

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Dr. M.H. Munshi

Trainee Investigator (if any) _____

Application No. 88-004

Supporting Agency (if Non-ICDDR,B) _____

Title of Study ICDDR,B SURVEILLANCE

Project status:

PROGRAMME, TEKNAF TREATMENT CENTRES.

- () 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
- 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
- Are subjects clearly informed about:
 - (a) Nature and purposes of study Yes No
 - (b) Procedures to be followed including alternatives used Yes No
 - (c) Physical risks Yes No
 - (d) Sensitive questions Yes No
 - (e) Benefits to be derived Yes No
 - (f) Right to refuse to participate or to withdraw from study Yes No
 - (g) Confidential handling of data Yes No
 - (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure Yes No

5. Will signed consent form be required:
 - (a) From subjects Yes No
 - (b) From parent or guardian (if subjects are minors) Yes No
 6. Will precautions be taken to protect anonymity of subjects Yes No
 7. Check documents being submitted herewith to 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.

(PTO)

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

[Signature]
Principal Investigator

[Signature]
Trainee

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1988

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SECTION I
RESEARCH PROTOCOL

1. Title : ICDDR,B Surveillance Program, Teknaf Treatment Centres.
- 2.1. Principal Investigator : Dr. M.H. Munshi
- 2.2. Co-Investigator : Dr. M.A. Islam
3. Starting date : Jan-01, 1988
4. Completion date : To be continued as long as the Centre requires.
5. Total direct cost : a) US\$ 23,822
b) Source of funding - USAID/Coop (TS)

6. Approval:

This protocol has been approved by the Laboratory Sciences Division.

Signature : *Imru Cipta*
Date: *Feb. 14 1988*

7. Abstract Summary

Teknaf is an endemic area for shigellosis and other diarrhoeal diseases. Over 5,000 patients are being treated annually at the ICDDR,B Treatment Centres in Teknaf. The surveillance Ppogram aims to evaluate the various clinical, epidemiological and microbiological data collected from all the patients attending ICDDR,B Treatment centres in Teknaf. This will be used to determine the spectrum of diarrhoeal diseases in Teknaf which possesses distinct socio-demographic-climatic characteristics in respect to other parts of rural Bangladesh.

The surveillance program will be the routine activity of the ICDDR,B treatment centres in Teknaf. Regular and necessary treatments will be provided to all patients by the usual clinical staff in the treatment centre. A questionnaire will be used in the treatment centre to obtain necessary information and a fresh sample of stool / RS will be collected from each patient for investigations. The patients/attending gurdians will be interviewed and the patients will be examined by the usual clinical staff in the treatment centre. The Surveillance Program will help us to monitor the spectrum of diarrhoeal diseases in Teknaf and to generate new ideas for further research into the control of diarrhoeal diseases, particularly shigellosis.

8. Reviews:

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

SECTION II
RESEARCH PLAN

A. INTRODUCTION

1. Objective:

Teknaf, during the last 12 years, has been found to be an endemic area for shigellosis with frequent epidemic outbreaks. During the last few years, Teknaf also experienced periodic Cholera epidemics. S.dysenteriae type 1 strains isolated in Teknaf have become resistant to commonly used antibiotics including Nalidixic acid. During 1987 over 5,000 patients attended in the ICDDR,B Treatment centres in Teknaf, and the attendance is increasing. The objective of this Surveillance Program is to evaluate detailed clinical, epidemiological and microbiological data from the patients attending ICDDR,B Treatment Centres in Teknaf. The surveillance data will be analysed on an ongoing basis.

01. To permit early recognition of seasonal or localised diarrhoeal outbreaks in the Teknaf area.
02. To determine the aetiologic agents of diarrhoea in Teknaf.
03. To study the changing trend of Shigella isolations and their antibacterial sensitivity in the Teknaf area.
04. To identify the evidence of outbreak of MARVc in Teknaf.
05. To generate new ideas for further research appropriate for controlling diarrhoeal diseases, particularly shigellosis.

2. Background

Diarrhoeal diseases are the major public health problems in the developing world. Diarrhoea is the leading cause of death in young children and constitutes an important contributing factor to malnutrition. Diarrhoea is recognised as one of the most important cause of morbidity and mortality in Bangladesh and similar developing countries (LC Chen, et al, 1977; WJ Van Zijil, et al, 1966; WH Baker, et al, 1975; JA Walsh, et al, 1979; RE Black, et al, 1980, LC Chen, et al, 1980). Shigellosis is a serious disease in childhood, particularly for children who are malnourished. The problem of increasing resistance to the drugs used to treat shigellosis means that shigellosis is a growing problem in Bangladesh and in the other parts of South Asia (ICDDR,B Annual Report, 1986, pp-25).

Teknaf is an endemic area for shigellosis with frequent epidemic outbreaks. The study of the transmission of shigellosis in Teknaf can considerably expand the understanding of the epidemiology of shigellosis.

The Teknaf Upazila is situated at the South-eastern tip of Bangladesh in the Cox's Bazar district. It is a narrow peninsula. The eastern side is bounded by the Naf river bordering Burma and the western side is circumscribed by the Bay of Bengal. The Upazila is about 56 KM long and about 6 KM wide. Almost two-thirds of the Upazila are hilly areas, constituting a part of the Reju-Teknaf range of reserved forest where human habitation is

not permitted. Human habitation is limited to the western bank of the Naf, the beach area on the western side and the southern plain.

A motorable road about 85KM long, links Teknaf and the district headquarter of Cox's Bazar. The communication within the Upazila is mainly on foot by the dirt roads. The water transport in the Naf river and motor transport along the beach is not properly developed, but used only during the winter season.

The climate of Teknaf is sub-tropical with three distinct seasons: monsoon, cool-dry and hot-dry. Monsoon usually starts in June and continues until September. Most of the 510 cms of average annual rainfall occurs during this season. It often rains several times daily with heavy showers, and it often rains continuously for days together. Due to the very quick natural drainage of rain water to the Bay of Bengal, the people of Teknaf are not inundated with flood-water as are the people of the deltaic and flooded regions of Bangladesh. Then follows the cool-dry season, which is very pleasant and extends until February. The hot-dry season begins in March and ends with the beginning of monsoon.

As there is a rocky layer underground, shallow tube-wells (hand pumps) cannot be installed in most of the habitable regions of Teknaf. As a result, the people are dependent on the polluted surface water from the dug-wells for their drinking and domestic uses. The usual water sources are ditches and ring-wells. Most

of the shallow water sources run dry and water shortages occur during the hot-dry season.

Almost all the people in Teknaf are Bangladeshi Muslims with conservative outlooks. There are a negligible number of tribal people in Teknaf. About ten percent of the population is literate. The principal occupations of the people are cultivation and fishing.

Rice grows in Teknaf only in monsoon, but plenty of betel leaves and betel nuts grow there. Large quantities of seafishes are caught in the Naf river and the Bay of Bengal. Consumption of good amount of fish results in good nutritional status, and absence of vitamin A deficiency in the community, but nutritional deficiencies in children have been observed in the pre-harvest period.

Crowding is relatively common in Teknaf. A few years ago, almost all the houses had earthen floor, bamboo walls and roofs made of leaves and straws. But very recently, due to the huge amount of foreign remittances from the Arab countries and the yields of border-tradings, Teknaf area has experienced a very rapid socio-economic change, resulting in the construction of pucca dwelling houses. Unfortunately, the literacy rate remains the same. Though the development process has already been initiated in Teknaf, it will not be possible to develop public health facilities in the near future. Due to the various topographical, climatic and other socio-cultural reasons, including crowding and rapid transition of population across the international border,

Teknaf still remains a hyper-endemic area for diarrhoeal diseases. Almost every year, at the beginning of monsoon, epidemic outbreaks are sure to occur.

ICDDR,B (former CRL) activities in Teknaf area in the form of a diarrhoeal disease treatment and surveillance program were instituted in later part of 1974 after a severe outbreak of dysentery caused by multiresistant Shigella dysenteriae type 1 (MM Rahaman, et al, 1975). A census was taken in December, 1974 and January, 1975 of Teknaf Upazila. Demographic and diarrhoeal surveillance was initiated in 1976 with a population of about 46,000 in 4 Union Parishad areas.

The diarrhoea treatment centre provided free services to the community for diarrhoeal diseases, was staffed by a Physician, a Nurse and other staff. The treatment centre was backed up by a field laboratory with the facilities of stool microscopy and bacteriological cultures for common enteric diseases. The field laboratory was equipped with innovative technologies such as kerosene run refrigerator, kerosene-run incubator (egg hatcher), pressure cookers and demineralizer.

The beach area was covered by a chain of community-based ORS distribution centres. In 1980, the Water and Sanitation Intervention Study was undertaken in a Community and the study was completed in 1983. Regular diarrhoea surveillance was discontinued in 1981. A second demographic census was taken in 1982. A new village was included and a new demographic surveillance at monthly interval was initiated in 1983 under the

DSS-Teknaf protocol, in a population of about 61,000. Since the starting of ICDDR,B (former CRL) activities in Teknaf, a number of scientific publications have been made using the information generated through the surveillance and treatment centre programmes.

The demographic characteristic of Teknaf are quite remarkable, with a very high Crude Birth Rate and a high marital separation rate. The CBR in Teknaf is the highest in Bangladesh. The IMR in Teknaf has been recorded in 1983 as 153.8 (M. Rahman, et al, 1983 ICDDR,B Scientific Report # 66, pp-4). One out of five deaths in children of age 1-4 yrs in 1977 was caused by diarrhoeal illness (M. Rahman, et al, 1979 ICDDR,B Working Paper # 13, 1979, pp-24); and for the years 1982 - 1985, 23% deaths in children between 1- and 59 months of age were attributed to diarrhoea and dysentery (ICDDR,B Annual Report, 1986, pp-37).

Since the inception of ICDDR,B activities, Teknaf has been found to be endemic for shigellosis, the predominant strain is S.flexneriae. The proportion of patients attending treatment centre with loose/watery diarrhoea was found to be less than 20 % during the years 1976 to 1980, but the proportion has increased to 33 % in 1986. During 1986, 201 Vibrio Cholerae isolates were made in the field laboratory.

During 1986, there were simultaneous epidemics of cholera and shigellosis due to S.dysenteriae type 1. The strains of S.dysenteriae I isolated were resistant to most of the commonly used antibiotics. Nalidixic acid was introduced in the middle of

1986, but resistance to nalidixic acid was detected and the percentage of the resistant cases increased over time. By the end of 1986, nalidixic acid became virtually useless for the treatment of shigellosis caused by S.dysenteriae I in Teknaf. Previously, resistance to nalidixic acid was thought not to be associated with a transferable plasmid; however, in Teknaf, resistance to nalidixic acid appears to be mediated by a 20 megadalton plasmid (MH Munshi, et al, 1987). As we have begun using Pivmecillinum as the only currently available antibiotic in Bangladesh to treat patients infected with resistant S.dysenteriae type I strains, the monitoring for the resistance to this drug in the community is highly imperative.

During the period of 1978 to 1982 in Teknaf laboratory, only 12 strains of Vibrio cholerae were tested for antibiotic sensitivity. All the strains were sensitive to Tetracycline, and all were resistant to Ampicillin. After 1982, no Vibrio strain was tested.

The appearance of Multiple Antibiotic Resistant Vibrio Cholerae (MARVc) in Bangladesh (MU Khan, et , 1986; MI Huq, et al; RI Glass, et al, 1980) and increasing numbers of isolations of Vibrio in Teknaf emphasize the need for further studies in Teknaf, particularly monitoring for MARVc.

Besides Shigella and Vibrios, ICDDR,B studies indicated that Enterotoxigenic Escherichia coli (ETEC) and rotavirus are important aetiologic agents of diarrhoeal disease in rural Bangladesh (RW Ryder, et al, 1976; RE Black, et al, 1980). From

the samples collected during the Water and Sanitation Intervention Study in Teknaf, 8.5% of MacConkey's yielded a positive diagnosis of E.coli containing enterotoxins and 3% of the PBS samples were positive for rotaviruses (MM Rahaman, et al, report of the WSI study in Teknaf, ICDDR,B June 1985). So far, no effort has been made to isolate Campylobacter as an aetiologic agent for diarrhoeal disease in Teknaf, although ICDDR,B studies suggested that Campylobacter infection is common in Bangladeshi children (MJ Blaser, et al, 1980).

Considering the socio-cultural, topographical, climatic and demographic characteristics of Teknaf, the determination of E. coli, Rotaviruses and Campylobacter as aetiologic agents of diarrhoeal disease, can certainly widen the understanding of the epidemiology of diarrhoeal diseases in similar rural settings.

3. Rationale

Similar surveillance systems are continuing in ICDDR,B Dhaka and Matlab Hospitals. There is no question about the importance of surveillance systems in order to monitor and better characterize the enteric pathogens in both rural and urban settings, and to monitor the changes in morbidity pattern to forecast epidemic outbreaks.

Over 80% of the patients attending the Treatment Centre at ICDDR,B Teknaf are residents of the Teknaf Demographic

Surveillance area with DSS identification numbers, and they can be traced to the household levels. A Shigella epidemiological study is anticipated in Teknaf. But before that we would like a continued utilization of the facilities of ICDDR,B in Teknaf with this surveillance proposal to collect base line information by monitoring the changing pattern and antibiotic sensitivity of the aetiologic agents of diarrhoeal diseases. ✓

B. Specific Aims

01. To establish ongoing surveillance of all patients attending the ICDDR,B Treatment Centres in Teknaf, irrespective of residence.
02. To determine the aetiologic agents of diarrhoeal diseases for patients attending ICDDR,B Treatment Centres in Teknaf according to age/sex/clinical picture/seasons.
03. To collect information pertinent to epidemiology of diarrhoeal diseases, eg. food history before the onset of diarrhoeal diseases, water uses, uses of latrine, nutritional status, practices of hand washing before taking food and after defaecation, associated illness, uses of ORS/antibiotics, etc.
04. To generate new ideas for further research appropriate to controlling diarrhoeal diseases, particularly shigellosis.

✓

C. Methods and Procedures

All patients with diarrhoeal disease attending the ICDDR,B's Treatment Centres in Teknaf will be included in this surveillance program. About 5,000 patients attended the Treatment Centres annually, but recently an increasing attendance has been observed. It has been a regular practice for the last 12 years that whenever a patient attends our Treatment Centre, he is interviewed and examined by a clinical staff and asked to provide a fresh sample of stool for examination. The patients from DSS area are also required to bring their DSS card for identification. The community has accepted this procedure, and as the same procedure will be followed in this surveillance program, no written consent will be required. Verbal consent will be obtained from the patients/attending guardians. After completion of history taking and clinical examination, using the set questionnaire, the patient will be asked to provide a sample of fresh stool in a clean container (provided by the treatment centre). After collection and proper labelling, the sample will be sent to the laboratory for microscopic examination (both saline and iodine preparation) and microbiological culturing for enteric pathogens. If fresh stool sample cannot be collected, R/S sample will be collected for culture. The R/S sample will be streaked in the Treatment Centre on TEA/SS/McC/TTGA plates and the plates, after proper labelling with identification numbers, will be sent to laboratory for incubation. In those cases, stool microscopy will be done later on during followup visits.

In the laboratory, culture specimens will be processed for pathogenic Vibrios, Shigella and Salmonella using standard laboratory methods. From each culture, 10 lactose positive colonies with typical E. coli morphology will be picked from MacComkey's agar plates and preserved on nutrient agar slants. Those will be sent to Dhaka Laboratory periodically for LT & ST testing. A 10% systematic samples of stool/RS from patients (when the case number ends with zero) will be inoculated on to a 'Campy-BAP' medium for isolation of Campylobacter. Those plates will be incubated in candle jars at 40 C for 48 hours. The identification of organisms as Campylobacter jejuni will be done according to standard criteria (MJ Blaser, 1980). A second sample of stool/RS will be collected from each patient under 5 years of age, and will be refrigerated in PBS tubes. Those will be sent to Dhaka Laboratory in ice flasks for further testing for rotaviruses.

Sensitivity to antibiotics (Ampicillin, Tetracycline, Gentamicin, Nalidixic acid, Pivmecillinum and TMP-SXT) will be performed by standard disc diffusion method (AW Bauer et al, 1966) on bacterial isolates; 20% of S. dysenteriae I, 10% of S. flexneri, 10% of other Shigella, 10% of Vibrios and 10% of Campylobacter jejuni will be tested. In the laboratory a list of all positive isolates will be prepared according to the date of testing. From this list, systematic samples as required will be selected for antibiotic sensitivity testing.

For all patients, physical examinations including vital signs, admission weight, state of hydration and signs of nutritional deficiencies, will be done in the treatment centre by the attending Physician/clinical staff. When available, appropriate follow-up entries will be made in the forms. The results of the bacteriological tests will be incorporated in the questionnaire forms. The data collected will be preserved properly. The questionnaire forms will be precoded and completed forms will be sent periodically to Dhaka for computerization. Monthly data analysis will be performed in Teknaf by hand tabulation by tallying the patient data at the end of each month by age/sex/residence/clinical presentation/enteric pathogens.

The hand tabulation result at the end of each month will be distributed to ICDDR,B Treatment Centre staff in Dhaka, Matlab, Chandpur etc. and to Epidemiology Department of ICDDR,B. Quarterly or yearly reports to summarise the finding of the Surveillance Programme will be prepared for distribution to people involved in patient care and data collection. Whenever an epidemic is identified by the Surveillance Programme, Epidemic Control Preparedness Programme of the ICDDR,B will be informed. In collaboration ECPP and local government health authorities, definitive epidemic intervention measures will be undertaken. This type of collaborative programmes will eventually strengthen the resources and responses of Teknaf Treatment Centre to face epidemic outbreaks in Teknaf area in the future.

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D. Significance

This surveillance activity will generate a wide range of data on patients attending ICDDR,B Treatment Centres in Teknaf. This surveillance program will monitor the changing pattern of isolation of aetiologic agents causing diarrhoeal diseases in Teknaf and their susceptibility to antibacterial drugs.

After establishment of this surveillance activity, whenever appropriate, this can be linked to other epidemiological studies in Teknaf or this can serve as a basic data collection unit.

E. Facilities Required

No additional space for office/clinic/laboratory is required. No additional logistic support is required. The modified battery/electric-run incubator supplied by the Dhaka Microbiology Laboratory is to be renovated for Campylobacter culture. Laboratory personnel will need inhouse training for isolation of Campylobacter and for the preparation of Campy-BAP medium. ST/LT determination for E. coli and assays for rotavirus will be performed in Dhaka laboratory. Help from Animal Resources and reagents for Elisa will be required. Culture media, drugs, stationery and computer tapes will be needed.

F. Collaborative Arrangement

None other than inhouse arrangement, will be required.

SECTION III

A. DETAILED BUDGET

ICDDR,B Surveillance Programme, Teknaf Treatment Centres)

1. Local Salary, A/C No. 3100

Job Title	Level	Man month	Rate	Amount in US\$
Sr. Lab. Tech	GS-4	9	228	2,052
Lab. Tech	GS-3	12	302	3,624
Sr. Lab. Asstt.	GS-2	12	268	3,216
Cleaner	GS-1	12	227	2,724
			Sub Total	11,616

2. Local Consultant

A/C No. 3300

R.O./Sr. Microbiologist;

Dhaka - Teknaf - Dhaka Trip:

Per diem	168
Travel Cost	172
Sub Total	340

3. Local Travel

A/C No. 3500

Asstt. Scientist, Medical Officer, Lab. Tech;

Teknaf - Dhaka - Teknaf Trip;

Per diem	168
Air Ticket	200
Ground Expenses	68
Other expense	30
Sub Total	766

4. Supplies & Materials
A/C No. 3700

3702	850
3704	500
3705	1,000
3706	150
3707	600
3708	150
3709	150
3710	100
3712	3,000
3713	1,000

Sub Total 7,500

5. Other Cost
A/C No. 4000

3800	1,500
4300	500

Sub Total 2,000

6. Inter Deptl. Services
A/C No. 4800

4801	750
4808	750
4814	100

Sub Total 1,600

Total direct operating cost for 1987 US\$ 23,822

SECTION III

B. BUDGET SUMMARY

(ICDDR,B Surveillance Programme, Teknaf Treatment Centres)

BUDGET SUMMARY

Expense category

A./C No.	Description	1987 (IN US\$)
3100	Local salaries	11,616
3300	Consultant	340
3500	Travel Local	766
3700	Supplies & Materials	7,500
3800	Other costs	2,000
4800	Inter. Departmental services	1,600
Total direct operating costs		23,822

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VERBAL CONSENT STATEMENT
(ICDDR,B Surveillance Programme, Teknaf Treatment Centres)

As you know, Teknaf is a hyper endemic area for diarrhoeal diseases, and ICDDR,B is providing you with free investigations and treatment for your diarrhoeal diseases through the treatment centres in Teknaf for last 12 years. It has been a regular practice in ICDDR,B treatment centres that when a patient attends the treatment centre, he is interviewed and examined by a clinical staff and he is also asked to provide a fresh stool sample/rectal swab sample for necessary investigation. Also the patients from the DSS area are required to bring their DSS card, for identification.

ICDDR,B is continuing a surveillance programme for determination of the changing trend of aetiologic agents and their antibacterial susceptibility in Teknaf area. If you participate in this surveillance programme, you will be provided with usual treatment for your diarrhoeal diseases; we will examine the patient as usually and will need a fresh stool sample/rectal swab sample as we have been doing last 12 years. All the answers you give and all the investigation report will be treated as confidential. If you have any additional question about this surveillance programme, we will try to answer them. We request your participation in this programme by giving your verbal consent. You may, at any time, refuse to participate at your free will; even in that case, you will get usual services from ICDDR,B Teknaf.

মৌখিক সন্যুতি পত্র

উদরাময় পর্যবেক্ষণ পদবসগা
আই, শি, ডি, ডি, আর, বি, টেকনিক শাখা

আপনি নিম্নলিখিত জ্ঞানস্বরূপ, টেকনিক উদরাময় রোগের প্রকোপ বেলী এবং আনুষ্ঠানিক উদরাময় পদবসগা কেন্দ্র, টেকনিক শাখা গত ১২ বৎসর যাবত এই রোগের চিকিৎসা ও যাবজীবন পরীক্ষাদি বিষয়গুলো করে আসছেন। এই চিকিৎসা কেন্দ্রে প্রত্যেক রোগীর কাছ থেকে একজন সুশিক্ষিত দ্বারা কিছু তথ্যাদি সংগ্রহ করা হয় এবং রোগীর মল বা মলদূর থেকে যেটা জীবাণু পরীক্ষা করা হয়। কার্ভারী রোগী বা পরিচিতির জন্য কার্ড দিয়ে আসেন।

বর্তমানে এই প্রতিষ্ঠান উদরাময় রোগ সুশিক্ষিত বিজ্ঞ জীবাণু ও তাদের বিরুদ্ধে কার্যকরী ঔষধ সমূহ মুছে গেছে একটি পর্যবেক্ষণ চালিয়েছে। আপনি এই পর্যবেক্ষণে অংশ নিতে চাইলে আমাদের আগনাকে বা আগনার রোগীকে কিছু প্রশ্ন করব এবং প্রয়োজনীয় পারিবারিক পরীক্ষা করব। রোগীর মল বা মলদূর থেকে একটা কাঠির মাধ্যমে তলা দিয়ে পায়খানা সংগ্রহ করা হবে পরীক্ষার জন্য। আগনাদের সহযোগিতায় এ কার্যক্রম গত ১২ বৎসর ধরে চলে আসছে। আগনার/রোগীর যাবজীবন তথ্যাদি ও পরীক্ষার ফলাফল গোপন রাখা হবে। তবে আপনি চাইলে আমাদের জ্ঞান তথ্যাদি আগনাকে জানানো হবে। আপনি আগনার মৌখিক সন্যুতি দিয়ে আমাদের এ পর্যবেক্ষণে অংশ নিতে পারেন। আপনি ইচ্ছা করলে যে কোমর সময়ে এই পর্যবেক্ষণে অংশ নিতে সন্যুতি জানালেও আগনার/রোগীর স্বাভাবিক চিকিৎসার ব্যাঘাত ঘটবে না।

ABSTRACT SUMMARY FOR THE ETHICAL REVIEW COMMITTEE

1. All patients attending Diarrhoea Treatment Centres of ICDDR,B in Teknaf Station will be studied. The study will not interfere with the routine medical care. Treatment will be provided as usual, with emergency cases treated on a priority basis. Special questionnaire will be administered by the clinical staff and on duty physician will perform a complete physical examination. Weight will be recorded on admission and on discharge. Stool samples will be examined in the laboratory.
2. No risks involved.
3. No risk is involved for the patient, so the question does not arise.
4. All clinical records will be handled only by the Investigators. Code numbers will be used instead of patient's name.
5. Because there will be no risk involved in the patient, only verbal consent will be obtained.
6. Approximately 10 minutes will be required to interview the patient/guardian. This will be done in the Treatment Centre after the Clinician has seen the patient and decision of any immediate care has already been made.
7. No additional benefit will be gained by the patient. But the data collected will be useful in assessing the quality of medical care provided and making recommendations for its improvement. This will benefit all patients in future. The data collected will allow us to know any change in diarrhoeal disease pattern which is important for taking appropriate measures for treatment and prevention. It also may generate new ideas for future research.
8. Stool will be obtained for culture and microscopic examination.

ICDDR,B Surveillance Programme
Tehar Treatment Centres

Dia/Dys Reporting Form

Case # _____ Vill. _____ Pars _____

Patient's Name: _____ Father's Name: _____

Date of previous visit: _____ Previous Case # _____

Study /___/ Card /___/
1 2

Case #: /___/___/___/___/___/___/ Date of Reporting: /___/___/___/___/___/___/
3-7 8-13

CID # /___/___/___/___/___/___/___/___/ Sex: /___/ Male = 1, Female = 2
14-23 24

Age (Yr/Mon/Days): /___/___/___/___/___/___/
25-30

Duration of dia before arrival (days): /___/ 1=<1 day, 2=1-3 days, 3=4-6 days
4=7-9 days, 5=10-12 days, 6=13-15 days, 7=>15 days.
31

Use of fluid before arrival: /___/ 0=None, 1=ORS packet, 2=IV Fluid, 3=Combination
32

Use of Chemotherapy before arrival: /___/___/ 00=None, 01=Tetra., 02=Furez.,
33 34
03=Metro., 04=Amp., 05=Genta., 06=Nalid., 07=Cotrimox., 08=Cepha., 09=Rifamp.,
10=Comb., 11=Antipyretic, 12=Antispasmo, 13=Others (Specify) _____
14=Unknown.

No. of persons eating from same cooking pot: /___/___/
35 36

No. of household members having dia/dys in last 1 month: /___/
37

No. of household members having dia/dys presently: /___/
38

Source of water used for drinking: /___/ 1=TW, 2=RW, 3=Ponds, 4=Ditch,
39 5=Spring/fountain

Source of water used for washing/bathing: /___/
40

Place of defaecation: /___/ 1=Sanit., 2=Semi-sant., 3=Open Pit/Dug-hole,
41 4=No fixed place.

Practice of Hand-washing before eating: /___/ 1=Only water, 2=Mud & water
42 3=Ash & water, 4=Soap & water

Practice of Hand-washing after defaecation: /___/
43

Out-side food taken during 3 days before onset of dia: /___/ 0=No, 1=Yes.
44

No. of stools in last 24 hrs: /___/ 1=3-5 Times, 2=6-10 Times, 3=11-15 Times,
45 4=16-20 Times, 5=>21 Times.

Character of stool: /___/ 1=Watery, 2=Loose, 3=Mucoid, 4=Bloody, 5=3+4.
46

Abdominal pain: /___/ 0=No, 1=Mild, 2=Mod, 3=Severe.
47

Prolapse rectum: /___/ 0=Absent, 1=Present.
48

Vomiting in last 24 hours: /___/ 0=None, 1=1-3 Times, 2=4-8 Times,
49 3=9-15 Times, 4=16-25 Times, 5=>26 Times.

Fever: /___/ 0=None, 1=Mild, 2=Mod, 3=High
50

Last urine passed - hours before reporting: /___/ 0=Upto 6 hrs., 1=7-24 hrs.
51 2=>24 hrs.

History of sickness during last 45 days: /___/ 0=None, 1=Dia., 2=Dys., 3=Fever,
52 4=ALRI, 5=Measles,
6=Others (Specify) _____ 7=Comb. (Specify) _____

PHYSICAL EXAMINATIONS

General condition: /___/ 1=Normal, 2=Restless, 3=Lethargic/Drowsy, 4=Coma.
53

Clinical assessment of dehydration: /___/ 0=None, 1=Mild, 2=Mod, 3=Severe.
54

Oedema feet: /___/ 0=None, 1=Present.
55

Anaemia: /___/ 0=None, 1=Mild, 2=Moderate, 3=Severe.
56

Temperature: /___/ 0=Upto 98.4 F, 1=Upto 100 F, 2=Upto 102 F, 3=>102 F.
57

Radial pulse: /___/ 1=Normal rate & volume, 2=Rapid & weak, 3=Not palpable.
58

Respiration: /___/ 1=Normal, 2=Faster than normal, 3=Deep & rapid.
59

Lungs: /___/ 1=Clear, 2=Congested.
60

Abdomen: /___/ 1=Normal, Sound present, 2=Distended, Sound present,
61 3=Distended, Sound absent.

Prolapse rectum: /___/ 0=None, 1=On Straining, 2=Reduces without aid,
62 3=Persistent, Oedematous (Swollen).

Weight: /___/___/___/ Kg.
63 64 65

Nutritional status as per weight for age: /___/ 0=Over 90% standard,
66

1=75-89% standard (1st degree), 2=60-74% standard (2nd degree),
3=Below 60% standard (3rd degree). Oedema/Kwashiorkor is always 3rd degree.

Diagnosis: /___/ 1=Uncomplicated diarrhoea, 2=Uncomplicated dysentery,
67 3=Complicated diarrhoea, 4=Complicated dysentery.

