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ETHICAL REVIEW COM	MITTEE, ECHORAL-12	92 0
Principal Investigator Dr. Guo Cunsan	Trainee Investigator (if any)	2 3 Z
About string No. 4 -4 -7 7 1	Supporting Agency (if Non-ICDO)	and the supplemental statement of the supplement

citie of Study (1 study to determine the role Project status:

shigelleides as a cause of New Study

Continuation with change patients Seen at LCDDR B Dlake Hispatal No change (do not fill out rest of form)

Circle the appropriate answer to each of the following (If Not Applicable write NA). Source of Population:

5. Will signed consent form be required: (a) [11] subjects No

(a) From subjects (b) Non-ill subjects No From parent or guardian (c) Minors or persons

(if subjects are minors) (Yes) No under guardianship (Yes) No Will precautions be taken to protect Doos the study involve: anonymity of subjects (a) (Yes) No

Physical risks to the Check documents being submitted herewith to subjects Yes Committee:

(b) Social Risks Yes Umbrella proposal - Initially submit an (c) Psychological risks

overview (all other requirements will to subjects Yes be submitted with individual studies). (d) Discomfort to subjects Yes (No

Protocol (Required) (e) Invasion of privacy Yes Abstract Summary (Required) (f) Disclosure of informa-

Statement given or read to subjects on tion damaging to subnature of study, risks, types of questject or others Yes No

ions to be asked, and right to refuse Does the study involve: to participate or withdraw (Required) (a) Use of records, (hosp-Informed consent form for subjects ital, medical, death,

Informed consent form for parent or birth or other) Yes (b) Use of fetal tissue or guardian

Procedure for maintaining confidentialabortus Yes (No) ity (c) Use of organs or body

Questionnaire or interview schedule * Huids (Yes) No If the final instrument is not completed Are subjects clearly informed about: prior to review, the following information (a) Nature and purposes of

should be included in the abstract summary. fudy No A description of the areas to be (b) Procedures to be covered in the questionnaire or followed including

interview which could be considered alternatives used Yes NA either sensitive or which would (c) Physical risks Yes (09) constitute an invasion of privacy. (d) Sensitive questions Yes

Examples of the type of specific Benefits to be derived (Yes) (e) questions to be asked in the sensitive (f) Right to refuse to areas.

participate or to with-An indication as to when the questiondraw from study No naire will be presented to the Cttee.

Confidential handling (g) for review. of data Yes) No (h) Compensation 6/or treat-

ment where there are risks or privacy is involved in any particular procedure (Yes) No

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

rincipal Investigator

SECTION I - RESEARCH PROTOCOL

87-007/10

1. Title

A study to determine the role of <u>Plesiomonas shigelloides</u> as a cause of diarrhea among patients seen at ICDDR,B Dhaka Hospital.

2. Principal Investigator: Dr. Guo Cunsan

<u>Co-Investigators</u>

: Mr. Zeaur Rahim Dr. Nigar Shahid Dr. Bradford A. Kay Dr. David A. Sack Dr. A.N. Alam

3. Starting Date

: When fund is available

4. Completion Date

: Six months after starting date

5. Total Direct Cost

: US \$ 4980

6. Scientific Program Head:

This protocol has been approved by the

Disease Transmission

Working Group.

Signature of Scientific Program Head:

Date: 12 March 1987

7. Abstract Summary

Plesiomonas shigelloides has been the sole agent identified in several outbreaks of diarrhea and from a number of isolated cases. Its role as a human pathogen is not clear since isolates have not yielded positive results in the rabbit ideal loop test and do not produce enterotoxin.

P. shigelloides is isolated from about 6% of human stool specimens submitted for culture at Dhaka Hospital. The purpose of this protocol is to determine whether P. shigelloides is a cause of diarrhea using a case—control study design.

8.	Revi	ews

a.	Ethical Review Committee :
b.	Research Review Committee :
c.	Director:

and who had been in Thailand at least 5 weeks (chi square = 3.65).

Among the indigenous groups in Thailand, P. shigelloides was identified in 2.4% of hospitalized children <2 years of age whether they had diarrhea or not, and it was not detected in newborn stools. A trend was observed toward isolation of P. shigelloides in a greater number of cases than controls among urban children 0-2 years of age (13% vs. 3%) and 2-10 years of age (43% vs. 10%) but the numbers of cases and controls were small.

The association between <u>P. shiqelloides</u> and diarrhea in hosts with impaired immunity is better established (9,10). Penn et al. described an 83 year old with achlorhydria and small bowel diverticula who had chronic diarrhea and malnutrition (9). <u>P. shiqelloides</u> was isolated from stool and a small bowel aspirate, the latter had 3×10 colonies per ml. The patient responded to treatment with tetracycline to which the organism was sensitive.

The mechanism by which <u>P. shiqelloides</u> causes diarrhea is unknown. The isolate reported by Penn et al. did not produce toxin measured by the infant mouse or chinese hamster ovary assays (9). Pitarangsi and coworkers found that none of <u>11 P. shiqelloides</u> strains produced mannose resistant agglutination of human or bovine red blood cells (RBC), and supernatants from 0 of 27 strains were cytotoxic for Y1 adrenal cells, hemolyzed rabbit or bovine RBC, distended suckling mouse intestine at 4 hours or caused fluid accumulation in ligated rabbit ileal loops at 18 hours (8). One strain from a patient with severe diarrhea was given to five rhesus monkeys and no symptoms were observed. Sanyal et al. (11) also tested <u>P. shiqelloides</u> isolates

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objectives:

The objective of this study is to determine whether <u>p</u>. shigelloides is a cause of diarrhea and risk factors for acquiring the infection.

2. Background:

<u>Plesiomonas</u> <u>shiqelloides</u> is a gram-negative, fermentative, oxidase and catalase-positive motile bacilli in the family <u>Vibrionaceae</u> (1). It has been isolated from a number animal species including humans, water and sludge (2).

Since its first description in 1947 (3), controversy has existed over the role of <u>P. shiqelloides</u> as a cause of diarrhea in humans. Several outbreaks of foodborne disease were attributed to <u>P. shiqelloides</u> in Japan during the 1950s (4). In addition, a number of reports have documented its presence in a low percentage of patients with diarrhea, frequently with other enteropathogens (5,6,7). These studies have usually not included controls, particularly controls without diarrhea.

Pitarangsi et al. (8) looked at five groups of people in Thailand. Two of the groups consisted of American Peace Corps Workers and the other three groups included newborns, hospitalized children less than two years of age and residents of an urban community. P. shiqelloides was isolated from 13 (33%) of 39 American Peace Corps workers with diarrhea compared with 5 (14%) of 35 control subjects who did not have diarrhea

from children with diarrhea using a rabbit iteal loop. Four isolates were repeatedly examined and found to cause a small accumulation of fluid on occasion, unlike <u>Aeromonas</u> strains which consistently caused marked bowel distension. One can conclude from this information that <u>P. shigelloides</u> probably causes diarrhea in humans; however, it is not by an as of yet defined mechanism.

Since October 19, 1986, P. shiqelloides has been identified routinely from stool specimens submitted for culture at ICDDR, B Dhaka Hospital. This identification was the result of one of the co-investigator's (ZR) ability to distinguish P. shiqelloides from Shiqella by colony morphology from the Shiqella-Salmonella agar plates used routinely in the laboratory for the isolation of Shiqella sp and Salmonella sp. Colonies of P. shiqelloides are lactose-negative like Shiqella sp. but are slightly larger in size. The colonies are confirmed as P. shiqelloides using inositol, lysine arginine, ornithine, mannitol, oxidase and 0129 biochemical tests.

The stool culture results for the period October 19 to December 5, 1986 have been reviewed by the P.I. of this protocol. During this period, 1283 stool specimens were submitted for culture and 561 (43.7%) yielded a bacterial pathogen. Shigella sp. were isolated from 235 (18.3%), Vibrio sp. from 175 (13.6%), P. shigelloides from 77 (6%), Aeromonas sp. from 39 (3%), Salmonella from 12 (0.9%) and others from 24(2%). P. shigelloides was identified as the sole pathogen from 51(66% of 77 stool specimens yielding this bacterium. The mean/median ages for patients with P. shigelloides as the sole pathogen were older (18.5/17.5) than patients with Shigella sp. (12.4/3.5) and Vibrio sp. (12.6/5.7).

The proportion of patients less than 10 years of age was significantly less among those with diarrhea associated with \underline{P} . shigelloides (44%) compared with \underline{Vibrio} sp. (65%) or Shigella sp. (68%) (p <0.05 by chi square).

3. Rationale:

At ICDDR, B a pathogen can be identified only about 60% of cases. Newer agents for diarrhea need to be identified. This protocol will help determine it if plesiomonas is a causative agent of diarrhea and if so, identify risk factors for acquiring the infection.

. SPECIFIC AIMS

- 1. To determine whether <u>P</u>. <u>shigelloides</u> associated with causes diarrhea in patients seen at ICDDR, B Dhaka hospital using a case-control study design.
- 2. If <u>P. shigelloides</u> causes disease, to determine risk factors for acquiring infection by this organism.
- 3. To delineate the clinical features of diarrhea associated with this bacterium.

. METHODS OF PROCEDURE

Patients enrolled into the Dhaka hospital surveillance programme and living within 6 miles of the ICDDR, B hospital with a stool culture yeilding P. shigelloides but no Salmonella or Shigella or Vibrios will be eligible for included into the study. Informed consent will be requested from the patient or their guardians.

If consent is obtained, the patient or quardian will be asked about food and environmental exposures in the previous three days, and questions about their home, types of water used and diarrheal symptoms in family members. Rectal swabs will be obtained for identification of other pathogens Vz C. jejuni, ETEC and Rotavirus (12,13,14). We will also obtain acute and convalescent (14 day) sera on the index case to measure agglutinating and hemagglutination antibodies against the strain isolated from their stool. Diarrhea will be defined as 3 or most loose or watery stools per day. A rectal swab will be required for P. shigelloides isolation on 14th day.

The next three surveillance patients admitted who do not have a bacterial pathogen isolated from their stool will be used to identify controls. A family member from these patient's family of the same sex and of similar age will be selected if they have not had diarrhea in the previous month. If a suitable control can not be identified among the family members of the first patient, the next patient will be chosen and the process repeated until suitable controls are found. Permission will be requested from these controls for a rectal swab for identification of P. shigelloides a serum sample, and the completion of a questionnaire similar to that use of with the case-patient.

The age criteria used to select the controls will be: for children <2 years of age - another child <2 years; for a child 2-6 years - \pm 1 year but at least 2 years of age; for a child 7-14 years - \pm 2 years but at least 7 years of age; for a person \geq 15 years - \pm 10 years but at least 15 years of age.

C	ollection	of sampl	es	
Sera	Stool	Sera	Stool	
1	1 +			
2 +	+2	+	+	
	Sera 1 +	Sera Stool 1 1 + +	Sera Stool Sera	1 1 + +

¹ Acute sample

All rectal swabs will be placed in Cary Blair transport media and taken to the Dhaka Hospital Microbiology Laboratory where they will be cultured using routine methods. P. shigelloides can be identified from the Salmonella-shigella (SS) agar plate as a lactose-negative colony slightly larger in size than Shigella sp. Suspect colonies will be tested for oxidase, catalase inositol, lysine, arginine, ornithine, mannitol and motility.

Information is not available regarding the presence of <u>P. shiqelloides</u> in stool of patients without diarrhea. If one assumes that it will be isolated from 2% of rectal swabs from control - patients (representing the 2% of patients currently seen at Dhaka Hospital who have <u>P. shiqelloides</u> plus another pathogen) and from 6% of patients with diarrhea, 1237 patients with diarrhea and 147 control subjects will be necessary using $\alpha=0.05$ and $\beta=0.1$. This number of controls could be obtained using a 3:1 control to case match (4% of patients will have <u>P. shiqelloide</u> as the only enteric pathogen = 49 patients).

² Convalescent sample (14 days after onset)

D. SIGNIFICANCE

The results will improve our understanding of epidemiology, and to determine whether <u>P. shigelloides</u> causes diarrhea allow us to assess the public health significance of the diseae in our population. Risk factors for infection will be identified. This information will be helpful in the identification of high risk groupps in the population, and in the development of effective interventions for prevention and control of the infection.

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ICDDE, B BUDGET PROPOSAL (In US \$)

PARTICULARS Program name: LABORATORY SCIENCES & EPID.DIV. Protocol title: A study to determine the role of Plesiomonas shigelloides as a cause of diarrhea among patients seen at ICDDR, B. Dhaka Hospital. P. I's name: Dr. Guo Cunsan Starting date: When fund is available Protocol no: Budget code: Column C : Column D .Column B EXPENSE CATEGORY 1st year . 2nd year, 3rd year ! Project Jan. -Dec. (Jan. - Dec.) Jan. - Dec.) A/C Description Refer Page No. 1200 3100 Local Salaries 3200 Inti. Salaries 3300 Consultants 14 3500 Travel Local 15 3600 Travel Intl. 280 3700 Supplies & Mat. 18 200 3800 Other Costs 19 3300 4800 Inter Deptl. Ser.20 4980 Total Direct cost 0000 Indirect cost = 31% of total direct cost TOTAL OPERATING COST 0300 Capital expenditure Refer page no. 21

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TOTAL PROJECT COST

PERSONNEL_REQUIREMENT-(LOCAL_STAFF)_lat/2nd/3rd_year

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	No.of positions	No. of man months	: \$ Amount
Sirect Project/Protocol/Branch Chaff at starting date Sourced from Page 3	0	0	0
	,		·
Sourced from Page 4	2	12	1200
taff allocated from other area Sourced from Page 5	0	0	0
(i) Sub-Total	2	12	1200
tess:		- · - · · · · · - · -	
7. Separations Sourced from Page 6	0 -	0	0
F. Staff allocated to other area Sourced from Page 7	0 :	0	0
(ii) Sub-Total	0	0	0
(i)-(ii) TOTAL	2	12	* 1200

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!*Agrees with:
! Page 1
! A/C No.3100:

SUPPLIES AND MATERIALS-1ST/2ND/3RD YEAR

FEEEEE		
Code:	Item Description	\$ Amount
3701;	Drugs (used for medication in the hospitals and field stations)	:
3702:	Glasware (bottle, beaker, cylinder, petridish, aluminium seal, slides, stopper, tube etc.)	; ; 50
3703;	Hospital supplies (bandage, gauze, blade, bowl, catheter, cotton, needle, syringe, solution, leukoplast, towel etc.)	; 50 ;
3704;	<pre>Stationery and office supplies (battery, book register, binders, files, pencil, fastener, paper, ribbon, stapler etc.)</pre>	50
3705:	Chemicals and media (acid, reagent, dextrose, sodium, bactoagar etc.)	100
3706:	Materials for upiform (cloth, button etc. required for making uniforms)	· · · · · · · · · · · · · · · · · · ·
3707;	Fuel, oil and lubricants (diesel, mobil, petrol, kerosene etc.)	.,
3708:	Laboratory supplies (aluminium foil, bag, blade, brush, cap, container, film X-Ray etc.)	30
3709:	Housekeeping supplies (aerosol, battery, wiping cloth, duster, lock and key etc.)	· · · · · · · · · · · · · · · · · · ·
3710;	Janitorial supplies (bleaching powder, brush, detol, detergent, insecticide, soap etc.)	·
1	Page total (balance b/d) . :	280

Contd. to page 18

Budget86.17 Aziz-13.

SUPPLIES AND MATERIALS-1ST/2ND/3RD_YEAR

(Contd.	from Page No. 17)	
(A/C : code:	Item description	\$ Amount
;	Page total from page 17 (balance c/d)	280
3711:	Tools and spares (automobile spares, tyres, tubes, battery, stores required for maintenance services etc.)	
3712	Non-stock supplies (materials not normally kept in stock and purchased only against specific requisitions)	;
;	Sub-Total	
3713	Freight and other charges add 30% for import	;
	TOTAL	280
000000		AGREES WITH PAGE 1 A/C 3700 COLUMN D

Note For rates please contact Supply Ext.260 (add 10% to rates for inflation)

Budg : t86.18 Aziz 13.

OTHER_COST-1ST/2ND/3RD_YEAR

A/C : code:	Accounts Description	: \$ Amount
3800;	Repairs and maintenance (maintenance and repairs of vehicles, equipments, furniture and building)	:
3900;	Rent. communication and utilities (postage, telephone, telegram, electricity etc.)	,
4100:	Bank charges	
4200:	Legal and professional expenses (professional membership fee, legal fee, audit fee etc.)	
4300:	Printing and publication (printing of forms, books, journals, reprints etc.)	200
4400:	Bospitality & donation (guest house accommodation, donations, hospital food, lunch, refreshment etc.)	:
4500:	Service charges (porter, labour, washing, laundry and other misc. exp.)	
4600:	Staff development and training (training course fee, training materials, stipend, scholarship, subsistance paid to the staff)	· · · · · · · · · · · · · · · · · · ·
	TOTAL	200
udget8	36 19	: AGRRES WITH : PAGE 1 : A/C No.3800 : COLUMN D

Budget86.19 Aziz-13.

**IHTERDEPARTMENTAL_SERVICES-1ST/2HD/3RD_YEAR

A/C ; code : Service Area	; \$ Amount
4801 : Computer	<u> </u>
4802 Transport Dhaka	1249
4803 . Transport Matlab	
4804 : Water transport-Matlab	
4805 : Transport Teknaf	;
4806 : Xerox	100
4807 Pathology	
4808 . Microbiology tests	1556
4809 Biochemistry	<u> </u>
4810 X-Ray	
4811 ; I.V. Fluid	
4812 : Media	;
4813 : Patient hospitalisation study	
4814 ! Animal research	345
4815 : Medical illustration	, 50
4817 : Telex	
4818 : Out patient care	
4819 : Maintenance charges	
4820 : Vehicle maintenance charges	* *
4821; Library service charges	
4830 : Transport subsidy	•
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	<b>; *</b> 3300
** Please contact Cost Office on Ext. 281.  for rates.	: *AGREES WITH : PAGE 1 : A/C 4800

#### Abstract Summary

surveillance patients seen at ICDDR, B Dhaka Hospital with a A11 stool culture yielding P. shigelloides and no other pathogen will eligible for inclusion into study. Following the identification of the index case, the patient or guardian will be asked some question, including questions about their home. With permission, stool specimens or a rectal swab will be obtained. We will also obtain acute and convalescent sera on the case to measure agglutinating and hemagglutination antibodies against the strain isolated from their stool. The next three surveillance patients who do not have a bacterial pathogen isolated from their stool will be used to identify controls. A family member from these patient's family of the same sex and of similar age group as the index case (P. shigelloides +ve) will be selected if they have not had diarrhoea in the previous month. Permission will be requested from these controls for a rectal swab completion of a questionnaire similar to that use of with the case-patient.

- 1. Controversy has existed over the role of P. shigelloides as a cause of diarrhoea in humans. By conducting this study we hope to determine whether P. Shigelloides causes diarrhoea in patients using a case control study design, and will try to identify the risk factors for acquiring this bacterium.
- 2. There are no potential risk to the subjects of this study.

  Only stool and 0.3ml blood will be collected for examination for acute and convalescence serology.

- 3. There are no significant risk to the subjects of this study.
- 4. The data will be coded and all files will be keep under lock and key. Hence anonymity will be maintained.
- 5. A signed consent will be obtained from the patient or guardian on the consent form attached.
  - a. The nature and purpose of each diagnostic procedure will not be withheld for the subject/guardians.,
  - b. No potential risks to the subjects.
- 6. The case and controls will be interviewed either at the hospital or at their homes. Information will be collected about their illness and exposure to suspected risk factors for P. shigelloides approx. 25 min will be required.
- 7. Individual patients will benefit from the treatment provided, the information will be helpful in the development of effective intervention for prevention and control of the infection. Control subjects will be provided treatment in case a pathogen is identified.
- 8. In this study Hospital records of patient will be used, sera and stool will be used for the diagnosis of P. shigelloides and to determine the risk factors.

#### CONSENT FORM

(Plesiamonas shiqelloides Study - for Casee)

(Statement to be read to the patients' family when consent is obtained)

At ICDDR,B a pathogen can be identified in only 60% of diarrhoea In an attempt to identify new agents of diarrhoea in our population we would like to see whether P. shigelloides is a cause of diarrhoea in Pangladesh. This organisms has been increminated as a diarrhoeal pathogen in many countries. We have also isolated the organism in our laboratory but are not sure whether it causes diarrhoea. The ICDDR, B wishes to determine whether the organism causes diarrhoea, to identify risk factors for acquiring the infection and to describe its clinical features. To answer these questions you will be asked a series of questions about your home, type of water used and diarrhoeal symptoms in family members. Since we have isolated the new organism i.e. P. shigelloides from your stool we require 2 additional rectal swabs specimens from you today to rule out the possibility of your having rota virus or campylobacter. also request for another rectal swab on day 14. To measure the antibodies against the strain isolated from your stool specimen we require 0.2 ml of finger-pride blood today and on day 14. receive all appropriate medical care and facilities. You are at libenty to with draw from the study at anytime.

If you agree to participate in the study please sign or put your left thumbs impression.

vestigator

Signature/Left thumb impression of responsible family member Date:

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#### CONSENT FORM

### (Plesiomonas shigelloides Study - Control)

(Statement to be read to the patients family when consent is obtaineds)

At ICDDR,B a pathogen can be identified in only 60% of diarrhoea cases. In an attempt to identify new agents of diarrhoea in our population we would like to see whether P. shigelloides is a cause of diarrhoea in Bangladesh. This organisms has been increminated as a diarrhoeal pathogen in many countries. We have also isolated the organism in our laboratory but are not sure whether it causes diarrhoea. The ICDDR,B wishes to determine whether the organism causes diarrhoea, to identify risk factors for acquiring the infection and to describe its clinical features. To answer these questions you will be asked a series of questions about your home, type of water used and diarrhoeal symptoms in family members.

You/your child has been chosen as a control subject in our protocol. Although you/your child may not be having diarrhoea now he/she may be carrying an organism which you do not know about. We request you provide a rectal swasbs for identification of  $\underline{P}$ . shigelloides, to provide 0.2 ml of finger prick blood which shall use to measure antibodies against the strain isolated from the rectal swab and answer some questions about your home and water use.

You/your child will be treated for any condition with appropriate medication if an organism is detected. You are at liberty to withdraw from the study at any time.

If you agree to participate in the study please sign or put your left thumb impression below.

Signature of Investigator	Signature/Left thumb impression of
	responsible family member.
	Date:

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Librar solvents are solvents - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 - 1940 -

(Less) of Leasts witheres of contract of the c

# PLESIOMONAS STUDY INFORMATION SHEET

1.	Name	Father's/Spouse's name
2.		
3.		/_/ (1)
4.	Case No	/_/_/_/_/_/_/_/_/_/_/_/_/_/_/_/_/_
5.	Ocupation: 1 = Ser 2 = Bus 3 = Far	
6.	Date of onset of illne	ss (Day/Month/Year) /_/_/_/ (9-14)
7.	Date admitted	(Day/Month/Year) //_/_/ (15-20
8.	Date discharged	(Day/Month/Year) /_/_/_/_/ (21-20
9.	Went out within 3 days	•
10.	History of persistant	diarrhea with 6 months (>14 days diarrhea)  0 = No 1 = Yes 9 = Unknown
11.	Hospitalized for diarr	
12.	Early feeding 1 = Bre 2 = Bot 3 = Mix 4 = Oth	ast tle
13.	Sources of Water used	
	c. River d. Pond	(31) (32) (33) (34) (35)

14.	Contacted wi before illne	th out	tside w days of	ater (Ri onset	ver, Pon	d, Ditch	) within	:		
	(0 = No, 1 =	Yes,	9 = Un	iknown)		if y	es how m	any hour	s contacte	đ
	a. Catch fis b. Swimming c. Drink col d. Playing w e. Washing f. Other	d wate ater	er		•••••••• •••••••	••••••	********		/ (36-38 / (39-41 / (42-44	))))
15.	Food within	3 days	of on	<b>s</b> et						
	(0 = No, 1 =		-		•	4 = Wel	, 2 = Ra: 1 done, :	ne, 3 = 1 9 = Unkno	Medium own)	
•	a. Fish b. Shellfish c. Shrimp d. Crab e. Oyster f. Other	• • • • • •	* * * * * * * * * * * * * * * * * * * *			••••••			(54-55) (56-57) (50-59) (60-61) (62-63) (64-65)	)
17.	Did you eat illness?	f foo			.'		ays befor	re the	onset of	
				Days b	efore	onset		_		
	alar daga asali sahasalar bahasalar ayanaga kan	¥.	1 N.	U. Y.	N. U	. Y.	3 N.   U.			
	Breakfast							-	(66-74)	
	Lunch							-	(75-83)	
	Dinner							_	(84-92)	
	Other time							-	(93-101)	
<b>17.</b> i	* Y = How many anim			, U = un e in you			•	_ {		
•	Kind Chic	cken	Duck	Goose	Ca+	Dog	Goat	Cow	Other	
	Number		]				1			

## 18. Household members (Close Contacts)

Relation			Sex	ge			Di	arr.	da	te		T		
No. with Na patient		Name	l=Male 2=Female	Ye	ear 	Mo:	nth 	Occupa- tion	( o:	f oi nth	nse	t ¦	Appendix	
<del>1.</del>									_					(310 307
		<u></u>		-								<u> </u>		(118-127)
2.														(128-127)
3.					-									(138-147)
4.	* * *				_	-		<u></u>	_		_		<del></del>	(148-158)
5.									_					(159-167)
6.	-					-		<del></del>					<del></del>	(168–177)
7.								<del></del>						(178–187)
8.												-	<del></del>	  (188–197)
9.														( <b>198–</b> 207)
10.												-		(208-217)
11.					_					-				  (218-227)
12.										-				(228–237)
13.														(238–247)
14.														(248–257)

Occupation: 1 = Servant, 2 = Business, 3 = Farmer, 4 = Labour 5 = Student, 6 = Housewife,7 = Fishman, 8 = Other.

- 19. Discharg status (1 = Complete cure, 2 = partial cure, 3 = No change, 4 = Dead, 9 = Unknown) ..... /_/ (258)
- 20. Discharge diagnosis (0 = No, 1 = yes, 9 = unknown)

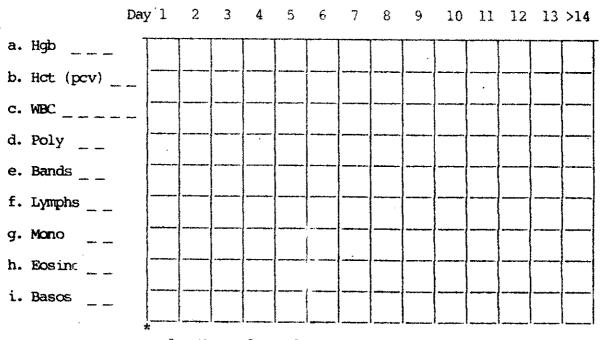
1.	Acute diarrhea	11	(259)
2.	Persistant diarrhei	1	(260)
3.	Malnutrition	ر کستر	(261)
4.	Dyhydration	( part )	(201)
5.	Pneumonia	المسرا	
ξ.	Other	//,	(263)
U.	Vuitt	//	(264)

21.	Character of s	tool	at (	onset	t (1	= W	ater	y,2	= Lo	ose,	3 =	form	ed).	. /	1	(265)
22.	Content of stor	ol at	c on	set	(1 =	Nor	mal,	2 ==	Muc	Lus.	3 <b>≈</b> '	Rian	4			
23.	No of stool per	r 24	hrs	at o	unset	2 + t	خ, ••••	9 == ••••	unk	nown	)	* * * *	• • • • •	//.		(266) (267-268)
24.	Abdominal pain	at c	nsei	t (0=	No.	l=Mi	ld pa pain	ain,	2=Mox	lera	te pa	ain .	• • • •	1.		(269)
25.	Vomiting in fir	rst 2	24 hi	rs				• • • •	• • • •		• • • • :		/		/	(300-301)
26.	Plesiomonas Ant resistant patte	tibic	tic	sens	it-it	7110	nati	ררדנם	Sac							
	Telra Amp. S	Strep	t (	hlo.	Se	pt.	Furc	X .	Gent	a F	(ena	Na	lid			(302-311)
27.	Clinical flow s	heet	<b>;</b> ,				•									
-	Da	y 1	2	3	4	5	6	7	8	9	10	11	12	13	>14	`
a.	Temperature F (Max)	T	<u> </u>	T	<u> </u>		T -	T	T		<del>T</del>	T	Ţ	T	<del></del>	Т
b.	Antibiotic (kind)*		ļ	<u> </u>		\ <u></u>		-			<u> </u>	<u> </u>			-	-
		*	Ant	ibio	tic	cate	gory	as	abov	e "2	6"	. [		.l	.1	.1
c.	Abd. pain (0.1)*							<u> </u>		<u> </u>	<u> </u>				T	T .
đ.	Abd. distention				***********		-									
e.	Nausea				- <del></del>		<u> </u>		ļ							
f.	Chill				~	p	<u> </u>									
g.	Headache															
h.	Watery stool															-
i.	Blood in stool		<del>- 1,000,000,000</del> .		*********									<u> </u>		
j.	Mucus in stool															

0 = None, 1 = present, 9 = unknown

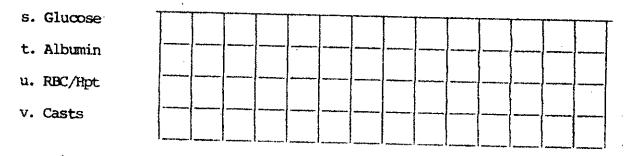
Day	/ 1	2	3	4	5	6	7	8	9	10	11	12	13	>1.4
k. Vomiting(time)	)	T	T			Γ	<u> </u>							
1. Diarrhea(time)	,		<b> </b>	<b></b>										
m. Dyhydration (degree)														
n. I I.V.(ml)	T	<u> </u>	]			<u> </u>		]						
N o. T O.R.S.			<b></b>			ļ					·			
p. K Others E														
	·		·	1		·					1		<u> </u>	·
q. O stool (ml)		<del></del>												
r. T Urine										*				
s. U Vomit														
t. Other														
u. X-Ray (chest)	T					·		' <del></del> '			'			

# 28. Laboratory date (blood)



	Day	1	2	3	4	5	6	7	8	9	10	11	12	13	>14	
j. C	reatinine			T	T	Ţ		<u> </u>		T	Τ		ļ — ļ		<u> </u>	Γ.
k. N	la		l				-		 							
1. K	e desire and the	-			<b></b>				-							
m. C	1															
n. O	0															
o. B																
p. S	COT					<del></del> -										
q. S	GPT															
r. P.	.Antibody															
	*				]	l										

r. P. Antibody: File of agglutinating antibody agent plesiomonas



S Glucose, t Albumin (0 = None, 1 = present, 9 = unknown) v Casts (0 = None, 1 = Granular, 2 = hyalin, 3 = WBC casts, 4 = RBC casts.