Attachment 1.

Date July 20, 1982

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator DR.A.H.BAQUI

Trainee Investigator (if any)

Application No. 82-032 (Rev)

Supporting Agency (if Non-ICDDR,B)

Title of Study ICDDR,B Surveillance Program - Matlab Hospital.

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 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 NA Yes No
   (d) Sensitive questions NA Yes No
   (e) Benefits to be derived (Yes) No
   (f) Right to refuse to participate or to withdraw from study (Yes) No
   (g) Confidential handling of data (Yes) No
   (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure NA 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 Cttee. for review.

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

Mabaqui

Principal Investigator

Trainee

SECTION I - RESEARCH PROTOCOL

1. Title : ICDDR,B Surveillance Program - Matlab Hospital.

2. Principal Investigator : Dr. A.H. Baqui

   Co-Investigators : Dr.K. Zaman, Dr. N.S. Shahid, Dr. E. Haque, Dr. A. Mitra, Dr. Giasuddin, Mr. B. Hossain & Mrs. H. Banu.

   Consultant/Adviser : Dr. A.R. Samadi

3. Starting Date : October 1, 1982.

4. Completion Date : To be continued as long as the Institute requires.

5. Total Incremental Cost : US$ 11,204.30

6. Scientific Program Head

This protocol has been approved by the Disease Transmission Working Group.

Signature of Scientific Program Head : A.Samadi

Date : 20/7/1982

7. Abstract Summary :

Since 1963 the Matlab Field Station of ICDDR,B (Formerly, The Cholera Research Laboratory) has been conducting health research and providing health services in a well defined surveillance area. Matlab Treatment Centre, located at Matlab Bazar provides free therapy to any patient with diarrhoea who reports directly to the Treatment Centre, an average of 10,000 patients annually. Approximately 40% of these patients reside in the surveillance area, the rest come from outside of this area. Rectal Swab cultures are obtained routinely from surveillance area patients.

Patients from outside the area receive routine treatment, but to date, there has been no attempt to study these patients in depth. The current budget does not permit us to study each of these patients in depth.

Because the Matlab Field Station of ICDDR,B has conducted a series of Socio-demographic, epidemiological and nutritional studies and provided health services for surveillance area residents, it cannot be assumed that the spectrum of diarrhoeal disease at Matlab surveillance area is still typical of rural Bangladesh. For this reason, we have chosen to study a systematic sample, 10% of all admissions, including both patients from the surveillance area and from outside. We propose to compare these two groups of patients to determine if there are significant differences between them. This study will help us to better understand the disease spectrum in the patient population we treat, to assess the quality of care we now provide and to generate new ideas for future research.

During the study, treatment will be provided to all patients as usual, by the usual hospital staff, with emergency cases treated on a priority basis. The study population will be selected by systematically sampling 10% of all patients admitted to the Treatment Centre. A questionnaire will be administered to sample patients by a health assistant and a physician will perform a detailed physical examination. Patients in the sample will also be studied with additional laboratory tests and anthropometry. Information on hospital course and outcome will be systematically collected.

8. **Reviews :**

a. **Ethical Review Committee :** _____

b. **Research Review Committee :** _____

c. **Director :** _____

d. **BMRC :** _____

e. **Controller/Administrator :** _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objective :

Each year, an average of 10,000 patients are admitted to the Matlab Diarrhoea Treatment Centre of ICDDR,B. In depth study of each patient is neither practical nor possible given the current budgetary constraints. The objective of this protocol is to establish a hospital surveillance system to evaluate detailed clinical, epidemiological and microbiological data from a systematic sample of all Matlab Treatment Centre patients. The surveillance data will be analysed on an ongoing basis:

i. To permit early recognition of seasonal or localised diarrhoeal outbreaks.

ii. To monitor the principal aetiologic agents of diarrhoea and detect any changes in their nature or prevalence.

iii. To generate clinical descriptive data for each aetiologic agent which will assist physicians and paramedics in diagnosis and case management.

iv. To measure the prevalence and describe the epidemiology of certain common conditions which are associated with or are complications of diarrhoea.

v. To analyse the spectrum of diarrhoeal disease among patients who reside outside the Demographic Surveillance System (DSS) area and compare them with the patients who reside in the

DSS area. Non-DSS patients have never been systematically studied inspite of the fact that they account for approximately 60% of the total Treatment Centre admission.

vi. And finally to generate new questions for future research.

2. Background :

Diarrhoea - particularly childhood diarrhoea is a major cause of morbidity and mortality in developing countries. [1,2] Since 1963 the Matlab Field Station of ICDDR,B (Formerly, The Cholera Research Laboratory) has been conducting health research and providing health services in Matlab Thana, Comilla District, a rural area of Bangladesh. One component of this field program is a longitudinal Demographic Surveillance System (DSS). This system consists of periodic censuses with intervening registration of births, deaths, migrations, marital unions and dissolutions in the study population. The demographic surveillance population is 1,80,000 and includes 149 villages. The Matlab Diarrhoea Treatment Centre, located at Matlab Bazar, provides free therapy to any patient with diarrhoea who reports directly to the Treatment Centre. The actual catchment area of the Treatment Centre extends far beyond the boundaries of the demographic surveillance area, drawing patients from radius of approximately 30 kilometers or more. At the present time, approximately 40% of the Centre's patients reside in the demographic surveillance area; the remaining 60% are from outside this area. (In 1981, 65% of patients were from outside - calculated from Hospital admission register).

The epidemiology, clinical characterstics, etiologic agents and treatment of diarrhoeal diseases seen at ICDDR,B has changed during its years of

operation. Between 1973 and 1974, there was a shift in the predominant biotype of Vibrio cholerae from the virulent classical biotype to the less severe El Tor biotype.[4] In December 1979, a Vibrio cholerae 01 resistant to Tetracycline, Ampicillin, Kanamycin, Streptomycin and Trimethoprim - sulphamethoxazole was isolated from a patient at Matlab Hospital. All 256 isolates of V. cholerae 0:1 stocked in the previous six months were tested for antibiotic sensitivity. 54 (21%) were resistant to Tetracycline and 44 (17%) of these were resistant to all five antibiotics mentioned above. A resistance plasmid was identified.[5] The emergence of Multiple Antibiotic Resistant Vibrios (MARV) created a difficult treatement problem for clinicians since the patients with the resistant strains purged longer and in greater volume.

There have been similar changes in other diarrhoea-causing agents. In the 1960's most Shigella isolates were Shigella sonnei. There were few Shigella flexneri and no Shigella dysenteriae type I. In 1970, Shigella dysenteriae type I was isolated for the first time, and by 1973, had incrased in frequency until it constituted about two-thirds of all Shigella isolates.[6] Though the number of Shigella dysenteriae has subsequently decreased cases are still identified. Since 1974, there has been an increasing number of Shigella flexneri isolates. At present, Sh. flexneri is the predominant species isolated from Matlab patients (based on a review of rectal swab cultures from hospitalized patients, 1974 - present). Antimicrobial resistance of Shigella, particularly Sh. dysenteriae type 1, was first noted in 1974 in Bangladesh.[7] Mutanda (1981) found that 6% of 87 Shigella isolates in 1979 were resistant to Ampicillin. In a recent study at

Matlab Treatment Centre, 7% of 118 Shigella isolates tested were Ampicillin-resistant and 3% were resistant to Trimethoprim-sulpha-methoxazole[8]. The abuse and overuse of antibiotics by village practitioners may have contributed to the increase in antibiotic-resistant strains in rural Bangladesh. Because this overuse is continuing, the situation must be monitored and alternative antibiotics may soon be needed.

While classic bacterial pathogens cannot be isolated from most patients with diarrhoea, recent studies indicate that Enterotoxigenic Escherichia coli (ETEC) and rotaviruses are important etiologic agents[9-11]. A two-year study of bacterial, viral and parasitic agents associated with diarrhoea in rural Bangladesh was conducted at Matlab Treatment Centre during 1977-78 by Black RE et al[11]. ETEC was the most frequently identified pathogen for patients of all ages. Rotavirus was isolated from 50% of patients less than two years of age. A bacterial or viral pathogen was identified for 70% of these young children and for 56% of all patients with diarrhoea. However, this study included only patients who resided in the DSS area.

In August 1979, Campylobacter was first isolated at ICDDR,B. Eight isolates were identified from 105 patients with bloody mucoid diarrhoea[12]. To determine the prevalence of infection with Campylobacter jejuni in Bangladesh, culture surveys of three populations were conducted. In Dacca, Campylobacter was isolated from 5.2% of 97 individuals with clinical dysentery and from 13.3% of 204 patients with diarrhoea. This differences may have resulted from the greater population of young

children in the second group. Campylobacter was also isolated from 17.7% of the healthy village children aged 1 to 5.5 years and from 38.8% of the 1 year old children. More infected children (48%) had a history of recent diarrhoeal ~~illness~~ than did a group of matched controls (20%). These findings suggest that Campylobacter infection is common in Bangladeshi children.[13] Although there is an Association with diarrhoea, the presence of this organism in many healthy children raises significant questions of interpretation. A possible explanation is that Campylobacter isolates that have been identified is not a single organism but a group of related organisms, only some of which are pathogenic.[14]

There is currently no systematic monitoring of these agents at Matlab Treatment Centre. The only surveillance activity ongoing at present is routine rectal swab culture of all patients who reside within the DSS area. Rectal swabs are cultured for the classical bacterial agents only (i.e., Vibrios, Shigella, and Salmonella). Routine cultures are not obtained from hospitalized patients who reside outside the DSS area. Inspite of the fact that these patients represent a majority (60%) of the patient population. These non-DSS area patients have never been systematically studied.

Ongoing hospital surveillance should detect changes in the occurance of the established pathogens and help to clarify the roles of the newly recognised ones. A properly functioning surveillance system that detects changes in the pattern of illness, seasonal incidence and severity of cases will also serve to provide early warning of the threat of epidemics indicating need for epidemiological investigations, reinforcement of treatment and sanitation facilities and institution of control measures.

3. Rationale :

In August 1979, Dr. R. Wilson initiated a pilot surveillance system at the ICDDR,B Treatment Centre in Dacca in order to monitor and to better characterise the enteric pathogens in an urban Bangladeshi facility. The pilot project established that such as system is both workable and useful. Since than, Dr. B. Stoll and others have been conducting surveillance of urban diarrhoeal patients at Dacca Station.

We propose to implement a surveillance system at Matlab that is similar to the system currently in place in Dacca, a system which integrates more extensive microbiological surveillance with better personal and clinical data from all (rather than a select group) of Treatment Centre patients. Because of the obvious differences in living conditions (e.g., socio-economic status, housing, sanitation and water sources) between urban and rural settings, the epidemiological, clinical and microbiological data are likely to be different. Consequently the need for a separate and independant surveillance system is indicated for the rural Treatment Centre.

Since its inception, the Matlab Field Station of ICDDR,B has conducted several cholera vaccine field trials and a series of socio-demographic, epidemiological and nutritional studies within the DSS area. In addition Matlab Station has provided health services to residents of the DSS area. To-day, microbiological surveillance of hospitalized DSS area patients continue while the majority of the Treatment Centre patients (i.e., those who reside outside the DSS area) have never been systematically studied. Because of the numerous studies and interventions in the DSS

area, it may no longer to be correct to assume that patients from this area are representative of the total patient population. The surveillance system proposed here includes non-DSS area patients in sampling frame and provides for future comparisons of the spectrum of diarrhoeal diseases in the two groups.

B. SPECIFIC AIMS:

1. To establish ongoing surveillance of all patients seen at Matlab Hospital, ICDDR,B irrespective of their area of residence, by concentrated study of a systematic sample similar to that of Dacca Hospital.

2. To outline the causative organisms of diarrhoeal illness seen at Matlab Hospital in relation to age, sex, season and clinical aspects.

3. To collect information on the use of oral rehydration and the effect of oral rehydration and to follow the course of treatment in Matlab Hospital.

4. To collect information on important socio-economic factors relating to diarrhoeal diseases.

5. To determine whether any significant differences in the disease pattern exist between the DSS - resident patients and the non-DSS patients.

C. METHODS AND PROCEDURE

Patients for study will be selected by a 10% systematic sampling of all patients hospitalized at the Matlab Treatment Centre, ICDDR,B (i.e., every tenth admission). Since the hospital assigns each patient a 6 digit hospital number, in sequence, on admission, the patients in the sample group will be those who have a "0" as the terminal digit of their assigned number. Using this method, it will be unnecessary to flag the medical record in a way that would be obvious to the medical staff. All patients will receive routine care as provided by the paraprofessionals and physicians in the Treatment Centre. No attempt will be made to influence care.

Only after the patient is seen by the clinic personnel and the initial decisions about the treatment are made will informed consent be obtained from the patient (or his/her parent) and the initial interview be conducted by the Health Assistant. The surveillance team will not discuss the interview findings with any of the paraprofessional personnel who are providing direct patient care. Study assistants will be on duty from 8:30 A.M. to 5:00 P.M. Sample patients who arrive at the Centre between 8:00 A.M. and 4:00 P.M. will be interviewed in the order in which they arrive. Sample patients who arrive between 4:00 P.M. and 8:00 A.M. will be treated as usual and will be interviewed by a study assistant the following morning. The study assistant will administer a detailed questionnaire to collect personal data and information about the signs and symptoms of the present illness, prior medical history and previous therapy (see Appendix-I).

A detailed physical examination including vital signs, admission weight, state of hydration, signs of vitamin deficiency, malnutrition and detection of other associated infections or complications will be performed by a physician (see Appendix - I). Information on therapy and hospital course will be collected and recorded by a study assistant. Anthropometry including height, weight and arm circumference will be done prior to discharge to accurately assess the severity of initial dehydration (dehydration as a per cent of body weight = discharge weight - admission weight ÷ discharge weight) and to assess the nutritional status of the patients.

Freshly passed stool will be collected from each sample patient for microscopic examination (M/E) in saline and iodine preparation. If, for any reason, stool cannot be collected, specimens will be obtained by rectal catheter. Since the clinical pathology section closes at 5:00 p.m. specimens from patient who arrive after 5:00 p.m. will be collected in MIF solution for ME to be performed the following morning. Rectal swab (RS) will be collected from each patient for culture. All specimens will be plated immediately and incubated. Culture specimens will be processed for pathogenic vibrios, Shigella and Salmonella using standard methods. Vibriolike colonies identified on trypticase-tellurite-gelatin plates will be further characterized in terms of biochemical, serotypic and salt tolerance properties and will be classified as Vibrio cholerae group 0:1, non-group 0:1 vibrios, Vibrio parahaemolyticus, or group F vibriolike organisms[15,16]. From each culture, 10 lactose-positive colonies with typical E. coli morphology will be saved from MacConkey's agar plates and

will be pooled on nutrient agar slants. These pools will be tested with the chinese hamster ovary cell assay for heat-labile toxin (LT) and with the infant mouse assay for heat-stable toxin (ST)[17,18]. A portion of specimen from every fourth surveillance patient will be inoculated onto a Campy-BAP medium (Brucella agar base, with 5% sheep blood and the following antimicrobial concentrations per litre: vancomycin, 10 mg; trimethoprim, 5 mg; polymyxin B, 2500 I.U; amphotericin B, 2 mg; and cephaltothin, 15 mg) for isolation of Campylobacter. All plates will be incubated in candle jars, at 42°C, for 48 hours. Identification of organisms as Campylobacter jejuni will be done according to standard criteria[19]. A second rectal swab will be taken from each under five patient and will be refrigerated in phosphate-buffered saline for subsequent testing by modified enzyme linked immunosorbent assay (ELISA) for rotavirus antigen[18,20,21].

The data collected will be kept separate from the regular hospital records. Questionnaire form will be precoded and data will be entered into the computer at the end of each month. Monthly data analysis will be performed by hand, at Matlab. The investigators will tally the sample patient data at the end of each month by age, sex, community of residence (study area, comparison area, non-DSS areas) and by presentation (watery diarrhoea dysentery, others). In addition, a monthly listing of enteric pathogens will be compiled. Periodic reports will be circulated to the hospital staff. For comparison of DSS area patients and non-DSS area patients, the annual data will be stratified according to the distance from residence to hospital. The groups will also be compared by age, sex, socio-economic status, and clinical presentation to determine whether further stratification is needed to assure a valid comparison of the frequency of individual pathogens

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in the two groups.

D. SIGNIFICANCE

The surveillance activity will generate a wide range of data on patients seen at Matlab Treatment Centre, ICDDR,B. These data are essential to understand the patient population we see, to assess the quality of care and outcome of treatment we now provide and to help to generate new research ideas. This study is also essential to see any difference between the two groups of patients (i.e. DSS area patients and non-DSS area patients). This study will provide a comparable data set between the urban and rural diarrhoeal patients. After the surveillance system is established, other protocols may be linked with basic data collection system. The findings of this surveillance activity will be of great interest to health personnel in Bangladesh as well as in other countries.

E. FACILITIES REQUIRED

1. No new office space is needed.

2. Personnel - Supervisor, Study Physician - The Investigators themselves supervise and perform the job of study physician - part-time.

3. No new laboratory space is needed.

4. Hospital support - No new facility required. The study will utilize the current facilities that are presently offered to patients by ICDDR,B.

5. Animal resource - fpr ST and LT determinations, approximately 50-100 mice will be needed per month.

6. Logistic support - None

7. Major items or equipments - No major item or equipment will be needed except the reagents for ELISA assay and mice for ST and LT determinations.

8. Other special requirements - culture materials, medicine, computer tapes and stationery will be needed.

F. COLLABORATIVE ARRANGEMENTS

Collaboration with outside institute or scientists is not needed at present.

REFERENCES

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2. ICDDR,B Annual Report, 1979.

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5. Glass RI, Huq I, Alim ARMA, Yunus M. Emergency of multiple antibiotic resistance Vibrio cholerae in Bangladesh. J Infect Dis. 142 (6): 939-942. Dec. 1980.

6. Khan MU and Curlin G, Shigella dysentery: A New Health Hazard in Bangladesh. Bangladesh Med J. 3:42 (1974).

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21. Yolken RH, Wyatt RG, Kapikian AZ. ELISA for rotavirus (letter). Lancet 2:819, 1977.

SECTION III - BUDGET

A. DETAILED BUDGET

1. PERSONNEL SERVICES

Name	Position	% Time used	Salary (first year) Taka	Dollar
Dr. A.H. Baqui	Prin. Investigator	20%	11,500	-
Dr. K. Zaman	Co-Investigator	10%	4,580	-
Dr. N.S. Shahid	Co-Investigator	10%	8,512	-
Dr. Emdadul Haque	Co-Investigator	10%	4,580	-
Dr. Amal K. Mitra	Co-Investigator	10%	3,820	-
Dr. Giasuddin	Co-Investigator	10%	3,820	-
Dr. B. Hossain	Co-Investigator	10%	3,000	-
Mrs. Hasina Banu	Co-Investigator	10%	5,594	-
To be named	Health Assistant (3)	100%	54,000	-
To be named	Programmer (1)	10%	6,000	-
		Sub Total :	105,106	

2. SUPPLIES AND MATERIALS

Item	Unti Cost	Taka	Dollar
Stool culture	365 x 3 x 30	32,850	-
Rotavirus assay	365 x 3 x 10	10,950	-
E. coli toxin (ST, LT)	365 x 3 x 14	15,330	-
Stool microscopy	365 x 3 x 10	10,950	-
Stationery, form etc.		10,000	-
Medicine		5,000	-
Miscellaneous		500	-
	Sub Total :	85,580	-

3. EQUIPMENTS - None

4. PATIENT HOSPITALIZATION

For this study no special patient hospitalization is needed.

5. OUTPATIENT CARE - None

6. ICDDR,B TRANSPORT - None

	Taka	Dollar
7. TRAVEL AND TRANSPORTATION OF PERSONS		
Local Travel	5,000	-
International Travel	-	-
Sub Total :	5,000	-
8. TRANSPORTATION OF THINGS	2,000	-
9. RENT, COMMUNICATION AND UTILITIES - None		
10. PRINTING AND PUBLICATION		
Forms, Xerox	5,000	-
Special reproduction	5,000	-
Publication	-	300
Sub Total :	10,000	300
11. COMPUTER COST		
Computer time will be required as follows :		
Data entry @ Tk. 20.00/hr. - 15 x 20 x 12	3,600	-
Terminal time @ Tk. 20.00/hr. - 10 x 20 x 12	2,400	-
Computer time @ Tk. 20.00/hr. - 10 x 20 x 12	2,400	-
Sub Total :	8,400	-
12. OTHER CONTRACTUAL SERVICES - None		
13. CONSTRUCTION, RENOVATION, ALTERATION - None		

BUDGET SUMMARY

	Category	Taka	Dollar
1.	Personnel Services	105,106.00	-
2.	Supplies and Materials	85,580.00	-
3.	Equipments	-	-
4.	Patients Hospitalization	-	-
5.	Outpatient Care	-	-
6.	ICDDR,B Transport	-	-
7.	Travel and Transportation of Persons	5,000.00	-
8.	Transportation of Things	2,000.00	-
9.	Rent, Communication and Utilities	-	-
10.	Printing and Publication	10,000.00	300.00
11.	Computer Cost	8,400.00	-
12.	Other Contractual Services	-	-
13.	Construction, Renovation, Alteration	-	-
	Total:	216,086.00	300.00

Conversion Rate US$ 1.00 = Tk. 20.00

Grand Total US$ 11,204.30

ABSTRACT SUMMARY

Matlab Diarrhoea Treatment Centre of ICDDR,B treats an yearly average of 10,000 patients. Approximately 40% of these patient population reside in the Matlab Demographic Surveillance System (DSS) area and the rest come from outside. Rectal swab cultures are obtained routinely from surveillance area patients. Patients from outside the area receive routine treatment. but to date, there has been no attempt to study these patients in depth. In depth study of each of these patient is neither practical nor possible given the current budgetary constraints. However, this data is very much importnat to understand the disease spectrum in the patient population we treat, the assess the quality of care we now provide, and to stimulate new ideas for future research.

For that reason we propose to implement a surveillance system at Matlab that is similar to the system currently in place in Dacca, a system which integrates more extensive microbiological surveillance with better personal and clinical data. Because of the obvious differences in the living conditions (e.g. socio-economic status, housing, sanitations and water sources) between the urban and rural settings, the epidemiological, clinical and microbiological data are likely to be different. Consequently the need for a separate and independant surveillance system is indicated for the rural treatment centre.

Since its inception, the Matlab Field Station of ICDDR,B has conducted a series of studies and intervention programs in the Matlab DSS area. Because of these numerous studies and interventions it may no longer be correct to assume that Matlab DSS area is still representative of rural

Bangladesh. For this reason we have chosen to study a systematic sample, 10% of all admissions, including both patients from the DSS area and outside. We propose to compare these two groups of patients to determine if there are significant differences between them.

During the study, treatment will be provided to all patients as usual, by the usual hospital staff, with emergency cases treated on a priority basis. A special questionnaire will be administered to sample patients by a health assistant and a physician will perform a detailed physical examination. Patients in the sample will also be studied with additional laboratory tests and anthropometry. Information one hospital course and outcome will be systematically collected.

1. It will be necessary to include children in the study as they form a bulk of patients coming in with diarrhoea. Verbal consent will be taken from parents or guardians.

2-3. No risk involved.

4. Complete confidentiality will be maintained. All patients will be given a study number.

5. Because there are no risks to the patient, only verbal consent will be obtained.

6. Approximately 15-20 minutes will be required to interview each patient. This will be done after the physician/nurse has examined the patient and decision about immidiate care has already been made.

7. The potential benefits to the patients include more personal contact with health workers and more personal care. Moreover, data collected will be useful in assessing the quality of care provided and in making recommendations for its future improvement.

8. Stool will be obtained for microscopic examinations and rectal swab will be obtained for culture.

INFORMED CONSENT FORM

Statement to Patients :

The Matlab Station of the International Centre for Diarrhoeal Disease Research, Bangladesh (Formerly the Cholera Research Laboratory) is studying every 10th patient who come to the Matlab Diarrhoea Treatment Centre. This is to learn more about the patients who come here for medical care. A special questionnaire will be administered to you or your parent/guardian after you have been examined by a paramedic or doctor. If you are very sick, care will be given first and you will be interviewed after your condition has improved. Rectal swab will be obtained for culture and stool will be collected for examination under microscope. All records will be kept strictly confidential. There are no risks associated with this study; only potential benefits to you, such as more contact with the health workers and more personal care.

সম্মতি পত্র

আন্তর্জাতিক উদরাময় গবেষনা কেন্দ্রের নতুন হাসপাতালে যে সব রোগী আসেন তাদের প্রতি ১০ম রোগীর বিস্তারিত তথ্য সংগ্রহ করা হয়। ডাক্তারের পরীক্ষার পর আপনাকে/আপনার পিতামাতাকে/আপনার অভিভাবককে কিছু প্রশ্ন করা হবে। আপনি খুব বেশী অসুস্থ থাকলে প্রথমে আপনার প্রয়োজনীয় চিকিৎসার ব্যবস্থা করা হবে এবং আপনি যখন সুস্থবোধ করবেন তখন আপনাকে প্রশ্ন করা হবে। রোগজীবানু পরীক্ষার মাধ্যমে আপনার অসুস্থতার কারন নির্নয়ের জন্যে আপনার নিকট থেকে কিছু পরিমান পায়খানা সংগ্রহ করা হবে।

এই গবেষনায় সহযোগিতা করলে আপনার কোন বিপদের সম্ভাবনা নেই। আপনার সকল ব্যক্তিগত তথ্য গোপন রাখা হবে।

আপনি আপনার প্রদত্ত সহযোগিতা যে কোন সময় প্রত্যাহার করতে পারবেন। এতে আপনার চিকিৎসার কোন ত্রুটি হবে না।

FORM I

I

ICDDR,B SURVEILLANCE PROGRAM

MATLAB HOSPITAL

Name : _____ Father's/Spouse Name : _____

Address: _____

Census No. : _____

_____

Study No. ..... / / / / (1 2 3)

Case No. ..... / / / / / / / (4 5 6 7 8 9)

Card No. ..... / / (10)

Interviewer : ..... / / (11)

Date : (Day/Month/Year) ..... / / / / / / / (12 13 14 15 16 17)

Age : (Year/Month/Day) ..... / / / / / / / (18 19 20 21 22 23)

Sex : (1=Female, 2=Male) ..... / / (24)

Religion : (1=M, 2=H, 3=Christ, 4=Others) ..... / / (25)

Before coming to ICDDR,B did you :

(a) Receive any care ? 0=None ..... / / (26)

If yes, then where ? 1=Bari mother
2=Community Health Worker
3=Qualified allopath
4=Unqualified allopath
5=Homeo path, 6=Kabiraj
7=Totka, 8=Other (specify)

(b) Take any medication ? 0=None 1=Antibiotics ..... / / (27)
2=Other (not known)
3=1+2

(c) Received oral rehydration ? 0=N ..... / / (28)
1=Packet, 2=Salt+Sugar
3=Labon+Gur, 4=Barley+Salt
5=1+4, 6=4+2
7=4+3 8=No experience of ORS

How many persons eat from the same pot ..... / / (29 30)

How many children are < 5 yars of age in your family : ..... / (31)
(Code8if more than 8 children)

Has any member of your household had diarrhoea in the past 7 days : ..... / (32)
0=No, 1=Yes

Feeding (Children < 3 years) : ..... / (33)
1=Breast Milk, 2=Cows/Powdered Milk, 3=Breast Milk+Cows/Powdered Milk
4=Solid Food+BM/CM/PM, 5=Family Food,

Education of patient's Father and Mother (applicable to children <12 Yrs.) :

Father/Male ..... /__/ 34

0=None/Maktab, 1=Incomplete primary education
2=Complete primary education, 3=Incomplete secondary education
4=Complete secondary education

Mother/Female ..... /__/ 35

Income of household : 1= < Tk. 500. 2=Tk. 500-999, 3=Tk. 1,000-1,499 ..... /__/ 36
4=Tk. 1 500-1,999, 5= > Tk. 2,000

Water Source : (a) Drinking : 1=River, 2=Canal ..... /__/ 37
3=Earthen Well, 4=Tubewell
5=Pond, 6=Other (specify)

(b) Cooking & Washing : ..... /__/ 38

Place of defaecation/disposal of faeces : ..... /__/ 39

1=Sanitary latrine, 2=Service. 3=Water-Seal
4=Dug-hole, 5=Open Latrine, 6=No fixed place

Weight on admission (Kgs) ..... /__/__/__/ 40 41 42

Weight on discharge (Kgs.) ..... /__/__/__/ 43 44 45

Height (in cm) ..... /__/__/__/ 46 47 48

Weight/Height (%) : ..... /__/__/ 49 50

Temperature (Rectal) : 0=below 98.6°F 1=98.6°-100°F ..... /__/ 51
2= > 100-102°F 3= > 102°F

MEDICAL HISTORY :

Duration of Diarrhoea : 1= < 1 day, 2=1-3 days, 3=4-6 days ..... /__/ 52
2=7-9 days, 5=10-12 days 6=12-14 days
7= > 14 days (Specify)

Character of Stool : 1=Watery 2=Non-watery ..... /__/ 53

Content of Stool : 0=None, 1=Mucous, 2=Blood, 3=Mucous+Blood .... /__/ 54

Number of stool in past 24 hours : 1=3-5, 2=6-10, 3=11-15 ..... /__/ 55
4=16-20, 5= > 20

Vomiting : 0=None, 1=Yes, Preceeding diarrhoea, 2=Yes, after diarrhoea .... /__/ 56

History of cough : 0=NOne, 1=Prior to onset of diarrhoea ..... /__/ 57
2=After the onset of diarrhoea

Other diseases : 1=had measles in past month ..... /__/ 58
2=had night-blindness (inability to see in early evening)
3=had convulsion in past 24 hours
4=had measles and night-blindness
5=had measles & convulsion
6=had night blindness & convulsion
7=others (specify)

Physical Examination :

Assessment of Dehydration (Guide for physician)* :

Thirst : 0=Normal, 1=Mild thirsty, 2=Very thirsty ..... /___/ 59

General Appearance : 0=Normal, 1=Restless ..... /___/ 60
2=Lethargic but irritable when touched
3=Drowsy/cold & sweaty extremities/coma

Redial Pulse : 1=Normal rate & volume 2=Rapid & weak ..... /___/ 61
3=Rapid feeble/sometimes impalpable

Respiration : 1=Normal, 2=Faster than normal, 3=Deep & rapid ..... /___/ 62

Anterior Fontanelle : 1=Normal, 2=Sunken, 3=Very sunken ..... /___/ 63

Skin Elasticity : 1=Normal (pinch retracts immediately) ..... /___/ 64
2=Pinch retracts slowly
3=Pinch retracts very slowly (> 2 sec)

Eyes : 1=Normal, 2=Sunken, 3=Very sunken..... /___/ 65

Tears : 1=Normal (Present), 2=Absent ..... /___/ 66

Mucous Membranes : 1=Normal (moist), 2=Dry, 3=Very dry ..... /___/ 67

Urine Flow : 1=Normal, 2=Reduced amount & dark ..... /___/ 68
3=None passed for 12 hours

Clinical Assessment of Dehydration : 1=No dehydration ..... /___/ 69
2=Mild, 3=Moderate, 4=Severe

Other Physical Findings :

Vit. A deficiency : 0=Normal, 1=Xerosis..... /___/ 70
2=Bitot's spot, 3=Keratomalatia
4=Corneal ulcer, 5=Blind

Ear: Otitis media : 0=Absent 1=Otitis media ..... /___/ 71
2=Other (specify)

Mouth : 0=Normal 1=Angular stomatitis ..... /___/ 72
2=Glossitis 3=Pharyngitis
4=Tonsilities 5=Thrush

Chest : 0=Clear, 1=Bronchial rales..... /___/ 73
2=Crepitation, 3=1+2, 4=Other (specify)

Abdomen : 1=Normal, sounds present, 2=Distended, sounds present ../___/ 74
3=Distended, sounds sluggish, 4=Distended, sounds absent

Liver & Spleen : 0=Normal 1=Liver enlarged ..... /___/ 75
2=Spleen enlarged 3=Liver & Spleen enlarged

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*Physician Guides :

Without dehydration codes : from 59-68 subcodes (Normal)
Mild dehydration codes : from 59-68 subcodes (1)
Moderate dehydration codes : from 59-68 subcode (2) (Two or more signs)
Severe dehydration codes : from 59-68 subcode (3) (Two or more signs)

Rectum Prolapses : 0=Absent, 1=Present ..... /__/ 76

Extremeties : 0=Oedema absent, 1=Oedema present ..... /__/ 77

Diagnosis : 1=Uncomplicated diarrhoea ..... /__/ 78
2=Complicated airrhoea

Distance travelled in miles : 1= < 2 Kilometer ..... /__/ 79
2=2-5 Kilometer
3=5-7.5 Kilometer
4=7.5-10 Kilometer
5=10-15 Kilometers
6=15-20 Kilometers
7= > 20 Kilometers

ICDDR,B SURVEILLANCE PROGRAM

MATLAB HOSPITAL

Name : _____ Father's/Spouse Name : _____

Address : _____

Census No. : _____

MICROBIOLOGICAL AND TREATMENT FORMS

Study No. ..... / / / / (1 2 3)

Case No. ..... / / / / / / / (4 5 6 7 8 9)

Card No. ..... / / (10)

Stool Microscopy :

Stool Character : 1=Watery, 2=Mucous, 4=Mucous+blood..... / / (11)

pH : 1=alkaline, 2=acid ..... / / (12)

RBC : 0=None, 1= < 10, 2=10-19, 3=20-29, 4=30-39, 5=40-49, 6=50-69, 7=70-99, 8= > 100 ..... / / (13)

WBC : 0=None 1= < 10 2=10-19, 3=20-29 4=30-39 5=40-49 6=50-69, 7=70-99 8= > 100 ..... / / (14)

Macrophage : 0=None, 1= < 5, 2=5-9 3=10-19, 4=20-29, 5= > 30..... / / (15)

Fat : 0=None, 1=1+, 2=2+, 3=3+, 4=4+ ..... / / (16)

Stool Parasites :

Entamoeba histolytica: 0=None, 1=Histolytica, cyst..... / / (17)
2=E. histolytica, trophozoites
3=E. histolytica haematophagus trophozoites
4=1+2, 5=1+3

Giardia lamblia : 0=None, 1=Giardia cyst, 2=Giardia Veget..... / / (18)
3=1+2

Ankylostoma duodenale : 0=None, 1=1+, 2=2+, 3=3+, 4=4+ ..... / / (19)

Trichuris - trichuria : 0=None, 1=1+, 2=2+, 3=3+, 4=4+ ..... / / (20)

Ascaris lumbricoides : 0=None, 1=1+, 2=2+, 3=3+, 4=4+..... / / (21)

F buski : 0=None, 1=Yes ..... / / (22)

Strongyloides sterocoralis : 0=None, 1=Yes ..... / / (23)

Trichomonas hominis : 0=NOne, 1=Yes ..... / / (24)

Others (specify) : ..... / / (25)

Stool Culture :

Stool culture states: Neg=0, positive for one organism=1 ..... / / 26
positive for two organism=2
positive for three organism=3

Salmonella typhi (1) ..... / / 27

Salmonella (other) specify (2) ..... / / 28

Shigella flexneri (3) ..... / / 29

Shigella boydii (4) ..... / / 30

Shigella dysenteriae (5) ..... / / 31

Shigella dysenteriae II (6) ..... / / 32

Shigella dysenteriae (3-10) (7) ..... / / 33

Shigella Sonnei (8) ..... / / 34

EPEC: ..... / / 35

ETEC : ..... / / 36

EIEC : ..... / / 37

V. cholerae 01 (9) ..... / / 38

V. cholerae non 01=1 (10), V. parahaemolyticus=2 (11), ... / / 39
V. fluvialies=3 (12), Plesiomonas shigelloides=4 (13)
Aeromonas hydrphila=5.

Campylobacter jejuni -..... / / 40

Rotavirus ..... / / 41

Fastidius enteric adenovirus ..... / / 42

Yersinia enterocolitica ..... / / 43

Others (specify) ..... / / 44

Antibiotic Resistant Pattern: (First two column for pathogens and rest three column for sensitive antibiotics).

Pathogen I ..... / / / / / / / / 45 46 47 48 49

Pathogen II ..... / / / / / / / / 50 51 52 53 54

Pathoge III ..... / / / / / / / / 55 56 57 58 59

Treatment Received :

Patient treated initially by 1=ORS, 2=IV ..... /__/ 60

Outcome of rehydration with ORS ..... /__/ 61
1=Successful; 2=failed, changed to IV
3=Not applicable

Treatment given:

Rehydration : 1=Yes, 0=No ..... /__/ 62

Any antibiotic given : 1=Yes, 0=No ..... /__/ 63

Antibiotic :

1=Tetracycline, 2=Ampicillin, 4=Penicillin, 8=Chloramphenicol /__/__/__/ 64 65 66

16=Septrin, 32=Metronidazole, 64=Gentamycin, 128=Kanamycin

Duration of Stay ..... /__/__/__/__/ 67 68 69 70
Days Hours

ICDDR,B SURVEILLANCE PROGRAM

FORM III
I

MATLAB HOSPITAL

Name _____ Father's/Spouse Name _____

Address _____

Census No. _____

Study No..... / / / / (1 2 3)

Hospital No..... / / / / / / (4 5 6 7 8 9)

Census No..... / / / / / / / / / (10 11 12 13 14 15 16 17 18)

Card No..... / (19)

Weight on admission..... / / / / (20 21 22)

Weight on discharge..... / / / / / (23 24 25 26)

Height (cm)..... / / / / (27 28 29)

Initial rehydration: 1=ORS, 2=IVF..... / (30)

Amount of ORS (in litres)..... / / / / (31 32 33)

Amount of IVF (in litres)..... / / / / (34 35 36)

Outcome of rehydration with ORS: 1=successful, ... / (37)
2=failed and changed to IVF
3=Not applicable

Other clinical diagnosis/detection of complication in hospital..... / (38)
1=Aspiration pneumonia 2=Other chest infection
3=Hypernatremia, 4=Hyponatremia, 5=Hypokalemia
6=Hypoglycemia, 7=Hyperpyrexia, 8=Convulsion

To be filled in complicated cases only:

Serum Na on admission..... / / / / (39 40 41)

Serum K on admission..... / / / (42 43)

Serum bicarbonate on admission..... / / / (44 45)

Serum glucose on admission (if done)..... / / / (46 47)

Sp. Gravity on admission (1.0)..... / / / / (48 49 50)

Hct on admission..... / / / (51 52)

WBC: 1=<10,000 5=40,000-49,999
2=10,000-19,999 6=50,000-74,999 ..... / (53)
3=20,000-29,999 7=75,000-99,999
4=30,000-39,999 8=>100,000

Blood culture (if done) 0=negative, 1=positive (specify)..... / (54)

Urine culture (if done) 0=negative, 1=positive (specify)..... /___/ 55

Intracheal Aspirate Culture (if done)..... /___/ 56
0=negative, 1=positive (specify):

Treatment (Medical):

Tetracycline..... /___/ 57

Ampicillin..... /___/ 58

Septrin..... /___/ 59

Chloramphenicol..... /___/ 60

Penicillin..... /___/ 61

Metronidazole (Flagyl/Klion)..... /___/ 62

Gentamycin..... /___/ 63

Erythromycin..... /___/ 64

Vit A..... /___/ 65

Other (specify)..... /___/ 66

Associated Complications:

Respiratory Infection: 1=Upper respiRatory Tract Infection..... /___/ 67
2=Pneumonia 3=Bronchitis
4=Aspiration Pneumonia, 5=Whooping cough
6=Peural effusion, 7=Peural effusion & Penumonia

PEM:

1=Kwashiorkor, 2=Marasmus, 3=Marasmic-Kwashiorkor..... /___/ 68

Hypernatremic..... /___/ 69

Hyponatremic..... /___/ 70

Acidosis..... /___/ 71

Hypokalemia..... /___/ 72

Hypoglycemia..... /___/ 73

Septicemia: 1=Confirmed Septicemia, 2=Unconfirmed Septicemia ..... /___/ 74
3=Gram Negative Septicemic Shock

Convulsions: 1=Hypernatremic, 2=Hypoglycemic, 3=Meningitis,..... /___/ 75
4=Non-specific

Chronic Diarrhoea:
1=Lactose Intolerance, 2=Postmesles diarrhoea, 3=Others(specify).. /___/ 76

Vit. Deficiency: 1=Vit. A deficiency, 2=Vit. B Complex deficiency, ... /___/ 77
3=Other (specify)

Other Complications: Specify..... /___/ 78

Outcome: 1=cured, 2=Referred from Treatment Centre to Med. Ward
3=Discharged on risk bond, 4=Referred to other hospitals ..... /___/ 79
5=Died, 6=Died on admission