REVIEW BOARD ON THE USE OF HUMAN VOLUNTEERS Date _____
CRL

Principal Investigator DR. M.U. KHAN Trainee investigator(if any) 30

Application No 78-002 Supporting Agency(if Non-CRL) _____

Title of study Shigella Morbidity Intrafamilial 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 abstra t summar 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 protect ing 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 consei 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 cou se of action.

6. If study involves an interview, describe where and in what context the intervie 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 acti

Recd 9/12/77
78-002

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 for better understanding of morbidity, 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 and the study will be initiated on the 2nd day of admission of the index in CRL. Rectal swab 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 3 groups : 1) Antibiotic prophylaxis group 2) Health Education & provision of soap group and 3) Control group. Antibiotic treatment will be for 5 days. About 40 families in each group will be studied. Culture of R. S. will be done using standard technique. The domestic water will be cultured after millipore filtration. Analysis will be done on each group.

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 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. 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 minutes.
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. 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.

SECTION I - RESEARCH PROTOCOL

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

2) Principal Investigator : Dr. Moslemuddin Khan

3) Starting Date : January 01, 1978

4) Completion Date : December 31, 1978

5) Total Direct Cost : $ 22,185 (first year)

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 drug and 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 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) Antibiotic Prophylaxis group, 2) Health education with provision of soap group, and 3) Control group. Antibiotic treatment will be for 5 days. Severe cases from the families will be hospitalized for treatment. Mild cases will be treated with oralyte and diarrhea mixture (placebo). Types and quantity of water used will be recorded daily. At least 40 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 and health education 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 enforcing washing of hands and utensiles with soap and water or by use of drugs in urban and semi-urban areas of Dacca City. The pattern of development of resistance against ampicillin will also be revealed from this study.

2. Background : In 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. etal. Jour. Infect. dis. V 122 No. 3, September, 1970). On close follow up of diarrhea occuring in families in Rayer Bazar, 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. Jorn. V : 12 No. 2, April, 1968)• Craig's Rayer Bazar diarrhea study revealed that 16% of all diarrhea occurred in families affected with shigellae. In 1970 out of all CRL admission shigella was associated with 0.6% of cases where as in 1973 over 14% of cases were associated with Shigellae (Khan M. etal. Bangladesh Med. Jorn. V : 3 No. 2, October, 1974) The over all attack rate in the St. Martin Island Epidemic was 32% and fatality rate 6.4% (Khan M. etal, South East Asian Jorn. Trop. Med. and Pub. Health V : 6 No. 2, June, 1975). In one unpublished family study (Khan M. etal) in Dacca we have found that the subsequent case rate is over 22%. 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% (Statistics of CRL. Physicians). Gangasona 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 asymptometic infections were at least as common as symptometic 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 hospitalised 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

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weeks and untreated cases took 1 - 5 weeks for full recovery. He suggested water to be a vehicle of transmission. Rozenberg, M. L. et al. (Am Jorn. Epid. V104, No. 5, 1976) found association of shigellosis with sweeming in infected water. Merson, M. H. et. al. (Am. Jrn. 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 consistant 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 prevellance of antibodies to Shiga Bacillus dysentery in the affected community ranged from 20% to 50% and many cases of dysentery had been diagnosed and treated as amoebic dysentery.

R. Irene Hutchison (Pub. Health Lab., Southampton, office of the Med. Res. Council, 38 Old Green Street, Westminster SW1) had shown that Sh. Sonnei can survive for 17 days under favourable atmospheric conditions and after visiting the water closed 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 seperation 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. Jorn. 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 hand wash with wash agent including water was effective in removing infant acquired indigenous bacteria. Allen C. Steere et. al. (Anls. Int. Med. V83, No. 5, November, 1975) advocated hand wash with soap and water for removing nosocomial pathogens. MacCormak et. al. (WHO. Bull. V : 38, P. 787 - 792, 1968) had shown that intrafamilial spread of cholera cases can be intervened by using antibiotics as prophylaxis for 5 days. Levine, M. M. et. al. (Am. Jr. Epid. V104 No. 1, 1976) reported that S. Sonnei disease disappeared from a custodial institution following vaccination.

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 intra-familial spread. The mortality rate from shigellosis is 5 - 10 times higher than cholera. Using hygeinic practices and antibiotics the spread and the rate infection can be reduced. But in an endemic

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area like Bangladesh the mode of spread, rate of morbidity by age and sex, symptomatology of unhospitalised 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 use of antibiotics, if effective, in solvent families and hygienic practices, if well taught and effective, are not impossible.

Therefore, it is very important to study this problem area 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 withing the family contacts from whom the community at large may be affected.

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 inapparant infection can transmit the disease to other. For poor families or low Socio-economic communities as in Dacca, shigellosis is a cause of great concern; but there is no known efficient and workable preventive procedure. It has been seen that by hand wash nosocomial infection and indigenous infection can be considerably reduced. It has also been found that intrafamilial spread of cholera can be checked by tetracycline prophylaxis. Therefore, an intervention study is desirable in some affected families living in Dacca where shigellosis is occurring all the year round to study the efficacy of intervention in this locality.

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

3. Is ampicillin effective in preventing secondary infection of shigellosis in the family ?

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 begin 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 at least blood and mucous; he is to be 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 and do not have amoebic infection with shigellosis. 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. and stool microscopy. Daily 5 cases of presumptive shigellosis (in the openion of the attending Physician) will have their stool cultured and microscopically examined for E. Histolytica. Cases having E. histolytica will be excluded from the study. Those selected will be retained in the hospital at least for 1 night to see the culture result. In either case of a positive or negative culture result the patient will be discharged or retained in consideration of his condition. This will be decided by the CRL Physicians. The patients thus selected will be divided into 3 groups. Their detailed addresses will be obtained or in some cases the attendants will be taken with the team for identifying the residence of the cases. Group A will be Antibiotic therapy group; B will be soap and water use group and C will be control group. The age and sex will be matched between the three groups as far as possible. The symptometology of illness will be recorded from all the groups independant of Physicians while the patients are in the hospital either from the patients or from the attendants in case of children. A team of one trained male and one female field assistant will visit the families on the day after patient seen at CRL(day 1) with forms, plates, tubes, water sampling bottles etc. The family census forms and the Socio-economic forms will be filled in the premises of the cases where verification of certain items, like source of water, latrine, rooms etc. are possible. The size of the rooms used for living will be measured. After filling in the forms they will obtain R.S. on SS and Mac Conkey 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 shigella 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.

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Antibiotic group A. Out of all the antibiotics Ampicillin is the best for shigella though a few cases (0 - 10%) may be registant to it. The cost is cheaper than some other antibiotics. Although it has certain disadvantages like reactions and development of registance the drug is being used at random outside CRL. Considering the unrestricted use outside if we use the drug for 40 families it will add only a fraction of its disadvantages to the members; but we will provide best treatment. History of penicillin reaction will be obtained before use of drug. It is stated that if there is any reaction it will be very severe following a large single dose than a small dose. The prolong use also will have the chances of combating new infection at least during the first 5 days when majority of the subsequent infections appear. The team will feed the morning dose (2 caps, 250 mgm. each for adult, 1 for children between 10 to 15 and suitable dose of syrup for infants). The evening dose will be left in the house with sufficient instructions for use. Next morning members should be enquired whether they used the previous dose. The team will also ask for any skin reaction and in case of mild reaction the drug should be stopped and antihistamin (phanergan/Banistyl; tab/syrup) administered and in case of severe reaction the case is to be hospitalised immediately. All isolates will be tested for sensitivity and if any isolate is found to be resitant to ampicillin the family should be dropped and offered alternative therapy (Bactrim).

In case of severe dysentery or diarrhea from any group the patient should be hospitalised. In the cases of mild to moderate diarrhea/dysentery the contacts of all cases will receive oralyte and diarrhea mixture. If the diarrhea cases are not positive for any of the shigellae their stool should be brought for microscopical examination.

The team will supply for group B 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 6th day of visit. 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 verified and noted on every visit. In case of large family (over 8 members) one additional pitcher and a pair of soap, may be supplied. One cheap tin mug and half pair of soap case will also be supplied. Before supply the soaps will be divided centrally into two pieces to ensure use and to check selling. The team will verify everyday whether the soap has been used on the previous day and note it down. Every day they will instruct every member to use soap and water throughly. Whether the members follow the instructions will be verified every afternoon by the workers incharge of selection of cases in the morning. He will note down the amount of water and soap used and physically see whether they wash hands and utensils with soap and water from the pitchers. He will also see whether the pitchers are full or empty. The members should be insisted to fill the pitcher in the afternoon in the presence of the CRL worker.

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In the cases of control group C nothing should be influenced. Their ways of taking care of their sick, food, water and environment should not be interfared. No soap or antibiotic should be supplied for any member of group C.

Diarrhea mixture (B. P.) will be prepared in the CRL pharmacy. Families at least a short distance away from each other will be followed to avoid questioning on supply of soap and antibiotics. The forms should be regularly filled in with the reply of all questions. There should be record of sharing bed, food and cloths by the members.

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

Assuming that there will be 5 members in each family and there will be some non-cooperation and dropping at least 40 families in each group will have to be studied to show a difference of about 10% in the subsequent attack rates between case and control families. For analysis the socio-economic data will be first compared between cases and controls. 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. Various socio-economic factors will be tested to see the relation of attack rates between both cases and controls. The morbidity pattern of un-hospitalised 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 effectiveness of antibiotics will be analysed and compared between cases and controls. The sensitivity of shigellae obtained from both controls and antibiotic groups will be tested against ampicillin to see the development of resistant pattern. The data will be punched, tabulated and analysed using either the IBM machine or the computer. Significance test will be done by using the X^2 test. Other relavant analysis from the data collected will be attempted.

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. All types of antibiotics including ampicillin are randomly used by local practitioners. This study will reveal the pattern of developing ampicillin resistance if any.

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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 hospitalised for a night from the OPD. We will however, select 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 and diarrhea mixture..

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, swab sticks, paper, pencils, candy, ballons, aspirin, oralyte, diarrhea mixture, vitamins, etc. will be needed.

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

COLLABORATIVE ARRANGEMENTS

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

SECTION III - BUDGET

A. DETAILED BUDGET

PERSONNEL SERVICES

NAME	POSITION	% TIME USED	TAKA SALARY (1ST 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. Hazera Khatun	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

NAME	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
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 Tab.	Tk.100.00	5 tins	500	-
Iron tablet	Tk.100.00	1 tin	100	-
Oralyte	-	600 packets	-	-
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 packet	-	10.30
Miscellaneous stationery	-	-	1,000	-
Shigella type specific serum	-			100.00
Earthen pitcher	Tk. 4.00	100	400	-
Tin/Aluminum mug	Tk. 4.00	40	160	-

Soap case	Tk.	2.00	40	80	-
Soap (washing)	Tk.	2.50	100	250	-
Soap (bath)	Tk.	3.50	100	350	-
Stool cups	@ $	0.04	200		8.00
Stool microscopy	@ Tk.	4.00	200	800	-
GN Broth	$	30.00	1	-	30.00
			Sub total	64,507	1,652.34

3. EQUIPMENT

Nil

4. PATIENT HOSPITALIZATION

Day 1 x 60 cases x Tk. 135 = Tk. 8,100

5. OUTPATIENT CARE

Nil

6. CRL TRANSPORT

Milcage - Dacca

Transport M 40 X D 360 X Tk. 1.4	=	Tk.	20,160
Waiting charge H.3 X D 360	=	Tk.	3,240
Sub-total		Tk.	23,400

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% of price		$ 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.	2,100.00
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, RENOVATION, ALTERATION

Nil

B. BUDGET SUMMARY

	CATEGORY	YEAR - 1 TAKA	DOLLAR
1.	Personnel	1, 28, 053	2, 160
2.	Supplies	64, 507	1, 653
3.	Equipment	Nil	-
4.	Hospitalization	8, 100	-
5.	Outpatients	Nil	-
6.	CRL Transport	23, 400	-
7.	Travel Persons	1, 000	2, 500
8.	Transportation Things	-	100
9.	Rent/Communication	100	-
10.	Printing	2, 600	-
11.	Contractual Service	1, 000	50
12.	Construction	Nil	-
	Total :-	2, 28, 760	6, 463

Total $ 22, 185

REFERENCES

1. Mata LJ et al. J. Infect. Dis. 122: No. 3, September, 1970.
2. Khan M & Mosely 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, 1971
10. Rahman MM et al. J. Infect. Dis. 132: No. 1.
11. Rozenberg MI. 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.

NTERVENTION STUDIES Form-1

Date of Onset_____ Time_____

P. S. _____

Domestic Practices

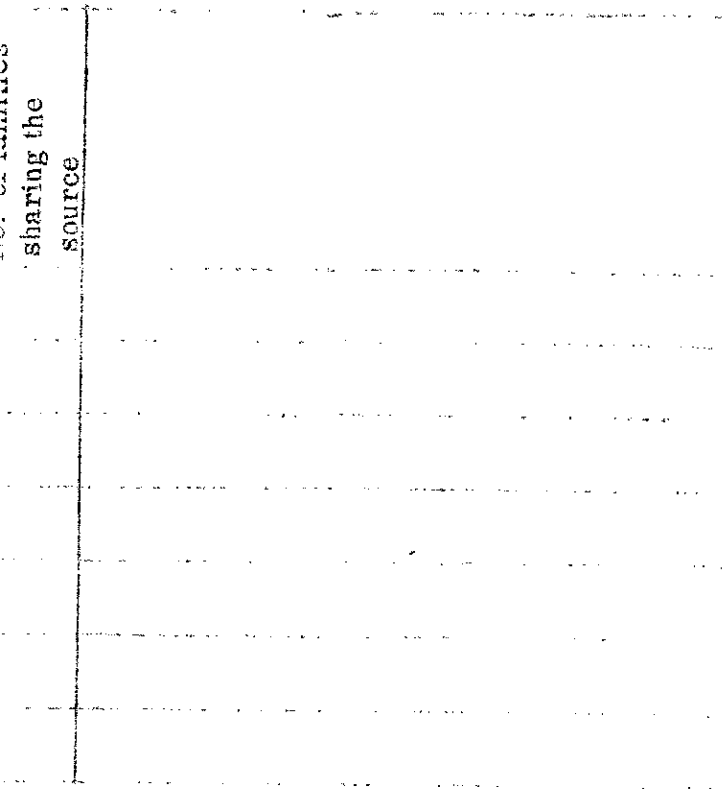
Shares meal in same plate	Prepares food	Feeds Children with hand	Distributes Food	Draws Water	Washes Utensils	Washes soiled Clothes	Washes Kid's Buttocks	Buthes Children

SHIGELLA MORBIDITY, INTRAFAMILIAL SPREAD AND

FAMILY NO..... FAMILY VISIT FORM

Hospital No._____ Diagnosis_____ Date of Admission_____ Time____
Village/Street_____ Land Mark_____

Indv. No.	A. Antibiotic gr. B. Health Edn. gr. C. Control gr. Name	Age	Sex	Relation with Head	Occupation of the Individuals	Diarrhea in last 5 days 5	4	3	2	1	Shares Lungi/ Shari	Indv. sleeps
1 (Indx)												
2												
3												
4												
5												
6												
7												
8												
9												
10												



Latrine cleaned by			
shing ater	Pouring water	Removed by sweeper	None

SHIGELLA MORBIDITY, INTERFAMILIAL SPREAD AND INTER
WATER AND LATRINE

FAMILY NO.....INDEX NO.....

Sources of Domestic Water	Location		Distance from Kitchen	Type of use						Place of wash			Place of bath			Source of
	Within Compound	Outside Compound		Drink	Cook	Wash vegetable & food	Wash utensils	Wash Soiled linen & dirty things	Bath	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						Distance from Kitchen
	Sanitary closed	Sanitary open	Service Latrine	Open pit Latrine	Temporary fencing	None fixed	
Adult Male							
Adult Female							
Children							
All							

Bathing

Pitcher full	Pitcher empty	Quan used	Quan. now left	Sample taken

8th day used	9th day used	10th day used

Shigella Morbidity Spread and Intervention Studies
Water and Soap Inspection Form

Fam No. Index No.

	Drink(Put No & Quan in seers)				Cook				Wash			
	Pitcher full	Pitcher empty	Quan. used	Quan. now left	Pitcher full	Pitcher empty	Quan. used	Quan. now left	Pitcher full	Pitcher empty	Quan. used	Quan. now
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
Washing									
Bathing									
Both									
Wash hands*									
*with soap after defec									

TERVENTION STUDIES

SULT

	7th			8th			9th			
R	Cnd	RS	CR	Cnd	RS	CR	Cnd	RS	CR	Cnd

, 3 = Severe diarr. /Dys., 4 = Hospitalized.
Sh. Dys. Types; F1, F2, F3 etc. = Sh. Flexneri types:

ood or pus or both.

SHIGELLA MORBIDITY, INTRAFAMILIAL SPREAD ANI

AMILY NO. . . . . INDEX NO. . . . . DATES OF STOOL/R.S. COLLECTION AND

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

Cnd = Condition of individual, O = No diarr/dys., 1 = Mild diarr./Dys., 2 = Moderate diarr./D
✓ = R.S. Obtained, A = Absent, R = Refused, CR = Culture Result, Dys.-1, Dys.-2, Dys. 3-
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

Form - 5

the time of study)

ark all applicable)

rvice/Business
iving/Rickshaw pulling
king/Day labourer
tting House
tty business
riculture
nestic servant
ner
arity

rs in the Family

e Head Tk

ner Tk

Tk

Shigella Morbidity Spread and Intervention Studies
Socioeconomic Form

Residence

	Room 1	Room 2	Room 3	Room 4	Kitchen
Size					
Floor					
Wall					
Roof					
No. Living in the room					
Any attached bath?					
Electrified					
Total no. of rooms					
Own house					
Yes					
Rented					
Monthly rent	Tk				

Economic Status (

Source of income

No. of Earning Me

Monthly Income of

Monthly Income of

Total monthly inc

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 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. #_____

সম্মতি পত্র

বিগত কয়েক বৎসরে ঢাকা ও বাংলাদেশের নানাস্থানে আমাশয় জাতীয় রোগ বহুগুনে বেড়ে গেছে, সেটা সরকারের ও একটি সমস্যা, কলেরা গবেষণাগারের বিজ্ঞানীরা এর বিস্তারের কারণ ও প্রতিরোধের উপায় গবেষণা করছেন, এই প্রচেষ্টা দেশ ও দশের জন্য প্রয়োজন।

এইজন্য কয়দিন (৩০ দিন) আপনাদের মলদ্বারের মল ও বাসস্থ ব্যবহারের সব রকমের পানি পরীক্ষা করা হবে, এছাড়া আপনাদের - স্বাস্থ্য, পারিবারিক অবস্থা, পানির ব্যবহার ইত্যাদি - জানা দরকার, এইসব পরীক্ষায় আপনাদের কারোরিক বা আর্থিক কোন ক্ষতি হবেনা, উপরন্তু আপনাদের পেটের অসুখ বা আমাশয় হলে কলেরা হাসপাতালে বা আপনাদের বাসস্থ থেকে ও চিকিৎসার সুযোগ পাবেন।

এই পরীক্ষা কার্যের জন্য আপনি সম্মত হলে ও যেকোন সময় সহযোগীতা প্রত্যাহার অধিকার আপনার অক্ষুণ্ণ থাকবে, অবশ্য এহতে কলেরা হাসপাতালে চিকিৎসা পেতে আপনার কোন অসুবিধা হবেনা, আপনি এই মানবতার কাজে সহযোগীতা করায় সম্মত হলে নিম্নে স্বাক্ষর অথবা টিপ সই দিন।

আপনি আমার পক্ষে/পরিবারের পক্ষে - যেখানে সই দিলাম

নাম —
ঠিকানা —
ঠিকানা —
তারিখ
হি. আর. ঐল. রোগী নং —