chment 1. 86 Date 1-3-1982

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Dr.Syed S. Islam Trainee Investigator (if any) _____

Application No. 82-021(P) Supporting Agency (if Non-ICDDR,B) _____

Title of Study A retrospective study of diarrhoeal mortality pattern among patients treated in the ICDDR,B Dacca Hospital during 1980-81 & associated factors that influences

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 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.

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

Principal Investigator

Trainee

SECTION I - RESEARCH PROTOCOL

82-021(P)
2/5/82

1. Title: A retrospective study of the diarrhoeal mortality pattern among patients treated in the ICDDR,B Dacca Hospital during 1980-1981 and associated factors that influences it

2. Principal Investigator: Dr. Syed Shafiqul Islam

   Co-Investigator: Dr. M.U. Khan

3. Starting Date: 1st March, 1982

4. Completion Date: 31st August, 1982

5. Total Direct Cost: US$ 881.30

6. Scientific Programme Head:

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

   Signature of Scientific Progamme Head: [signature]

   Date: 22/4/1982

7. Abstract Summary: This is a retrospective study extracting informations from hospital records. Different well documented characters will be compared between cases and controls. The cases are those people died from diarrhoeal diseases and associated conditions at ICDDR,B Dacca Hospital between 1980-1981 and controls are those who did not die over the same period. The mortality pattern will be studied over the

same period and crude death rate, age, sex specific death rate, cause specific death rate, case fatality rate, standardized mortality ratio will be determined among the various age cohorts and different characteristics of the cohort will be compared in an effort to see it: influence on mortality.

8. Reviews:

a. Ethical Review Committee: _____

b. Research Review Committee: _____

c. Director: _____

d. BMRC: _____

e. Controller/Administrator: _____

ABSTRACT SUMMARY

It will be a retrospective descriptive and case-control study extracting informations from hospital records. All cases admitted to ICDDR,B Dacca Hospital will be identified according to diarrhoeal aetiology and the number of specific diseases will be obtained for the period 1980 to 1981. All the hospital records of the dead cases will be thoroughly reviewed to fill in a pre-set questionnaire which is designed to obtain maximum and specifc information regarding the cases. A control group will be selected from the hospital patients admitted over the same period and who did not die matching age sex and diagnosis (microbiological). Hospital records of the controls will be searched and the same questionnare as for the dead cases will be filled in for the control group also. When all the available informations will be collected they will be tabulated and analyzed using standard statistical methods. Different characteristics of the age and sex cohorts will be studied and an effort will be made to correlate it with the differences in the mortality rate.

Therefore the objective of this study is to determine: (a) Main diarrhoeal aetiology of death in patients treated in ICDDR,B, Dacca Hospital. (b) Crude death rate from diarrhoeal diseases, case fatality rate, seasonal pattern of death, standardized mortality ratio and proportionate mortality ratio from particular diarrhoeal disease. (c) Observations will be made on duration of illness, initial serological

parasitological and haematological variables at the time of admission such as blood glucose level, serum electrolyte, specific gravity of the blood, serum protein, WBC total and differential counts, nutritional status at the time of admission, rates of readmission by age and sex, pattern of medication such as antibiotic, I.V. fluid and oral fluid. These observations for the cases and controls will be tabulated and the frequency or the percentage of the characteristics present in each group will be calculated. The following variables will be compared between cases and controls:

(1) Hyper bicarbonaemia

(2) Hypo bicarobonaemia

(3) Hyper kalaemia

(4) Hypo kalaemia

(5) Hypoglycaemia

(6) Hyperglycaemia

(7) Low specific gravity of blood

(8) Low serum protein

(9) Duration of illness

(10) Number treated with antibiotic I.V. fluid, oral fluid,

(11) Nutritional status

(12) Degree of dehydration

(13) WBC - .

(14) Presence of parasites

SECTION II - RESEARCH PLAN

A. INTRODUCTION:

1. Objectives: The objectives of this study will be achieved in two phages. Phage I will be a descriptive part which will describe basic mortality pattern of different diarrhoeal diseases in ICDDR,B, Dacca Hospital. Therefore

   Phage I

   To determine mortality pattern of diarrhoeal diseases in ICDDR,B, Dacca Hospital.

   Phage II will be an analytical part depending on the findings of Phage I.

   Phage II

   Identification of risk factors for mortality in the most common diarrhoeal diseases.

2. Background: Mortality pattern in developing countries varies from that of developed countries because of socio-economic growth, availability of food, medical facility and public health development. Variation within a country is due to inequal development and accessibility to development programs. One of the major health problem facing Bangladesh and other

developing countries are higher mortality and morbidity from diarrhoeal diseases. About 2000 million cases are expected among the childrens of Asia, Africa and Latin America each year (Leonards Mata et al 1980). Prospective studies in Guatemalan village shown that 10% of all infant deaths were by diarrhoea 16% in 1 year-olds and 25% among 2 and 3 year- old (Mata 1978). Several estimations of total world mortality suggest about 10 million deaths in children under five years in 1975 (Nichol and Soriano 1975). Costa Rica had a specific death rate due to diarrhoeal diseases of 431 per 100000, a rate similar to that of UAR in 1970. More than 95% of diarrhoea deaths in 1977 were in infants (L. Mata and Mohs 1976).

In Bangladesh, on study in the rural areas showed that the most frequent causes of death are dysentery, tetanus, respiratory diseases and tuberculosis. About one quarter of all deaths were attributed to other unspecified circumstances (Ruzicka et al 1975). Despite some limitation it is worth noting that in one quarter of reported deaths, dysentery and diarrhoea were mentioned as cause. This percentage rose to 34 among the deaths of children aged 1-4 years (Ruzicka et al 1975). Mortality from diarrhoeal diseases in Bangladesh has a strongly pronounced seasonal variation. In most instances death rates were higher

for females than males, the only exception being infancy and age groups 30-34 and 40-59 years (Rizicka et al C.R.I & Scientific report no. 13). In Indonesia gastroenteritis is still one of the major causes of morbidity and mortality in children particularly those under five year age group. The case fatality rate was 62.2% in 1959 there and after introduction of oral solution and other preventive measures it is now down to 6% in 1980 (Tumbelaka et al 1980). In India maximum mortality in a children's hospital was due to tuberculosis. But next to it was gastroenteritis. Of the total 9.4% G.I. tract infection, 5.2% were gastroenteritis, 0.1% amoebiasis and 2.3% typhoid (Pandey et al 1980). Although in Costa Rica and in many other countries diarrhoea was displaced to a second or even lower position as a cause of death, it still remains leading health problem. In fact a strong correlation is still observed between diarrhoeal disease specific death rates and infant mortality rate (Leonardo Mata 1978, p 1-14).

Therefore diarrhoeal diseases were identified as a leading health problem in the developing world. To assess the magnitude of the problem mortality and morbidity figures are good indicator. In case of child mortality the major cases of neonateal mortality in developed countries are immaturity, congenital defects and birth injuries. For post neonatal deaths infection are the major cause

of death. For developing countries infection such as septicaemia tetanus, diarrhoeal diseases in addition to birth injury and congenital defects are the major causes of death. Like many other less developed countries, the rationale for focusing on death among children under age 5 in Bangladesh is strong (L.C. Chen 1980). It was estimated that in 1975-1977 children under 5 year age group contributed to 53.1% of all death in rural area of Bangladesh. Of the 12893 deaths reported in that area major causes of death were diarrhoea (watery and dysentery) which was 18.8% of all deaths (L.C. Chen 1980 page 26-27). Among infants most significant cause of death was tetanus. A significant shift in cause of death occurs in children 1-4 years of age. In this group 43.9% of death were due to diarrhoeal diseases and children who were below 65th percentile of Harvard weight for age standard experienced about 3 fold higher rate of mortality (L.C. Chen et al 1980). Infant mortality in rural area of Bangladesh showed infant mortality rate of 89, post-neonatal mortality rate 71 and of the total infant death, tetanus accounted for 21% , pneumonia 19%, prematurity 12% birth injury 7% fever 6% (CRL Scientific Report No. 44).

The most common diarrhoeal diseases that are encountered at the ICDDR,B, Dacca Hospitals are V. cholerae, Shigella, Salmonella, NAG, V. Parahaemolyticus, E. coli (ETEC, EPEC, EIEC) Campylobacter Rotavirus, Y. colitica, E. histolytica, Giardia lamblia etc.

The precise mortality rates of diarrhoea of different origin are not known beyond the areas studied by ICDDR,B. The mortality rate of about 40% of untreated severe cholera cases can be reduced to 0.5% by proper replacement of electrolyte and fluid. Mortality from shigellosis is not known for untreated cases but in ICDDR,B about 4% cases die (Review Article written by Dr. M.U. Khan and Dr. W.B. Greenough III for presentation at the international symposium on Bacterial diarrhoeal diseases, Osaka, Japan - Glimpse Vol 4, No. 2, Feb 1982. However, in 1976 Shigellosis was a major problem and it was shown that 30% of all deaths were associated with a positive diagnosis of shigellosis whereas 0.9% of deaths were attributed to cholera and 69% remained undiagnosed (M. M. Rahman, Scientific paper presented in the Technical Committee meeting in 1976).

There are a lot of variables that are known to be very important in mortality studies. Variables like age, sex, race, geographical location, socio-economic conditions, culutral beliefs, availability of health services etc. influences the mortality figures. One Bangladeshi study showed that there is a correlation between diarrhoeal mortality and distance from the treatment centre (M.M. Rahaman, KMS Aziz et al 1980).

The variables that describe the social and economic position of the individual family and house hold are often inadequate or unreliable.

Since such surveys have limited objectives and are not specifically designed to explore social and other differentials in mortality. Anthropological data such as family attitude to risk taking, to dangers of sickness and death, to cost of treatment and to the risks involved in deferring treatment are not available. Community variable such as structure and operation of health services, prevalence of disease such as malaria, quality of community sanitation and climatic characteristics are not available at micro level of analysis. As we know that it has got tremendous influence on mortality, Omission of them in a study of such nature may risk losing important influencing factor (WHO 1980). Keeping this in mind we are looking for only well documented data and reliable hospital records which will have less social variables and more disease related variables. We are aware of the limitations of the study but correlating the variables under consideration and comparing it with a control group we shall be able to provide further opportunity to the clinicians and public health workers in their effort to develop an effective strategy to prevent and reduce mortality from diarrhoeal diseases. As only one quarter of all deaths are due to diarrhoeal diseases, this study can only draw some inferences on what is happening in the community in relation to a particular disease group and it can in no way predict about mortality due to other diseases.

The CRL hospital in Dacca, now known as ICDDR,B, is the principal centre for the treatment of diarrhoeal diseases. No fees are charged for its services. It has been functioning since 1963. It became International Centre for Diarrhoeal Disease Research in 1978. Severe and moderate diarrhoea cases are brought here by people themselves. Cases are also referred by local people, physicians and by city hospitals. In addition to municipal area patients arrive in this hospital from all surrounding areas of Dacca city. Due to limitation of beds, admission are restricted to selected cases only. There had been no mortality studies in the past to answer questions like who are the people dying in this hospital, their demographic characteristics, diarrhoeal aetiology as confirmed by microbiology, nutritional status, duration of illness, duration of hospital stay, seasonality of death and other associated variables that may be a risk factor for mortality figure. In a study conducted in 1974, 1975, 1976 to find out how people utilize the facilities available in the urban area, it was found that 73.7% of all cholera patients came directly to ICDDR,B, Dacca hospital without consulting any one. This proved that the centre is well known to the population as a treatment centre for diarrhoeal diseases and also people are utilizing it frequently. However, not all the cases admitted to this hospital do have diarrhoeal aetiology and not all the cases have got confirmed microbiological diagnosis. In

all the cases diarrhoea was the main presenting symptom. Routine stool culture and microscopical examination were done to isolate and detect shigella, salmonella, V. cholerae, Entamoeba histolytica and other parasites. For other diarrhoeal diseases no routine microbiological investigations are done. In a random survey to study the feasibility to use microbiological diagnosis as disease aetiology I found that out of 99 death cases microbiological test and M/E were done in 95 cases. A large number of cases there is no confirmed diagnosis and tests for ETEC, Rotavirus and Campylobacter were/not done in most of the cases. According to this feasibility study cause specific death rate. Case fatality rate can be determined in diarrhoeal diseases such as Shigella, NAG, Vibrio cholerae, Salmonella, Entamoeba histolytica only.

Two commonly used differential mortality ratios in epidemiological studies are Standardized Mortality Ratio (SMR) and Proportionate Mortality Ratio (PMR). The SMR is the statistics of choice where the population at risk are known by age and sex. It provides information on a study groups overall risk of dying as well as risk for specific cause of death. On the other hand PMR is the tool of estimating cause-specific risk when available data consists only of deaths without knowledge of the characteristics of the population from which the data came (Pierre De confle et al 1980).

In a given situation, what ever the better of the two statistics, their joint computation and examiantion (provided necessary data are available may often be the most sensible course (Rodolfo Saracci et al 1981).

Rationale:

Phage I

A descriptive study of the mortality pattern will give us the opportunity to find out major causes of death. Various rates in relation to mortality that we will determine are going to help public health people in their effort to collect basic demographic data. Our finding can be utilized as an important observation and due to homogenicity of population in relation to sanitation, water supply, health habits and health services similar results are expected in other areas.

Phage II

The case control study will enable us to identify particular risk factor(s). This will also help clinicians to identify high risk group and adopt measures to control risk factor(s). It will also help in the design of future diarrhoea treatment centre. Some of the risk factors that we will determine can be followed prospectively by other investigators and further experiments can be carried out.

SPECIFIC AIM

Phage I

It will be the descriptive part of the study. The aims are :-

1) to determine crude death rate, cause specific death rate, case fatality rate for diarrhoeal diseases with or without associated conditions.

2) Determine standardized mortality ratio and proportionate mortality ratio for various age cohorts.

3) Observations on (a) nutritional status (b) duration of illnes (c) limited physical, microbiological, biochemical, serological, parasitological features (d) types of medication used such as antibiotic, intravenous fluid and oral fluid.

4) Observations on other associated diseases other than diarrhoeal aetiology as diagnosed by radiology, microbiology, blood cuture etc.

Phage II

This part will be the analytical portion evolving a case-control study. The aims will be:

1) To compare various characteristic as observed in phage I of the study between cases and controls.

2) Identification of possible risk factor(s) and confounding factor(s) and their effect.

METHODS AND PROCEDURES: Phage I

Methods of analysing mortality data to study association between mortality pattern and risk factors depend on overall availability of data. The traditional approach is to use population at risk as denominator and event as numerator. ICDDR,B Dacca hospital is a major centre for the treatment of diarrhoeal diseases. Any patient with diarrhoea and dysentery are examined by a medical assistant initially and treated with oral solutions at home. Records are available on how many patients attend the out patient. After being screened by the medical assistant cases are referred to a physician, who takes history and makes provisional clinical diagnosis. A separate recording is done at this stage and patients are kept under observation for few hours here and occasional stool for M/E are sent at this stage. After few hours of observation and treatment with only oral or I.V. fluid if the patients do not improve they are sent to diarrhoea wards where dark field microscopy and culture and other specific test for Shigella, Salmonella, Campylobacter, NAG, V. parahaemolyticus, Yersinia colitis, Rotavirus etc. are occasionally done. However some critically ill patients are directly admitted to hospital ward for further investigation and treatment. Therefore, confirmed microbiological diagnosis can be obtained only in hospitalized cases. All death cases that took place in hospital wards of ICDDR,B Dacca hospital between 1st July, 1980 to 30th June 1981 will be reviewed

retrospectively. The overall mortality rate will be determined by taking all the cases admitted to ICDDR,B, Dacca hospital, between July 1980 to June 1981 as denominator and all cases died during that period as numerator. Cause specific deaths rate will be determined by taking death cases with specific diagnosis as numerator and total hospital admission as denominated. Age specific death rates will be determined by taking age cohorts of 1-<1 year, 1-4 years, 5-9 years, 10-19 years, 20-29 years, 40-49 years, 50+ age groups. Case fatality rate in each cohort will be determined by taking the number of fatality in cohort from a specific cause as numerator and total number of specific cases in the cohort admitted to ICDDR,B hospital within the period mentioned as denominator. To get this denominator total number of cases according to diarrhoeal etiology over the same period will be collected from the hospital record as confirmed by microbiology. Overall case fatality rate will be determined by taking total number of cause specific cases as denominator irrespective of cohort and the number of death from specific cause as numerator. Standardized mortality ratio will be determined for each cohort which is observed death in the cohort divided by expected death in the cohort expressed as percentage. Expected number will be calculated by applying crude death rate of the total patients from all diarrhoeal cause to the stratum weight (i.e. total number of patients in particular cohort or disease group . Combined population will be taken /in case of standardizing death rates in different age cohorts. Proportionate mortality ratio will be determined by taking the number of cause specific

death as numerator divided by total death from all diarrhoeal cause as denominators. Seasonality will be determined by months.

The total number of death cases according to specific diarrhoeal aetiology will be taken from the bacteriological record of the hospital and as we know that routine stool culture are done for Shigella, Salmonella, and Vibrio cholerae including NAG only and microscopical examinations are done for E. histolytica, Giardia, and ova of helminths. Our denominator will be total number of cases where microbiology were done for the above mentioned diarrhoeal diseases and numerator will be total number of death cases, who have confirmed specific microbiological or serological diagnosis. In this laboratory stool culture for Shigella and Salmonella are done in MacConkey's and SS media and for V. cholerae TTGA is used. All of these medias are known to be the best mediums for growing colonies of the above three diarrhoeal agents. For E. histolytica routine microscopical diagnosis will be taken as screening test. Therefore all death cases for whom no bacteriological tests for the above were done will be omitted from the study. All other cases where microbiological findings for the above organisms are negative and there are no other specific diagnosis, will be considered under non-specific diarrhoea under whom falls presumably viral diarrhoeas, Campylobacter Y. colitica, E. coli (EPEC, ETEC, EIEC), V. parahaemolyticus etc. The mortality rates for non-specific diarrhoeas will be determined also. Following dummy table shows the distinctions of specific and non specific diarrhoeal aetiology for this study.

Table 1

Disease:	Specific test done	
	No. Positive	No. Negative
Shigella		
Salmonella		
Vibrio cholerae (including NAG)		
E. Histolytica		
Mixed infection		
Non-specific diarrhoea		

Total no. positive (specific diarrhoeal aetiology)	Total no. negative (non-specific diarrhoeal aetiology)

Another table will show:

Table II

Diseases not confirmed by microbiology, serology, blood culture and microscopical examination.	Assocaited microbes		
Total No.	Name	Where found	No. of Cases

Phage II

It will be a case control study and the selection of cases and controls will be as follows:

Case selection:

The cases will be any person died from diarrhoeal aetiology as evidenced by specific microbiological findings. Any of the following cases will be considered to have had specific diarrhoeal aetiology. They are (1) V. cholerae including NAG, (2) Salmonella sll groups (3) Shigella (4) Amoebiasis (5) mixed diarrhoeal aetiology. Others will be considered as non-specific diarrhoea in this study and will be excluded from case control study. Associated conditions are diseases such as (1) Pneumonia (2) Measles (3) Whooping cough (4) Meaningitis (5) Encephalitis (6) Protein energy malnutrition (7) Amaemia (8) Diabetes. For primary disease aetiology microbiological diagnosis will be taken as a valid criteria for diagnosis and for associated conditions clinical diagnosis accompained by radiological, haematological, microbiological and biochemical findings. Compatible with clinical diagnosis will be the valid criterion. In any case where clinical diagnosis is not compatible with theaccompanying radiological, haematological, microbiological and biochemical findings will be excluded from the study.

Control Selection:

Controls will be selected from the same hospital who were admitted over the same period with specific diaarhoeal aetiology and associated

conditions and did not die. The controls will be matched with cases in age sex and disease aetiology. By disease aetiology we mean diarrhoeal aetiology and associated conditions are same as mentioned for cases and the diagnositc criterion will be same as mentioned for cases. We are expecting 400 cases over the same period. For each case one control will be selected and the hospital registrar will be searched for each case onward to select a control. By matching the cases with controls in age sex and disease aetiology we are eliminating major source of bias. We are collecting similar information about the cases and controls as such there can be no bias regarding collection of data. Frequency of various characteristics of the cases and controls will be compared & a matched pair analysis will give R.R, (Relative risk) for each variable under study.

To make best use of our data a frequency table as follows will be prepared with various characteristics of the cases and controls:

Table III

Associated characteristics	Cases		Controls		Frequency in cases	Frequency in control
	Characteristic		Characteristic			
	(+)	(-)	(+)	(-)		
Pneumonia						
Meningitis						
Whooping Cough						
Measles						
Hyper natraemia						
Hypo Kalaemia						
Hypoglycaemia						
Etc.						

The number of frequency of characteristics under study for the cases and controls will be tabulated in a 2x2 table and odds ratio or relative risk will be determined using following proforma for matched pair analysis:

CASES	CONTROLS	
	With characteristics	Without characteristics
With characteristics	r	s
Without characteristics	t	u

Here RR (Relative risk)=s/t provided $t \neq 0$

Confounding effects of the different variables can be determined by a stratified analysis and controlled. Because of a large number of variables a multivariate analysis i.e multiple logistic regression will be done. Initially a crude analysis followed by stratified analysis will determine confounding effect.

Therefore matched pair analysis for Shigellosis, V. cholerae including NAG, SAlmonella and E. histolytica will be done and the resultant RR will identify risk factor.

The variables that we shall consider as a risk factor and will be analyzed are as follows:

(1) Associated diseases as supported by microbiological, clinical, haematological, serological or other specific diagnositic tests. They are speticaemia, meningitis, measles, whooping cough, diabetes, bronchopneumonia protein energy malnutrition.

(2) Anaemia as evidenced by Hct. If Hct is below 42 in females and below 40 in males will be considered as low.

(3) Hyper natraemia if serum sodium more than 144 mmol/l.

(4) Hyponatraemia if serum sodium below 137 mmol/l.

(5) Hyper bicarbonaemia if serum bicarbonate more than 28 mmol/l.

(6) Hypo bicarbonaemia if serum bicarobonate less than 23 mmol/l.

(7) Hyper kalaemia if serum pottassium above 4.5 mmol/l.

(8) Hypo kalaemia if serum pottassium below 3.5 mmol/l.

(9) Hypoglycaemia if fasting blood sugar below 3 mmol/l.

(10) Hyperglycaemia if fasting blood sugar above 5 mmol/l.

(11) Low specific gravity of blood if specific gravity below 1.023

(12) Low serum protein if serum protein below 60 gm/ liter

(13) Duration of illness, mean and two standard deviation and its correlation to mortality.

(14)a. Number treated with antibiotic (any) expressed in percentage and its correlation to mortality

b. number treated with I.V fluid and its correlation to mortality.

c. Number treated with oral fluid expressed as percentage and its correlation to mortality.

(15) Nutritional status as determined clinically by physician

(16) Nutritional status as determined by taking weight for age corrected for the degree of dehydration.

(17) Degree of dehydration will be taken as follows:

Mild - below 5% dehydration

Moderate - between 5% to 10% dehydration

Severe - above 10% dehydration.

(18) WBC changes: range as mentioned in the questionnaire.

(19) Presence of parasites such as giardia, OVA of AL, AD,TT,strongyloid stercoalis, necator Americana. If any one present will be categorized as presence of parasite and its correlation to mortality.

After frequency of all these variables are tabulated in a frequency table as mentioned earlier, we shall consider the most important of the above variables for a matched pair analysis. In determining the important variables the distribution of the characteristics between the cases and controls and the confounding variables will be considered. Stratified analysis will be done to see the effect of confounding and it will be controlled by appropriate method.

SIGNIFICANCE:

Phage I

Providing basic mortality data will help us understanding the magnitude of the problem in this hospital. If we know which disease is the major killer, we can also determine priority to take preventive action.

Phage II

The expected risk factors that are going to come out will give us opportunity to reevaluate or change our strategy both at hospital and community level. The risk factor(s) that we shall find can be followed prospectively and intervention can be done. Therefore the clinicians are going to strive maximum benefit out of this study because if he knows the risk factor for mortality and if he knows which particular group suffers most, he can easily make intervention and thus save a number of lives by timely action.

FACILITIES REQUIRED:

1. Office space: No additional space required

2. Laboratory space : Not required

3. Hospital resources - No additional requirements

4. Animal resources - Not required

5. Logistic support: Transportation from home to ICDDR,B hospital and back.

6. Major item of equipment - None

7. Specialized requirement - None

COLLABORATION ARRANGEMENTS:

None

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SECTION III - BUDGET

1. PERSONNEL SERVICES

Name	Position	% of effort	No. of Days	Annual Salary	Project Requirement Taka	Dollar
Dr. S. S. Islam	Prin. Investigator	100%	180	-	-	-
Dr. M.U. Khan	Co-Investigator	5%	60	-	-	-
(To be named)	Med. Rec. Keeper	50%	10	30,000	450	
			Sub Total:	30,000	450	
Data Management Branch						
(To be named)	Data Col. Asstt.	100%	30	24,000	2,000	-
" " "	Statisticians	25%	10	-	400	-
" " "	Statis. Asstt.	25%	10	24,000	170	-
" " "	Coding Asstt.	50%	10	24,000	335	-
			Sub Total:	72,000	2,905	
Computer Service (Contractual Service)						
(To be named)	Programmer	100%	5	42,000	590	-
" " "	Data Ent. Tech.	100%	3	24,000	200	-
	Computer Time	3 hrs. @Tk.400			1,200	-
	Computer Tape	1(one)			200	-
	Computer Punch Card	One Packet			200	-
				76,000	2,390	-

SUPPLIES AND MATERIALS

Item	Unit Cost	Amount Required	Project Requirement Taka	Dollar
Stationery office supplies and correspondence			4000	
Equipment - None				
Patient Care - None				
Out Patient Care - None				
Travel and Transportation of person - Nil				
PRINTING AND REPRODUCTION(Including foreign Publicastion)			7000	
		Sub Total:	11000	
		Grand Total:	16775	

US Dollar 881.30

19 Taka = US$ 1.

BUDGET SUMMARY

		Taka	Dollar
1.	Personnel	4,145.00	-
2.	Supplies	4,000.00	
3.	Equipment	-	
4.	Hospitalization	-	
5.	Outpatients	-	
6.	ICDDR,B Transport	-	
7.	Travel - Person	-	
8.	Transportation of things	-	
9.	Rent/Communication	-	
10.	Printing/Reproduction	7,000.00	
11.	Contractual Services	1,600.00	
12.	Construction	-	
	Total:	16,775.00	

Conversion rate US$ 1= Tk. 19.00

US$ 881.30

QUESTIONNAIRE FOR MORTALITY SURVEY

Name of the Patient:

Address:

Column	Items & Code	
1-5	Patient No.	/ / / / / /
6-11	Age	/ / / / / / (Yr. Mon. Days)
14	Sex : Male - 1 Female - 2 Unknown - 3	/ /
15-18	Date of admission	/ / / / /
19	Time of admission	
	0 hr. - 3 am = 1	
	3 am - 6 am = 2	
	6 am - 9 am = 3	
	9 am -12 am = 4	/ /
	12 am - 3 pm = 5	
	3 pm - 6 pm = 6	
	6 pm - 9 pm = 7	
	9 pm -12 pm = 8	
20-25	Date of onset of disease	/ / / / / / /
26-29	Date of death	/ / / / /
30-33	Time of death	/ / / / /
34	Onset-death interval	
	0 <3 days = 1	
	3- <6 days = 2	/ /
	6- <9 days = 3	
	9 <12 days = 4	
	12 <15 days = 4	

Column	Items & Code	
	15- < 20 = 6	
	20- < 30 = 7	
	> 30 = 8	
35-36	Admission weight	/ / /
37-39	Nutritional Status (Poor, Ave., Good)	/ / / /
40-41	Duration of hospital stay	/ / /
42-43	Onset - Admission interval	/ / /
44	Clinical diagnosis	
	Vibrio cholerae - 1	
	Salmonella - 2	
	Shigella - 3	
	E. Histolytica - 4	
	Septicaemia - 5	
	Meningitis - 6	
	Mixed - 7	
45	Microbiological diagnosis	
	Vibrio cholerae - 1	
	Salmonella - 2	
	Shigella - 3	
	E. Histolytica - 4	
	NAG - 5	
	Rotavirus - 6	
	Campylobacter - 7	
	ETEC - 8	
	Mixed - 9	

Column	Items & Code
46	Level of dehydration None 1 Mild 2 Moderate 3 Moderate severe 4 Severe 5 / /
47-48	Hct / / /
49	WBC total count Leucopenia - 2 (below 4000/cuml) / / Leucocytosis - 1 (above 11000/cuml) Normal - 0 (4000-11000/cuml)
50	Range Poly morph 2500-7500 (cuml) or 40 75%) Lymphocyte 1500-3300 (cuml) or 20-45% Eosinophil 40-440 (cuml) or 1-6% Basophil 0-100 (cuml) or < 1% / / Monocyte 200-800 (cuml) or 2-10% Eosinophilia - 0 above 440 (cuml) or above 6% Lymphocytosis - 1 about 3300 (cuml) or above 45% Polymorph. Leucocytosis-2 above 7500 (cuml) or above 75%
51	Normal Range Blood Glucose 3-5 mmol/L or 60-100 mg/100 ml (fasting) (Initial) Hypo - 1 Hyper -2 / / Normal-0
52	Serum electrolyte Normal Range Sodium Hyper 2 Hypo 1 Normal 0 137-144 mmol/L / /
53	Potassium Hyper Hypo Normal 3.5-4.8 mmol/L / /
54	Chloride Hyper Hypo Normal 96-108 mmol/L / /
55	Bicarbonate Hyper Hypo Normal 23-28 mmol/L / /

Column	Items & Code	
56	Oedema - Yes - 1 No - 2	/_____/
57	Fever - Yes - 1 No - 2	
58	Convulsion - Yes - 1 No - 2	/_____/
59	Anorexia - Yes - 1 No - 2	/_____/
60	Admission to other hospital - Yes - 1 No - 2	/_____/
61	Whether previously admitted to this hospital - Yes - 1 No - 2	/_____/
62	Whether received antibiotic or not - Yes - 1 No - 1	/_____/
63	Whether received I.V. fluid or not - Yes - 1 No - 2	/_____/
64	Whether received oral fluid or not - Yes - 1 No - 2	/_____/
65	Diet: Breast milk - 0; Artifical milk - 1; Rice curry - 2; Others - 3	/_____/
66	Parasitological findings	/_____/

Ova of Ascaris lumbricoides - 1

Ova of Ankylostoma duodenale - 2

Ova of Nector Americana - 3

Ova of Trichuris Trichura - 4

Larva of Strongyloid Stercoralis - 5

Giardia Lumblia in Stool - 6

E. Histolytica - 7
(cyst or vegetative form)

ABSTRACT SUMMARY

1. The population under study were all patients admitted to ICDDR,B Dacca Hospital between 1980-1981 and only the hospital records of such patients will be used.

2. As the patients are not physically or mentally involved with the study there is no physical, social, legal and other risks.

3. The procedure is a retrospective hospital record study and as such will have no potential hazard.

4. The cases and controls are selected using hospital records and there is no further enquiry about the patients, alive or dead in any form. The questionnaire involved is to fill data from existing documents available and the name and address of the patient will not be revealed in any part of the study. The data will be only numerical and as such there is no leakage of confidential.

5. There is no need for any signed consent or no informations are with held from the patients and there is no physical and mental or other association between the population under study and the present study.

will be required.

7. The benefit of this study does not go for the population under study but goes for the similar population in the future. The

The mortality pattern and the associated risk factors are a very important land mark for the public health physicians and also for Clinicians to formulate prevention and intervention.

8. The acitivities required are going through the hospital admission and medical records. No physical, biochemical or other tests are required. However records of the biochemical, physical, haemtological, microbiological and others will be studied which are already existing.

The approximate time to complete the study is 6 months.