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78-016 Rec'a 31/5/18

SECTION I - RESEARCH PROTOCOL

1)	Title:	Doxycycline	Prophylaxis	for	Diarrhea	of	Refugec	Children
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- 2) Principal Investigator: Dr. Munshi
- 3) Starting Date: 3 June, 1978
- 4) Completion Date: 1 November, 1978
- 5) Total Direct Cost: U.S. \$5,882.87

6) Abstract Summary:

One-hundred subjects aged 1-4 years who are residing at Ledha refugee camp near Teknaf, will be included in a double blind comparison of doxycycline 4mg/kg/dose, twice each week, as a prophylaxis against diarrheal disease. The subjects will be treated for three weeks with daily surveillance during the treatment period and for an additional three weeks (total six weeks surveillance). Rectal swabs culture will be obtained at the beginning of the study and with each diarrheal episode to document the pathogens in this epidemiologic setting.

7)	Rev	Reviews:						
	a)	Research Involving Human Subjects:						
	b)	Research Committee:						
	c)	Director:						
	d)	BIARC:						
	e)	Controller/Administrator:						



PILOT STUDY

DOXYCYCLINE PROPHYLAXIS FOR DIARRHEA OF REFUGEE CHILDREN

A. INTRODUCTION

- 1. Objective: To decrease diarrheal disease related morbidity in groups of people who have a greatly increased risk of diarrheal disease because of a disaster situation.
- 2. Background: Diarrheal disease, including both watery diarrhea and dysentery, are extremely common in didaster situations which are generally associated with poor water and sanitation facilities. The specific etiologic agents responsible for these diarrheal episodes have never been determined in this epidemiologic setting; however, it would be logical to assume that the usual enteric pathogens (shigella, and enterotoxigenic E. coli) would be most common with cholera occurring in specific defined epidemics.

During the last few months such a disaster situation has occurred in Bangladesh with many refugees (now numbering 150,000) coming from Burma because of persecution. These refugees are being held in camps located between Teknaf and Cox's Bazar, Bangladesh. Two of the camps, Ledha and Nila camps, are located close to Teknaf (eight to eleven miles respectively). Ledha camp is the most primitive in terms of water and sanitation services; that is, there is no well water, and only inadequate trench latrines for a population of 25,000. Water is being trucked from Cox's Bazar in a fire truck daily but much of the water comes from ditches. Housing is extremely conjected with several long houses built, a section

of which is assigned to one or two families. The section is about $8^{\circ} \times 8^{\circ}$ and normally houses about ten persons. Food supply is mainly wheat flour and is all donated.

The camps appear to be well organized socially with a headman (Maji) responsible for the persons which accompanied him from Burma. Usually 200-300 persons would be in one group associated with one Maji, and these people occupy one section of the camp.

Other relief organizations are attempting to provide well water and sanitation facilities; this will not be available for several days or even weeks.

A brief survey of 30 random families in the camp revealed a mean family size of 7.8 members per family. Twenty-five of 233 (11%) persons were between one and four years and six of these 25 had diarrhea on the day of the interview. Overall, 16 of the 233 (6.9%) persons had diarrhea and twenty of 233 (8.5%) complained of some type of illness.

It has been proposed that a tetracycline drug could be used effectively to decrease diarrhea related morbidity in an acute situation until improved sanitation facilities become available. This is based on the known sensitivities of the major pathogens (E. coli, Vibrio and Shigella (Seven of eight S. flexneri from the camp were tetracycline sensitive)). In previous observations in animals receiving Tetracycline, growth is improved and diarrheal episodes

are decreased. Also in travelers diarrhea, doxycycline has been shown to be an effective prophylactic agent. Doxycycline rather than tetracycline is to be used because of its long half life (about 20 hours) which allows for a less frequent dosage schedule, and because of its unique mode of excretion through the mucosa of the small intestine which places the drug at the site of the infection.

B. SPECIFIC AIMS

- To determine the incidence and etiology of diarrheal disease in the Burmese refugee population aged 1-4 years.
- 2. To determine the efficacy of prophylactic doxycycline in the prevention of diarrheal disease in this population.

C. METHODS OF PROCEDURE

Subjects: One-hundred Burmese refugee children aged 1-4 years (less than five years) living in Ledha camp chosen from randomly selected families will be included in the study. Children who are ill at the onset of the study (diarrhea, fever, severe malnutrition) and children who had received antibacterial medication during the previous week and children who are exclusively breast fed will be excluded. Persons allergic to tetracycline will be excluded. Written informed consent will be obtained from the subjects parents.

Randomization of subjects will take place by listing 120 children, then using a list of random numbers children will be assigned to one of four drugs, two of which are doxycycline, and two of which areplacebo.

Methods: The study will be described to the parents of the subjects and if they consent, the children will be entered into the study and a brief identifying questionaire will be filled out (see form).

Patients will be weighed and measured and questioned regarding recent medical illnesses. A rectal swab culture will be obtained.

The subjects will then be started on doxycycline or placebo, 4 mg/kg, twice each week for three weeks.

Surveillance (see accompanying form) will be carried out every
day during the drug treatment and for an additional three
weeks to determine the occurrence and severity of diarrheal symptoms, fever, or other symptoms. Body weight will be determined at
the beginning of the study, after three weeks and at the end of
six weeks. Diarrheal disease will be treated either by oral fluid
if mild or referred to the rehydration center if more severe.
Febrile patients or other ill patients will be referred to Dr.
Munshi.

Rectal swab cultures will be obtained at the onset of the study and with each visit when there has been diarrhea the day of the visit or the day perceeding the visit. If any of the subjects are treated at the rehydration unit, an attempt will be made to secure a rectal swab culture at that time also.

The rectal swab culture will be plated onto MacConkey, S.S., and Monsur's agar for isolation of salmonella, shigella, or vibrio. In addition, five \underline{E} . \underline{coli} isolates will be picked from the MacConkey plate for enterotoxin testing using the Y_1 adrenal cell and infant mouse assays. Also a rectal swab will be obtained for rotavirus assay using the elisa assay.

A diarrheal episode will be defined as the occurrence of three or more watery stools per day or the occurrence of blood or mucous in the stool.

Data Analysis: One-hundred patients will be included in this study.

This was based on an assumed attack rate of at least 50% in the placebo group during the three weeks of study and a possible drop our rate of 50% from the study. This will still give sufficient numbers to show a significant difference (p=0.05) if the protection rate is at least 80%.

Analysis of data will be by Fisher's exact or Chi Square analysis as appropriate.

D. SIGNIFICANCE

An effective preventative is needed to decrease diarrheal disease morbidity and mortality in disaster situations as a short term measure until effective sanitation and safe water is established.

SECTION III - BUDGET

A. DETAILED BUDGET

1. PERSONNEL SERVICES

Name	Position	% of time	Annual Salary	Project F	Requirements = DOLLARS =
Dr. M. Munshi Dr. M.M. Rahman Dr. D. Sack To be named (3) To be named Dr. Al-Mahmud	Investigator Investigator Investigator Field assistants Bacteriology tech Animal Resources	5% 5% 7 wks . 2 wks	Tk 35,424 Tk116,736 \$ 34,750 Tk 43,470	5,836.90 12,000 2,000	1,737.50
		Sub Tota		29,295.20	1,737.50

2. SUPPLIES AND MATERIALS

Items	Unit Cost	Amount Required		
Rectal Swab Culture Stock Culture Vial Y1 Assay ST Assay (supplies) ST Assay (mice) Rotavirus (elisa) Doxycycline & Placebo Paper, pens misc.	Tk 15.00 Tk 2.00 Tk 3.00 \$ 0.11 Tk 3.00 Tk 1.50 1 liter each	300 1500 1500 600 600 300	4,500 3,000 4,500 1,800 450 donated 3,000	66.00
		Sub Total:	17,250	66.00

3. EQUIPMENT

4. PATIENT HOSPITALIZATION

5. OUTPATIENT CARE

			Project R	<u>DOLLARS</u>
6.	CRL TRANSPORT			
	Dacca/Teknaf/Dacca - 722 miles - 2 trip. Tk 3/mile	s	4,332	
	Teknaf/Cox's Bazaar/T knaf - 6 trips		1,800	
	100 miles, Tk 3/mile	Sub Total:	6,132	*****
7.	TRAVEL AND TRANSPORTATION OF PERSONS			
	Dacca/Cox's Bazaar/Dacca - 6 trips by air @ Tk 340		2,040	
	by air e ik 5%0	Sub Total:	2,040	*****
8.	TRANSPORTATION OF THINGS			
	Import of Supplies		1,000	
		Sub Total:	1,000	
9.	RENT, COMMUNICATION & UTILITIES			
			1,000	****
			1,000	===== =
10.	PRINTING AND REPRODUCTION			
	Printing of forms Publication		1,000	300
		Sub Total:	1,000	300 ======
11.	OTHER CONTRACTUAL SERVICES			
12.	CONSTRUCTION, RENOVATION, ALTERATIONS			

B. SUDGET SUMMARY

	Gategory			Project Req	uirements DOLLARS
1.	Personne1			29,295.20	1,737.50
2.	Supplies and Materials			17,250	66.00
3.	Equipment				
4.	Hospitalization				
5.	Outpatients				
6.	CRL Transport			6,132	
7.	Travel Persons			2,040	
8.	Transportation Things			1,000	
9.	Rent/Communication			1,000	
10.	Printing/Reproduction			1,000	300.00
11.	Contractual Service				
12.	Construction				
			Total:	57,717.20	2,110.50
		Total	Dollars:	5,882.	87

Conversion rate \$ 1.00 = Tk 15.3

ABSTRACT SUMMARY

- 1. The subjects in this study will include 100 children aged 1-4 years who are residing at Ledha refugee camp near Teknaf, Bangladesh. This group is chosen because they are the group at highest risk of diarrheal disease and in whom an episode of severe diarrhea is most likely to be lethal.
- 2. The risks associated with the administration of doxycycline to this group are very low but include hypersensitivity reactions such as skin rashes, and super infection with resistant organisms. In children all tetracyclines may cause staining of teeth; however, the dosage used is less than that which would be expected to stain teeth and in Bangladesh, where beetle nut chewing is prevalent, teeth staining is not considered to be a significant risk.
- 3. Surveillance will be carried out daily and any reactions will be reported to a physician who can take necessary action.
- 4. Patients will be identified by number and at the end of the study, all names will be removed from data sheets, leaving only numbers. Also all records will be kept in a locked file in the investigators office.
- 5. Signed informed consent will be obtained. No information will be withheld.
- Subjects will be visited daily during the study to detect any episode of diarrhea.

- 7. The patients receiving doxycycline should have significant protection from diarrhea. Society may benefit from the development of an effective approach to the problem of diarrhea associated with acute unsanitary conditions such as with newly formed refugee camps. Doxycycline is an established drug with a known low risk.
- 8. Only stool or rectal swab material will be obtained.

PERMISSION FORM PROPHYLACTIC DOXYCYCLINE FOR UNSPECIFIED DIARRHEAL DISEASES

The Cholera Research Hospital is carrying out research to determine a method of preventing diarrheal diseases in children aged 1-4 years. We would like your child(ren) to participate in a study to determine whether one dose of doxycycline given two times per week would be effective in the prevention of diarrheal diseases. If this method of treatment is proven effective it would relieve human suffering among disaster stricken populations from diarrhea. If you agree to allow your child(ren) to participate in this study you can expect the following:

- We will visit your house every day to inquire about diarrhea or other illnesses in your child(ren). Treatment will be available for your child(ren) should any diarrheal disease develop.
- 2. Your child(ren) will receive either doxycycline or a syrup which looks like doxycycline but has no antibiotic in it. The syrup will be given to your child(ren) in one dose two times per week for three weeks.
- 3. Your child(ren) will be given some sort of identification for the purposes of the study. At the beginning of the study your child(ren) will be weighed and two rectal swabs will be taken. Rectal swabs will also be taken with each diarrheal episode for the following six weeks.
- 4. The risk of taking the medicine is extremely small. Side effects might include allergic reactions (such as skin rashes) or infection with another resistant organism. Also, taking the medicine for a very long time may result in some staining of the teeth but this should not occur at this dosage for three weeks of mediciation that we are planning.

- 5. Your child(ren)'s medical records will be kept confidential.
- 6. Your child(ren) does/do not have to participate in this study. If you do allow your child(ren) to enter the study you are free to withdraw them from the study at any time. If you decide not to allow your child(ren) to enter the study or if you withdray them from the study, you and your children may still be treated by us for diarrheal disease. Your decision regarding the study will not jeopardise you or your child(ren)'s medical care.
- 7. We will answer any questions you have.

If you agree to allow your child(ren) to participate in the study above, please sign your name here.

ı	(Signed)
	(Date)

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REGISTRATION FORM FOR DOXYCYCLINE PROPHYLAXIS STUDY

Study Number $\frac{1}{2} \frac{1}{3} \frac{4}{4}$	
Patient's Name	Age // years Sex //
Father's Name	Mother's Name
Maji's Name	
Date entered camp $\frac{1}{9} \frac{1}{10}$ day $\frac{1}{10}$	$\frac{1}{11} \frac{1}{12}$ mo. $\frac{1}{13} \frac{1}{14}$ year
Date of filling out form $\frac{1}{15}$	day $\frac{1}{17} \frac{1}{18}$ mo. $\frac{1}{19} \frac{1}{20}$ year
Breast feeding $\frac{1}{21}$ exclusi	vely=1 half and half=2 no=3
Recent (1 mo.) medical illnesses	/ / 22 / 23 None=01 Pneumonia=04 Measles=02 Dysentery=05 Fever=03 Diarrhea=06 Other=07
Any other members with dysentery/	~ `
None=1 Dysenter	y=2 Diarrhea=3 Both=4
Drinking source $\frac{1}{25}$ Ditch (Y,N)	
/ / Truck (Y,)	
$\frac{\sqrt{7}}{27}$ Tank (Y,N)	
$\frac{1}{28}$ Well (Y,N	
$\begin{array}{c} \text{Height} \ / \ / \ / \ / \ \text{cm} \end{array}$	

Weight $\frac{1}{32} \frac{1}{33} \frac{1}{34}$ kg

Any medicine taken within last week $\frac{1}{35}$ (Y,N)

DOXYCYCLINE PROPHYLAXIS IN LEDHA CAMP FORM

Study Number $\frac{1}{1}$	2 3 4			
Patient's Name	*************************************	Age / /years Sex / /		
Father's Name		Mother's Name		
Maji's Name				
	24 HOUF	R HISTORY		
Diarrhoes / / 7	Watery=1 Mucoid Loose=3 Bloody Mucoid and Bloody=5	r=4		
Frequency of diarr in last 24 hou	thoea / / / irs 8 9			
Vomiting in last 24 hours	/ <u>/</u> /	None=1, 5 times=2, More=3		
Fever / / / 11		None=1, Mild=2, Mod (102 ^o)=3		
Abd Pain / / 12		None=1, Occasional=2, Continuous=3		
Prolaps rectum / 13	/	Not present=1, On straining=2, Large=3		
Convulsion $\frac{14}{14}$		None=1, Mild=2, Severe=3		
Other complaints /	/ 15	Specify		
Clinical Dx $\frac{1}{16}$				
Diarrhea form fill	ed out yesterday /	/ (Y,N)		
Action taken / / 18		No action needed=1, Oralyte given=2 Referred to treatment center=3. Taken to treatment center=4, Other=5 (specify)		
Non-Diarrheal dise	ase / /	Fever=1, Other=2		