REVIEW BOARD ON THE USE OF HUMAN VOLUNTEERS

CRL

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

Application No 78-017 Supporting Agency(if Non-CRL)

Title of study Shigella Morbidity, Intrafamilial Spread and Handwash 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. Khan 14/6/78
Principal Investigator

Trainee

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

78-017
Rec'd 14/6/7

SECTION I - RESEARCH PROTOCOL

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

2) Principle Investigator: Dr. Moslemuddin Khan

3) Starting Date: July 1, 1978

4) Completion Date: June 30, 1979

5) Total Direct Cost: $ 22,205

6) Abstract Summary:

The incidence of shigellosis both in urban and rural areas has increased several folds. 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 health education can reduce the intrafamilial spread. The presumptive shigella cases would be identified and the family visited on the second day of admission. The shigellae obtained will be sub-grouped and tested for sensitivity. The families will be censused and rectal swabs and handwash obtained and cultured from family members for 10 days. Domestic water samples will be obtained for culture. Socio-economic history will be obtained. The shigellae-families will be grouped into (1) Health education with provision of soap group and (2) Control group. Severe cases from the families will be hospitalized for treatment. Other cases will be treated with oralyte if dehydrated. 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 use of soap and health education in reducing the rate of secondary infection.

7) Reviews:

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 enforcing washing of hands and utensils with soap and water in urban and semi-urban areas of Dacca city. The sensitivity pattern will also be revealed from this study.

2. Background: In the most developing countries of the tropical and subtropical zones of the world, diarrheal diseases still causes a great deal of morbidity and mortality, particularly in infant and children (Mata L.J. et. al. Jour. Infect. Dis. v 122 No. 3, September, 1970). On close follow-up of diarrhea occuring in families in Rayer Bazaar, Dacca it was found that shigellae accounted for less than 5% of all the diarrheas observed in 1968 (Khan M. et. al. E.P. Med. Jour. v 12, No. 2, April, 1968). Craigs Rayer Bazaar diarrhea study revealed that 16% of all diarrhea occured in families were affected with shigellae. In 1970 out of all CRL admission Shigellae was associated with 0.6% of cases whereas in 1973 over 14% of cases were associated with Shigellae (Khan M. et. al. Bangladesh Med. Jour. v 3, No. 2, Octoberm 1974). The overall attack rate in the St. Martin Island epidemic was 32% and fatality rate 6.4% (Khan M. et. al. South East Asian Jour. Trop. Med. and Pub. Health v. 6, No. 2, June 1975). In one unpublished family study (Khan M. et. al.) in Dacca we have found that the subsequent case rate is over 12%. The incidence of dysentery caused by shigellosis is on the increase (1940 cases in 1974 and 4833 cases in 1976 in CRL) and the mortality rate in the CRL ward is around 4% (observation of CRL Physicians). Gangarosa et. al. (J. Infect. Dis. v 122, No. 3 September, 1970) had shown that the attack rates in Guatemalan villagers was 36.5% for male and 30.5% for female in 1969 and asymptomatic infections were at least as common as symptimatic infection. Ceser A. Mendizabal - Morris et. al. (Am. J. Trop. Med. Hyg. v 20, No. 6, November, 1971) reported that case fatality rates in untreated cases were 8.4% in villages and 10-15% in acute hospitalized cases. Rahman, M.M. et. al. (Jr. Infect. Dis. v 132, No. 1, July, 1975) reported that 64% of cases were clinically cured in 2 weeks and untreated cases took 1-5 weeks for full recovery. He suggested water to

be a vehicle of transmission. Rosenberg, M.L. et. al. (Am. Jour. Epid. v 104, No. 5, 1976) found association of shigellosis with swimming in infected water. Merson, M.H. et. al. (Am. Jour. Epid. v 101, No. 2, 1975) also described a water borne shigella flexneri epidemic in a cruise ship where 90% of the passengers and 35% of the crew members developed symptoms consistent with shigellosis. Gangarosa et. al. also suggested that transmission occurred in a community outbreak through water. J. Mata et. al. (J. Infect. Dis. v 122, No. 3, September 1970) observed that the overall prevalence of antibodies to Shiga Bacillus dysentery in the affected community ranged from 20% to 50% and in addition many cases of dysentery had been diagnosed and treated as amoebic dysentery.

R. Irene Hutchison (Pub. Health Lab., Southamptom, office of the Med. Res. Council, 38 Old Green Street, Westminister SW1) had shown that Sh. sonnei can survive for 17 days under favourable atmospheric conditions and after visiting the water closet as many as 50% of the children might be hand carriers and the organisms remained alive on the skins of the fingers for 3 hours. Levine, M.M. et. al. (J. Infect. Dis. v 127, No. 3 March 1973) reported that only 10 organisms of shigella shiga can cause the disease. Many investigators have suggested person to person transmission of Shigellosis. Jack B. Weissman et. al. (Lancet, January 11, 1975) suggested that person to person transmission is the usual mode of spread, secondary spread within the household is common and there may be significant spread to the community. For control measure he suggested separation of infected from the non-infected members, use of antibiotics and correction of deficiencies in hygiene and health education. John D. Nelson et. al. (Am. Jour. Epid. v. 36, No. 3, 1967) suggested case findings from households and prompt treatment for control. Katherine Sprunt et. al. (Pediatrics 52: 264, 1973) had shown that routine handwash with washagent including water was effective in removing infant acquired indigenous bacreria. Allen C. Steere et. al. (Anis. Int. Med. v 83, No. 5, November 1975) advocated handwash with soap and water for removing nosocomial pathogens.

These studies therefore suggest that the percentage of intrafamilial spread and mortality are very high and a large number of cases in a family in an endemic area stem from intrafamilial spread. The mortality rate from shigellosis is 5-10 times higher than cholera under institutional treatment. Using hygienic practices the spread and the rate of infection can be reduced. But in an endemic area like Bangladesh the mode of spread, rate of morbidity by age and sex,

symtomatology of unhospitalized cases and whether intrafamilial spread can be intervened in situations as prevailing here have not been documented.

Use of vaccination is not too good. In Bangladesh situation some of the control measures like case finding, isolation, mass treatment and preventive vaccination are not feasible at the present time. But the hygienic practices if well taught and found effective may be advocated. From a pilot survey of 14 families the rate of secondary infection was 32.7% in control families and 6.7% in study families who used soap and water for washing hand and utensils. Therefore, it is very important to study this problem area in greater detail to specify the pattern of spread of infection among the family members of the affected families, identify symptomatology, role of water and possible control measure for prevention of spread within the family contacts from whom the community at large may be affected. Table of pilot work is as follows:

Group	No. of Index	No. of Contact	No. of Contact Infected	Secondary Infection Rate	Handwash Positive	Average water used daily (seer)	
						Drink + Cook	Wash and bath
Health education group	7	30	2	6.7%	-	6.09	23.43
Control Group	7	55	18	32.7%	2	4.49	17.97
		x^2 = 5.95					

3. Rationale : Shigellosis causes a high degree of morbidity mortality (5-10 times more than cholera) and a considerable loss of working hours. Multiple cases from a family or a community are frequently reported. Large number of inapparent and symptomatic infection can transmit the disease to others. For poor families or low socio-economic communities as in Dacca, shigellosis is a cause of great concern; but there is no known effective and workable preventive procedure. It has been seen that by handwash nosocomial infection and indigenous infection can be considerably reduced. Therefore, an intervention study is desirable in some affected families living in Dacca where shigellosis is occurring all the

the year round to study the efficacy of intervention in this locality as has been suggested by our pilot work.

B. SPECIFIC AIMS:

We want to answer the following questions:

1. What are the rates of intrafamilial secondary infection and cases and what age and sex groups have the highest secondary attack rates?

2. Do the quality and quantity of domestic water and use of soap effect the secondary attack rate significantly?

3. Pattern of sensitivity against antibiotics and whether the same organism in the same individual changes sensitivity pattern during the course of infection.

C. METHODOLOGY:

The confirmation of shigellosis is not obtained until third day of admission. If we wait until the third day we may miss many subsequent infections. Therefore, family study will be begun on the second day on receipt of NLF result from Microbiology branch.

The criteria for selection of cases will be as follows:-

> A case will be a patient of dysentery/diarrhea attending CRL for treatment. His stool should be associated with blood and or mucous; he is the first case in the family, has not used antibiotic for the present illness, lives in the Dacca city, has a family living with him, be co-operative. He may be of any age, sex and religion.

A Field Team will meet the patient to scrutinize the above criteria every morning and select cases for R.S. if the number of admitted cases are not sufficient. Daily 5 cases of presumptive shigellosis (in the opinion of the attending physician) will have their stool cultured. Those selected will be retained in the hospital at least for 1 night to see the culture result. In either event the patient will be discharged or retained in consideration of his condition by the CRL physicians. The patients thus selected will be divided into 2 groups. Their detailed addresses will be obtained and in some cases the attendants will be taken with the team for identifying the residence of the cases. Group A will be soap and water use group and B will be control group. The age and sex of the index will be comparable as far as possible. The symtomatology will be recorded from all while the patients are in the hospital either from the patients or from the attendants. A team of one trained male and one female field assistant will visit the families on the day of hospitalization with forms,

plates, tubes, water sampling bottles, etc. The family census forms and the socio-economic forms will be filled in the premises. After filling in the forms they will obtain R.S. on SS and MacConkey plates from all members, ask about diarrheal or dysenteric illness and take sample of domestic water in sterile empty bottles from the storage jars. The bottles will be kept in ice jars to keep it cool. They will wash the left hand fingers of the patients and shigellae positive contacts on a sterile petridish with 25 ml. G.N. broth and then pour it back to a sterile bottle. The culturing will be done using standard method in the laboratory.

In case of severe dysentery or diarrhea in any group the patient should be hospitalized. In the cases of mild to moderate diarrhea/dysentery the contacts will receive oralyte if dehydrated.

The team will supply for group A one bath and one washing soap, and 2 earthen pitchers for storing water on the first day. The second pair of soap will be supplied on the 5th day of visit or earlier. The pitcher should be filled in the morning and evening. The pitcher will be of measured size and the amount of water used from all the pitchers will be noted down on the following morning. In case of large family (over 6 members) one additional pitcher and a pair of soap may be supplied. One cheap tin mug and a soap case will also be supplied. Before supply the soaps will be divided into two pieces to ensure use. The team will ask and verify every morning whether the soap had been used on the previous day and note it down. Every day they will instruct every member to use soap and water thoroughly after defecation and before meals. Every morning the workers will note down the amount of soap used on the previous day and physically see whether they wash hands and utensils with soap and water from the pitchers. They will also see whether the pitchers are full or empty. The members should be insisted to fill the pitcher regularly for availability of ample water.

In the cases of control group B nothing should be influenced. Their ways of taking care of their sick, food, water and environment should not be interfared. No soap should be supplied for any member of group B. Serious cases should however, be encouraged to bring to CRL for treatment and other cases treated with oralyte if dehydrated.

Families living away from each other will be preferred to avoid questioning on supply of soap and pitcher. The forms should be regularly filled in with the reply of all questions in the field.

No new case will be usually taken up on holidays if there are sufficient number of families to follow. The follow up will be for 10 days as within this period almost all the subsequent infection and cases occur.

Assuming that there will be 5 members in each family and there will be some non-cooperation and dropping out at least 50 families in each group will have to be studies to show a significant difference of about 10% in the subsequent attack rates between case and control families. For analysis the age and sex distribution will be calculated. Water culture result will be analysed to see how often water is contaminated and whether new cases occur in the families after using the infected water. Socio-economic factors will be compared to see the relation of attack rates between both cases and controls. The morbidity pattern of non-hospitalized cases will be evaluated. The effect of use and not use of soap and water by the cases and controls will be tested for significance. The sensitivity of shigellae obtained from both groups will be tested to see if there is any change of resistant pattern. The data will be coded, punched, tabulated and analysed using either the IBM machine or the computer. Significance test will be done by using the X^2 test. Other relevant analysis from the data collected will be attempted.

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 hygienic practices. This will also reveal the symptomatology of milder cases which are not reported to the hospital and show the age and sex specific rate of secondary infection. All types of antibiotics including ampicillin are randomly used by local practitioners. This study will reveal the pattern of antibiotic sensitivity in different grades of cases and also change in sensitivity from one to another if any by the organism obtained from the same individual.

E. FACILITIES REQUIRED:

1. Office space: As the study would be conducted in the field no outside office space (other than CRL) will be needed. The Community Study's office will however be used.

2. Laboratory space: Laboratory work will be done in the CRL Microbiology Branch and as such no separate laboratory space is needed.

3. Hospital resources: If there are no suitable cases admitted in the CRL ward daily one or two cases may need to be hospitalized for a night from the OPD. We will however, prefer cases from the CRL admission for study. The severe cases from the study family will be admitted as usual outside cases. The mild cases will be treated in their home with oralyte.

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. One vehicle will be needed daily for about 5 hours in the morning and 3 hours in the afternoon on all the days of the week during the period of the study.

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

7. Other specialized requirements: Soap, earthen pitcher, tin mug, soap case, millipore filter paper, stool cups, G.N. broth etc. are the important special items needed for this study.

F. COLLABORATIVE ARRANGEMENTS:

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

REFERENCES

1. Mata LJ et al. J. Infect. Dis. 122: No. 3, September, 1970
2. Khan M & Mosley WH et al. (E. P. Med. J. 12: No. 2, (April 1968).
3. Dr. Craig JP, Rayer Bazar Diarrhea Morbidity Study (unpublished)
4. Khan M et al. Bangladesh Med. J. 3 : No. 2, October, 1974.
5. Khan M et al. South East Asian J. Trop, Med. & Pub. Health 6:No. 2, June, 1975.
6. Khan M et al. Unpublished observation on shigella affected families.
7. Unpublished observation on shigella mortality in CRL. Ward
8. Gangarosa et al. J. Infect Dis. 122: No. 3, September 1970.
9. Cesar A, Mandizbal Morris et al. Am. J. Trop. Med. Hyg. 20: No. 6, November, 19
10. Rahman MM et al. J. Infect. Dis. 132 : No. 1.
11. Rozenberg ML et al. Am. J. Epid. 104 : No. 5, 1976.
12. Merson MH et al. Am. J. Epid. 101: No. 2, 1975.
13. R. Irene Hutchison : Pub. Health Lab. Southampton. Office of the Med. Res.
14. Council, 38 Old Green Street, Westminster SW1.
15. Levine MM et al. Am. J. Epid. 104 : No. 1, 1976.
16. Levine MM et al. J. Inf. Dis. 127: No. 3, March 1973.
17. Jack B. Weissman et al. Lancet January 11, 1975.
18. John D. Nelson et al. Am. J. Epid. 36: No. 3, 1967.
19. Katherine Sprunt et al. Pediatrics, 52: 264, 1973.
20. Allen C. Steere et al. A...Int. Med. 83: No. 5, November, 1975.
21. MacCormack et al. WHO Bull. 38: 787 - 792, 1968.

SECTION III - BUDGET

A. DETAILED BUDGET

PERSONNEL SERVICES

	POSITION	% TIME USED	TAKA SALARY (IST YEAR) PROJECT REQUIREMENT	
Dr. M.U. Khan	Investigator	30%	18,695	
Dr. Michael H. Merson	Investigator	5%		$2,160 (approx.)
Mr. M.I. Haque	Investigator	5%	3,755	
Mr. Shahidullah	Supervisor	50%	13,008	
Mr. Dipak Kr. Barua	Field Assistant	80%	9,063	
Mrs. D. Purification	Field Assistant	80%	13,373	
Ms. Tahmina Begum	Field Assistant	80%	9,063	
One Field Assistant		80%	9,063	
Mr. Abdul Haque (Microbiology)		80%	19,066	
Mr. Nicholas (Media Room)		50%	8,694	
Mr. Mohashin (Statistics)		50%	6,672	
O.T. (approx) 20% except 1, 2, 3			17,601	
		Sub total	128,053	$2,160

2. SUPPLIES

N A M E	UNIT COST	AMOUNT	TAKA	DOLLAR
R.S: Mac. Media and plate/100	Tk. 65.00	243	15,795	-
SS media and plate/100	Tk. 85.00	243	20,655	-
Swab stick/100	Tk. 8.00	50	400	-
Water: Mac. Media and plate	Tk. 65.00	81	5,265	-
SS Media and 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
Multvit. Tab.	Tk. 90.00	5 btl.	450	
Multvit Syr.	Tk. 8.00	150 PL	1,200	-
Aspirin Tab.	Tk.100.00	5 tins	500	-
Iron tablet	Tk.100.00	1 tin	100	-
Oralyte	-	600 Pts.	-	-
Candy	Tk. 12.00	60 lb.	720	-
Balloons	Tk. 10.00	30 (packets)	300	-
Paper	-	-	1,000	-
Pencils (Ballpens)	-	-	300	-
Stencils			1,200	
IBM Cards	$ 10.03	1 pts.		10.30
Miscellaneous Stationery	-	-	1,000	-
Shigella type specific serum	-	-	-	100.00

Earthen pitcher	Tk. 4.00	100	400	
Tin/Aluminium mug	Tk. 4.00	50	200	-
Soap case	Tk. 2.50	150	375	-
Soap (washing)	Tk. 3.50	150	525	-
Soap (bath)	Tk. 3.50	150	425	-
GN Broth	$ 30.00	1	-	30.00
		Sub total	60,410	1168.30

		TAKA	DOLLAR
3.	EQUIPMENT		
	Nil		
4.	PATIENT HOSPITALIZATION		
	Day 1 x 60 cases x Tk. 135	8,100	
	Sub Total:	8,100	
5.	OUTPATIENT CARE		
	Nil		
6.	CRL TRANSPORT		
	Mileage - Dacca		
	Transport M 40 x D 360 x Tk. 3	43,200	
	Waiting charge H. 3 x D 360	3,240	
	Sub Total:	46,440	
7.	TRAVEL AND TRANSPORTATION OF PERSONS		
	Local travel	1,000	
	International travel		
	Transport		2,000
	Perdiem		500
	Sub Total:	1,000	2,500
8.	TRANSPORTATION OF THINGS		
	Transport of cards @ 25% of price		50
	Sub Total:		50

9. RENT, COMMUNICATION & UTILITIES

Postage	Tk.	100.00
Sub total	Tk.	100.00

10. PRINTING AND PUBLICATION

Printing forms	Tk.	2,100.00
Xerox cost	Tk.	500.00
Sub total	Tk.	2,600.00

11. OTHER CONTRACTUAL SERVICE

Typing charge	Tk.	1,000.00
Editing charge		$ 50.00

12. CONSTRUCTION, RESERVATION, ALTERATION

Nil

B. BUDGET SUMMARY

	CATEGORY	YEAR - 1	
		TAKA	DOLLAR
1.	Personnel	1,28,053	2,160
2.	Supplies	60,410	116,830
3.	Equipment	Nil	-
4.	Hospitalization	8,100	-
5.	Outpatients	Nil	-
6.	CRL Transport	46,440	-
7.	Travel Persons	1,000	2,500
8.	Transportation Things	-	50
9.	Rent/Communication	100	-
10.	Printing	2,600	-
11.	Contractual Service	1,000	-
12.	Construction	Nil	-
		2,47,703	5928,30

Total $ 22,205

ABSTRACT SUMMARY

SHIGELLA MORBIDITY, INTERFAMILIAL SPREAD AND HANDWASH 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 for better understanding of morbidity, pattern of interfamilial spread and whether intervention is possible by hygienic habits.

The cases will be selected for a 10 day follow up and the study will be initiated on the 2nd day of admission of the index in CRL. Rectal swab and hand wash will be cultured for 10 days, illness and socio-economic history obtained 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 2 groups : 1) Health Education & provision of soap group and 2) Control group. About 50 families in each group will be studied.

1. The population will be from all ages, sex and religion from the metropoliton area of the Dacca city.
2. No major risk is involved in this study. The obtaining of Rectal Swab is without any risk.
3. For minimising the difficulty in obtaining R.S. the Swab Sticks will be soaked in sterile saline. 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 family. They will be at liberty to withdraw at any time from 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 patient and then with the attendant of the 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 consent obtained from them. This interview may take about 15-30 minutes.
6. The diarrhea cases of the study families will receive treatment in CRL. The milder cases not admitted will also receive treatment. The health education group will learn the hygienic practices and also get soap during the period of study. If the spread can be prevented the immediate neighbourhood will be saved from the disease. This will outweigh the minor risk.
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.

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 and water for 10 days. They will ask about your health, socio-economic condition, water use, family etc. These examinations will not involve any physical or social risks. You will be offered treatment of diarrhea or dysentery either in your house or in Cholera Research Laboratory (CRL) hospital as per requirement of the patients.

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

_____

_____

Address _____

_____

Date _____

C. R. L. Case # _____

SHIGELLA MORBIDITY SPREAD AND INTERVENTION STUDIES

Water and Soap used during the preceeding 24 hours

Form No. . . . . Hospital No. . . . . .

	DRINK		COOK						
	# of Pitcher/ Jug/Tubewell/ Dekchi filled	Total seers used	# of Pitcher/ Jug/Tubewell/ Dekchi filled	Total seers used	# of Pitcher/ Jug/Tubewell Dekchi filled	Total seers used	# of Pitcher/ Jug/Tubewell Dekchi filled	Total seers used	Remark
Day 1									
Day 2									
Day 3									
Day 4									
Day 5									
Day 6									
Day 7									
Day 8									
Day 9									
Day 10									

Soap used for	Own stock 1st day	Soap supplied	1st day used	2nd day used	3rd day used	4th day used	5th day used	6th day used	7th day used	8th day used	9th day used	10th day used	Remarks
Washing													
Bathing													
Wash hands with soap after defication													

SHIGELLA MORBIDITY, INTRAFAMILIAL SPREAD AND INTERVENTION STUDIES
DATES OF HANDWASH CULTURE AND RESULT

FAMILY NO. . . . . .Hospital No. . . . . .

Sl No.	1st		2nd		3rd		4th		5th		6th		7th		8th		9th		10th	
	HW	CR	HW	CR	HW	CR	HW	CR	HW	CR	HW	CR	HW	CR	HW	CR	HW	CR	HW	CR
1																				
2																				
3																				
4																				
5																				
6																				
7																				
8																				
9																				
10																				
11																				
12																				

H.W. = Hand wash; ✓= Obtained; CR = Culture Result

SHIGELLA MORBIDITY, INTRAFAMILIAL SPREAD AND INTERVENTION STUDIES

DATES OF STOOL/R.S. COLLECTION AND RESULT

FAMILY NO.....Hospital No.....

S. No.	1st			2nd			3rd			4th			5th			6th			7th			8th			9th			10th		
	Cnd	RS	CR	Cnd	RS	CR	Cnd	RS	CR	Cnd	RS	CR	Cnd	RS	CR	Cnd	RS	CR	Cnd	RS	CR	Cnd	RS	CR	Cnd	RS	CR	Cnd	RS	CR
1																														
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10																														
11																														
12																														

Cnd = Condition of individual, 0 = No diarr/dys., 1 = Mild diarr./Dys., 2 = Moderate diarr./Dys., 3 = Severe diarr.
4 = Hospitalized, ✓ = R.S. Obtained, A = Absent, R = Refused CR= Culture Result, Dys-1; Dys-2; Dys.-3-10=Sh.Dys.T
F1, F2, F3 etc. = Sh. Flexneri types; B1-6, B7-11, B12-15 = Sh.Boyd types; Sh. Sn = Sh. Sonni
Diarrhea=At least 3 loose motion in 24 hours; Dysentery=Loose motion containing mucous, or blood or both.