.

For Group C and D nothing should be influenced. Severe diarrheal cases hould be sent to hospital and milder one treated with oralyte or placebo at home. Their ways of taking care of their sick, food, water and environment

should not be disturbed. No soap or antibiotic should be supplied in this group of families. Families away from each other will be preferred.

From all the groups the daily consumption of water for all purposes will be noted. The nature, use and distance of latrine from kitchen will be recorded. Detailed history of cooking, feeding and handling of food will be recorded in the forms. The record of sharing beds, food and clothes if any, will be recorded. The forms prescribed will be filled in right in the premises. No new cases will be taken up on Saturdays and Sundays if there are sufficient families to follow.

R.S. will be cultured for Shigellosis and sensitivity tests done. Sub-grouping will be done to earmark the secondary cases specifically.

The follow-up will be at least for 10 days. If there are delayed secondary infection the follow-ups will be prolonged for 12 days. There should be at least 50 families in each group.

The data will be coded, punched and analysed after completion. Analysis may be done either by card sorting or by computer.

D. SIGNIFICANCE

Shigellosis causes prolonged disabilities and financial involvement to both the patients and the contacts. This study will establish how much of these difficulties can be averted by intervention with a) antibiotics prophylaxis and b) hygienic practices. This will also reveal the symptometology of milder cases which are not reported to the hospital and show the age and sex specific rate of secondary infection. Whether screening for shigella infection is possible by passive haemagglutination technique will be shown from this study.

E. FACILITIES REQUIRED

1. Office Space: As the study would be conducted in the field no office space (other than CRL) will be needed.

2. Laboratory Space: Laboratory work will be done in the CRL microbiology and immunology branches and as such no separate laboratory space is needed.

3. Hospital Resources: We do not aim to hospitalize any study patients for the purpose of this study. We will however, select cases from the CRL admission for study.

4. Animal Resources: Animals will not be needed for conducting any test for the purpose of this study.

5. Logistical Support: The location of the study will be within the city. Two vehicles will be needed daily for about six hours on week days and about 4 hours on weekends during the period of the study. This will depend on the availability of cases.

6. Major items of Equipment: No major item is needed. Minor equipment like field bag, spirit lamps, umbrella, gumshoe, media, swab sticks, paper, pencils, candy, balloons, aspirin, oralyte, vitamins, etc., will be needed.

7. Other specialized requirements: Ampicillin and soap are the two important special items needed for this study.

F. COLLABORATIVE ARRANGEMENTS

For this proposed study no collaborative arrangement with outside personnel is needed.

SECTION III - BUDGET

A. DETAILED BUDGET

1. PERSONNEL SERVICES

Name	Position	% time used	Taka Salary (1st year) Project Requirement
Dr. M.U. Khan	Investigator	30%	17,712
Mr. M.I. Hoque	Investigator	10%	5,754
Dr. A. Ahmed	Investigator	5%	2,952
Mr. Shahidullah	Supervisor	50%	12,800
Mr. Maksud Ali Khan	Field Assistant	80%	9,920
Mrs. D. Purification	Field Assistant	100%	17,000
Ms. Hazera Khatun	Field Assistant	100%	10,296
One Field Assistant		100%	10,296
Mr. Abdul Hoque		15%	2,782
Mr. Nicholas		15%	21,134
O.T. (approx) 20% except 1, 2, 3			16,846
		Sub Total	127,492

2. SUPPLIES AND MATERIALS

Name	Unit Cost	Amount	Tk.	Dollars
R.S.: Mac. media and plate/100	Tk. 65.00	243	15,795	-
S.S. media and plate/100	Tk. 85.00	243	20,655	-
Swab stick/100	Tk. 8.00	50	400	-
Water:Mac. media & plate	Tk. 65.00	81	5,265	-
S.S. media & plate	Tk. 85.00	81	6,885	-
Enrichment broth/100 ml	Tk. 40.00	81	3,240	-
Millipore filter 47 size/100	$ 13.8	81	-	1118.00
Anti Shiga P.H.A. Test Manhour/1000	Tk.927.00	5	4,635	-
Material/1000	$ 188	5	-	940.00
Ampicillin Cap.	$ 58.08	3 bottles	-	176.04
Ampicillin Syr.	$ 1.40	150 "	-	210.00
Multivit Tab.	Tk. 90.00	5 "	450	-
Multivit Syr.	Tk. 8.00	150 PL	1,200	-
Phenargan Tab.	Tk. 25.37	10 PL	237	-
Phenargan Syr.	Tk. 6.00	50 PL	3,300	-
Aspirin	Tk.100.00	5 Tins	500	-
Iron Tablet	Tk.100.00	1 Tin	100	-
Oralyte	-	600 Pkts	-	-
Candy	Tk. 12.00	60 lb	720	-
Balloons	Tk. 10.00	30 Pkts	300	-
Paper	-		1,000	-
Pencils (Ballpens)	-	(	300	-
Stencils	-	-	200	-
IBM Cards	$ 10.03	1 Pkt	-	10.30
Miscellaneous stationery	-	-	1,000	-
Shigella type specific serum	-	-	-	100.00
		Sub Total:	66,182	2554.34
			=======	=========

3. EQUIPMENT

Nil

4. PATIENT HOSPITALIZATION

Nil

5. OUTPATIENT CARE

Nil

6. CRL TRANSPORT

Mileage - Dacca

2 Transport M30XD360 X Tk. 1.4 = Tk. 30,240

Sub Total: Tk. 30,240

7. TRAVEL AND TRANSPORTATION OF PERSONS

Local Travel	Tk. 1,000	
International Travel:		
Transport		$ 2,000
Perdiem		$ 500
Sub Total:	Tk. 1,000	$ 2,500

8. TRANSPORTATION OF THINGS

Transport of ampicillin and cards @ 25%	$ 100.00
Sub Total:	$ 100.00

9. RENT, COMMUNICATION & UTILITIES

Postage	Tk. 100.00
Sub Total:	Tk. 100.00

10. PRINTING AND PUBLICATION

Printing forms	Tk. 2,100
Xerox cost	Tk. 500
Sub Total:	Tk. 2,600

11. OTHER CONTRACTUAL SERVICE

Typing charge	Tk. 1000.00

12. CONSTRUCTION, RENOVATION, ALTERATION

Nil.

B. BUDGET SUMMARY

	Category	Year 1 Taka	Year 1 Dollars	Year 2 Taka	Year 2 Dollars	Year 3 Taka	Year 3 Dollars
1.	Personnel	127,492	-	133,867	-	140,561	-
2.	Supplies	66,182	2,555	69,492	2,683	72,967	2,818
3.	Equipment	Nil	-	-	-	-	-
4.	Hospitalization	Nil	-	-	-	-	-
5.	Outpatients	Nil	-	-	-	-	-
6.	CRL Transport	30,240	-	31,803	-	33,392	-
7.	Travel Persons	1,000	2,500	1,050	-	1,103	-
8.	Transportation Things	-	100	-	105	-	111
9.	Rent/Communication	100	-	105	-	111	-
10.	Printing/Reproduction	2,600	-	2,730	-	2,867	-
11.	Contractual Service	1,000	-	1.050	-	1,103	-
12.	Construction	Nil	-	-	-	-	-
	Total:	228,614	5,155	240,097	2,788	252,104	2,929
	Total $:	20,020		18,399		19,321	

SHIGELLA MORBIDITY, INTRAFAMILIAL SPREAD AND INTERVENTION STUDIES

Family Visit Form

FAMILY NO:.....

Hospital No._____ Diagnosis_____ Date of Admission_____ Time_____ Date of Onset_____ Time_____

Village/Street_____ Land-mark_____ P.S._____

Family: Antibiotic / Sh. Education / Sh.Control / Non sh.control /

Indv. No.	Name	Age	Sex	Relationship with Head	Occupation	Diarrheal Illness during last 5 days: 5	4	3	2	1	Uses soap for washing hand	Indv. sleeps together	Washes hand in same plate	Prepares food	Feeds Children with hand	Distributes food	Draws Water	Washes Utensils	Washes Soiled Clothes	Washes Kid's Motions	Handles raw Fish	Bathes children
1 (Indx)																						
2																						
3																						
4																						
5																						
6																						
7																						
8																						
9																						
10																						

Domestic Hygienic Practices (From last 5 days)

SHIGELLA MORBIDITY, INTRAFAMILIAL SPREAD AND INTERVENTION STUDIES

FAMILY NO. .....

1. Index:

Place of residence	Usual place of work	Occasional places of work	Time of leaving home	Time of returning home

2. Index:

Meals	How often	Place of Meals Taken: Home	Restaurant	Roadside Hawker	Charitable	Ceremonial	Lover	Relatives
Breakfast	Usually							
	Occasionally							
Lunch	Usually							
	Occasionally							
Dinner	Usually							
	Occasionally							
Snacks	Usually							
	Occasionally							

3. The index took meal in a family having a known diarrhea/cholera dysentery case within 5 days prior to onset,

Yes ☐ No ☐ If Yes, date_____, place_____ Kind of food_____

Water: source_____ quantity_____(seer/kg)
(drank)

4. Index took meal within 5 days prior to illness in restaurant/boat/public feast/roadside hawker's shop, Yes ☐ No ☐ If Yes, date_____, Place_____ Kind of food_____

Water: source_____, quantity_____(seer/kg)
(drank)

SHIGELLA EPIDEMIC, TRIAL AREA SURVEY AND INTERVENTION STUDIES

WATER AND LATRINE USE

FAMILY NO. .....

	Location		Distance from Kitchen	Verify no. and size of jars L,M,S for each					Place of Wash		Place of Bath			Quantity and Source for ablution water	Use soap(S), dettol use(O) to wash hand after abln.	No. Of soap found in room for WASH(A) BATH(B)	Use none but water for washing hand after [illegible]	Shared by [illegible]	REMARKS
	Within Compound	Outside Compound		Drink	Cook	Wash vegetable and food	Wash utensils	Wash soiled linen & dirty thing	At source of Water	In premises	In Kitchen	At Source	In Premises	In Bathroom					
Tap (WASA)																			
T. Well																			
Dug. well																			
Pond/Tank																			
Ditch																			
Canal																			
River																			

LATRINE USE PATTERN

Users	Type of Latrine used					Dis-tance from Kitchen	Feces cleaned by			
	Sanitary closed	Sanitary	Service Latrine	Open pit Latrine	Temporary non fixed fencing		Flushing Water	Pouring Water	Removed by sweeper	None
Adult Male										
Adult Female										
Childre[illegible]										
All										

SHIGELLA ... SPREAD ... SPECIES.

FAMILY NO ...

Dates of ...d/R.S. Collection and R...

Sl. No.	1st			2nd			3rd			4th			5th			6th			7th upto 12th			T/E/C.
	Cnd	RS	CR	Cnd	RS	CR	Cnd	RS	CR	Cnd	RS	CR	Cnd	RS	CR	Cnd	RS	CR	Cnd	RS	CR	
1																						
2																						
3																						
4																						
5																						
6																						
7																						
8																						
9																						
10																						
11																						
12																						
13																						
14																						

Cnd = Condition of individual, 0 = Not ill (diarrhea), 1 = Mild diarrhea, 2 = Moderate diarrhea dysentry/ dysentry/
3 = Sev... diarrhea, 4 = Hospitalized, ✓ = R.S. Obtained, ... R = Refused CR = Culture Result,
OO = No..., II, III etc. = Groups of NCV. Treated =T ... ; Control=C,
Diarrh... otion in 24 ... Dysentery = ... mucu...

SHIGELLA MORBIDITY, INTRAFAMILIAL SPREAD AND INTERVENTION STUDIES

Culture and Result Form (R.S., Water and Food)

Date: _____

Specimen No.	RS	WATER	FOOD	RESULT

STATEMENT TO BE READ TO THE SUBJECTS/LEGAL GUARDIANS AND EXPLAINED IN LOCAL LANGUAGE WHEN CONSENT IS OBTAINED.

The incidence of shigella dysentery has increased enormously within a few years in Dacca and Bangladesh. This is a great concern of the Government. The doctors of Cholera Research Laboratory are trying to findout the factors associated with this disease and how this disease can be prevented for the benefit of the people affected and the country at large.

The doctors will require to examine your rectal swab, water and food etc. for 10 days and finger tip blood for 2 days. They will ask about your health, socio-economic condition, water use, family etc. You will be offered treatment of diarrhea or dysentery either in your house or in Cholera Research Laboratory(CRL) hospital as is needed.

You will be at liberty to withdraw your consent at any time you like. This will not hamper your right of having treatment in the CRL. If you agree to co-operate with the CRL. for this national cause please sign your name or put your left thumb impression at the bottom.

I agree to co-operate

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Address_____

_____

Date_____

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