

ETHICAL REVIEW COMMITTEE, ICDDR,B.

98

Principal Investigator Najma Rizvi Trainee Investigator (if any) _____

Application No. 81-013 Supporting Agency (if Non-ICDDR,B) _____

Title of Study Hot and cold Project status:
Blank Belief System and its effect on Food Intake of
children 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).

Source of Population:

- (a) Ill subjects Yes No
- (b) Non-ill subjects Yes No
- (c) Minors or persons under guardianship Yes No

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.

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

Najma Rizvi
Principal Investigator

Trainee

SECTION I - RESEARCH PROTOCOL

- (1) Title: The Hot-Cold Belief System and its Effect on Food Intake of Children During Normal, Acute and Recovery Stages of Diarrhoea.
- (2) Principal Investigator: Najma Rizvi.
- (3) Starting Date: April 30, 1981
- (4) Completion Date: December 30, 1981.
- (5) Total Direct Cost: Tk.51,554.00
- (6) Scientific Programme Head: Dr. M. Mujibur Rahaman.

This protocol has been approved by the Nutrition Working Group.

Signature of Scientific Programme Head:

M. Mujibur Rahaman

Date: 27/3/1981

- (7) Abstract Summary: (The aim of this study is to plan a dietary regimen for increasing food intake in diarrhoea which is congruent with the hot/cold belief system. In planning effective strategies for promotion of food intake in diarrhoea, the proposed research will have to do the following
 - (a) Classify foods in accordance to their inherent hot and cold properties.
 - (b) Study the relationship between food intake in the normal, acute and recovery stages of diarrhoea and hot and cold beliefs about food and disease.

- (c) Explore the feasibility of increasing the intake of acceptable foods during the attacks of diarrhoeal illness.

The emic classification of food and disease i.e. how the people classify foods and disease into different categories will be collected through participant observation and informal interviewing. In addition, food intake will be measured in normal, acute and recovery stages of diarrhoea. Stool tests will be performed to find out the etiology of diarrhoea. Blood Sample will be collected through finger pricking during diarrhoeal state for hemoglobin tests. Acidity and alkalinity will be measured for hot and cold foods. Sample of 50 rural children of 0-4 age group will be selected for the study. It is believed such a study will aid in facilitating communication between doctors, health scientists and the caretakers of children and this can lead to an improvement in the mother's/ caretakers compliance with regard to increased food intake in diarrhoea.

(8) Reviews:

- (a) Ethical REview Committee: _____
- (b) Research Review Committee: _____
- (c) Director: _____
- (d) BMRC: _____

ABSTRACT SUMMARY FOR ERC

The purpose of the study is to plan a dietary regimen for increasing food intake of children, suffering from diarrhoea, which is congruent with the existing hot/cold belief system.

1. The subject population would include children of 0-4 age group who are afflicted with diarrhoea. Since food intake in diarrhoea has serious impact on young children's nutritional status and children suffer more frequently from diarrhoea, we feel we need to focus on the infants and young children.
2. The methods of research to be used include informal interviewing weighing of children's food intake, and blood and stool tests during the diarrhoeal episode. The blood will be taken through finger pricking and only with the approved consent of the mother or the caretaker. The methods to be used, therefore, do not pose any potential risks.
3. Not applicable.
4. The confidentiality of the data collected will be maintained at all times. The information will not be given out to any one and the data will be kept in safe custody. The anonymity of the sample households will be assured through the use of code numbers for the household and its members.
5. Informed consent will be obtained from the parent or the guardian of the children. The consent forms, written in local (Comilla) Bangla will be used. Every effort will be made to explain the procedure of our study. Consent will be obtained at the household.
6. The interview will take place in an informal setting in the children's own homes. At no time, any pressure will be given to the family to answer any questions. Also, the respondents, will be

allowed to continue with their routine work, if they wish to do so. The length of each interview will be around 2-3 hrs. and approximately 12 interviews will be conducted per child,

7. The parents of the subject will be told about the value of giving ORS, Labon-Gur and the availability of treatment at the hospital. If need arises, we will make arrangement to have the child sent to the Matlab Centre. The long-term benefit from the study will include effective dietary plan for increasing food intake. The study poses no risks.

8. The research will not require any hospital records, organs, or tissues. A few drops of blood collected through finger pricking in the diseased state is the only body fluid to be collected.

The study does not involve any sensitive questions, visitation of the households by myself or my co-workers may be considered to be an invasion of privacy. The interviewing will be informal, however, some structured questioning will be done to find out frequency, type and quantity of foods eaten by the child. In addition, information will be collected on food and disease classification, this will be done through indirect questioning.

CONSENT FORM FOR HOT/COLD BELIEF AND DIARRHOEA STUDY

In order to provide effective treatment for diarrhoea, we need to know the kind of foods you give and the foods you withdraw from the diet of a child while suffering from diarrhoea. This information will be very useful in guiding us to plan an effective dietary/medical treatment. The study will be conducted under my (Najma Rizvi) direct supervision. For the study, I and/or my field assistants will be visiting your home to find out if any of the children in your home has diarrhoea, if so, one of us will be visiting your home and ask you questions regarding the child's diet, and if circumstances permit measure the amount of food intake. We will be visiting the child until he/she gets back to normal state. To find out the general health status of the child, we would like to take little blood through finger pricking. Also, we would like to take the stool sample and have it tested in our Matlab hospital. These tests will be done only with your permission.

You or any member of your family are free to ask any questions, seek health advice from our workers and get treatment from our hospital. You may refuse to participate or withdraw at any time from the study. even if you refuse information or drop out from the study, you can get health services from our hospital.

Please sign or give thumb imprint in behalf of your child/children if you agree to participate in our study.

Signature/L.T.I.
of the parents.

Father's Name _____
Mother's Name _____
Household No. _____
Bari No. _____
Village _____
Date _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objective: The objective of this study is to plan a dietary regimen for increasing food intake in diarrhoea among children, which is congruent with the hot and cold belief system of food and disease.
2. Background: Malnutrition and diarrhoeal infections are the major health hazards faced by the children of Bangladesh. Several researchers Martorell et al (1980), Mata et al (1977), Briscoe (1979) and Molla et al (1980) have reported about the decrease in food intake during diarrhoeal episodes, which results in the exacerbation of the existing malnutrition. For the malnourished children of Bangladesh, the reduced food intake during diarrhoeal infection assumes critical importance, because, it makes them vulnerable to repeated attacks of diarrhoea.

Molla et al's recent study reports that although reduction of nutrient intakes are associated with the episodes of diarrhoeal illness, intestinal absorption do take place during acute and recovery stages of diarrhoea. This finding has great implication for both nutritional improvement and diarrhoea prevention programme. However, in attempting to encourage mothers to increase their children's food intake during diarrhoeal episodes, it has become apparent that simply advising the mothers about the necessity of increasing food intake in illness is not enough. Dr. Yunus has reported that education given to others about the necessity of increased food intake had no effect on nutritional status of children. He found no difference in nutritional status of the children of control and the children of mothers who had received education on the importance of increased food intake during diarrhoeal illnesses (personal communication). It becomes apparent, then, that the physician's or health scientist's advice regarding the necessity of increased food intake is not complied by the mother or the caretaker. A basic assumption of this study is that this non-compliance with the physicians' suggestion occurs because physicians and health scientists fail to understand the system of beliefs about food and disease which guides the feeding pattern especially in times of illnesses are believed to be caused by an imbalance in the bodily humors and

Accordingly the body is believed to be in "hot" or "cold" states. Like illness, food and medicines are also classified according to their inherent hot and cold properties.

3. Rationale: Although anthropologists have studied hot/cold belief system, such studies have mainly been carried out in Latin American countries (Currier 1966; Fester 1967; Adams 1952, Cosmensky 1972; Logan 1973). In Bangladesh, food beliefs have been studied by a few researchers (Lindenbaum 1965; Rizvi 1977, 1979; Maloney et al 1980). However, none of these studies have examined food beliefs in relation to a specific disease, such as diarrhoea. The implication of the hot and cold belief system in normal acute and recovery stages of diarrhoea can be highly useful in developing programme of increasing food intake in diarrhoea. This research is urgently needed to develop an effective strategy for encouraging mothers to increase food intake of children in diarrhoea - the most prevalent infectious disease of children.

SPECIFIC AIMS: The specific aims of this study are :-

- 1) Classify foods in accordance to their inherent hot and cold properties.
- 2) Study the relationship between food intake in the normal, acute and recovery stages of diarrhoea and hot and cold beliefs about food and diseases.
- 3) To explore the feasibility of increasing the intake of acceptable food during attacks of diarrhoeal illness.

SAMPLES AND METHODS: The study population will consist of children in the 0-4 age group. It would be useful to divide them into two groups:-

- 1) The children who are fed mainly liquid food (0-1).
- 2) The children who are eating the regular adult food (2-4).

By distinguishing these two groups, it would be possible to identify the "high risk" group in diarrhoea - malnutrition complex. Moreover, the milk and other liquid substitutes, which form infant and young children's diet can be viewed in relation to the conceptual scheme of "hot" and "cold". Anthropological investigations requiring almost total immersion into the people's life styles can be carried out only with small groups. Similarly food intake studies tests cannot be effectively carried out in a large sample. Therefore, the sample size will have to be small. Since the sample size will be small, it seems appropriate to select the sample from children who are already afflicted with diarrhoea. In this way, we can be sure of getting 50 sample children in diarrhoeal stage. Instead of following children from normal to diarrhoeal and recovery stages of diarrhoea, we would

begin with diarrheal children and follow them up until they reach their normal state. The variation in food intake from normal to diarrhoea and recovery stages of diarrhoea will be measured both qualitatively and quantitatively. The selection of 50 children with diarrhoea will be done over a period of time

If more than one child per family with diarrhoea can be located, the time needed for terminating the selection process will be less than if we get one or less per family. Our plan is to follow the child for one diarrhoeal episode only, which means, if the child begins to have another attack after being normal, the second episode will not be followed. The observation and interviewing will be done in (1) disease state (2) recovery state and (3) normal state. Theoretically, the time span of each of this period can be viewed from two perspectives :

- 1) Ethnomedical, i.e., mothers or caretakers perception.
- 2) Clinical.

In our study, we intend to include both the perspectives. It is believed that by doing this, we will be able to see the degree of congruity/incongruity between the ethnomedical and clinical perspectives. Tentatively, we wish to make 4 visits in the diseased state 3 visits each for recovery and normal state. However, the frequency of visits during diarrhoeal state may be increased by curtailing the number of visits in normal state. To cover 50 children for 12 days each, we would need at least 600 man days to complete the field work. We plan to have 3 junior field assistants (available from Chandpur study) and a senior research assistant to be hired part time from outside.

The study will be carried out in one of the villages in the Chandpur thana, because the on-going project personnel and resources available there can be utilised. Moreover, its proximity to the Matlab Field Research Laboratory makes it an ideal site. The households in Chandpur being less exposed to field workers investigation will be a better and less biased site than Matlab.

Participant observation, the most widely used and the most effective tool for studying culture pattern will be used for unravelling the underlying system of belief about food and illness. In the initial phase of observation, the emphasis will be on establishing rapport, rather than collecting any specific data. However, even at this stage, information related to food and disease will be revealed during the informal interaction between the researcher anthropologist and other members at the household. It is believed that from such interaction the research assistant can pick up the clues on how to elicit information and establish rapport with the members of the household and community at large. Gradually the informal interviews will be followed by more standardized questioning. The information derived through informal interviewing will be checked against actual behaviour associated with child feeding. The degree of adherence to the belief system will be noted; Careful attention will be given to the following areas :-

1. The range of foods available in the household and what foods are ordinarily given at different age groups 0-1 and 2-4.
2. After a child is afflicted with diarrhoea, what changes take place in the feeding pattern of children - the foods withdrawn and the quantity given etc. will be noted.
3. In the recovery period, what foods (ascending and descending ~~each for recovery and normal state. However, the frequency of visits~~ properties of hotness) are included and in what order? during diarrhoeal state may be increased by curtailing the number of visits in normal state. To cover 50 children for 12 days each, we would need at least 600 man days to complete the field work. We plan to have 3 junior field assistants (available from Chandpur study) and a senior research assistant to be hired part time from outside.

The study will be carried out in one of the villages in the Chandpur thana, because the on-going project personnel and resources available there can be utilised. Moreover, its proximity to the Matlab Field Research Laboratory makes it an ideal site. The households in Chandpur being less exposed to field workers investigation will be a better and less biased site than Matlab.

Along with participant observation and interviewing, a few biochemical tests will be performed. These include,

- (1) Blood tests to find out Haemoglobin level during diarrhoeal state.
- (2) Stool tests to find out the etiology of diarrhoea.
- (3) The acidity and alkalinity of foods belonging to hot and cold categories will be measured to find out if the popular belief has any scientific basis.

The type and amount of food intake will be recorded for the normal acute and recovery stages of diarrhoea. Test weighing will be done.

- D. SIGNIFICANCE: The results of this research will aid in the development of an effective medical/dietary regimen. It will show that the hot/cold classification of food and disease is highly relevant in the treatment of malnutrition in diarrhoea. It will facilitate communication between the doctor and the child's caretaker and thus can lead to an improvement in the mother's/caretaker's compliance with the medical/dietary regimen, specially the advice on increasing food intake in illness. By examining the belief system in relation to its perceived and real effect on body physiology, the research will emphasize the need for greater co-operation between health and social scientists.

REFERENCES:

1. Adams, Richard N. 1952, "An Analysis of Medical Beliefs and Practices in a Guatemalan, Indian Town", Guatemala: Institute Indigentista Nacional de Guatemala.
2. Briscoe, John. 1979, "The Quantitative Effect of Infection on the Use of Food by Young Children in Poor Countries". American Journal of Clinical Nutrition 32: 648-676.
3. Cosminsky, S. 1972 "Decision Making and Medical Care in a Guatemalan Indian Community. Ph. D. Dissertation". Brandeis University.
4. Currier, Richard L. 1966, "The Hot-Cold Syndrome and Symbolic Balance in Mexican and Spanish American Folk Medicine Ethnology", 5:251-263.

5. Logan, Michael, 1973, "Humoral Medicine in Guatemala and Peasant Acceptance of Modern Medicine", Human Organization (32 (4): 385-396.
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8. Mata, L.S., R.A. Kromal, J.J. Urrutia and B. Garcia, Effect of Infection on Food Intake and the Nutritional State: Perspectives as Viewed From the Village", Am. J. Clin. Nutr. 30:1215, 1977.
9. Lindenbaum, I. Infant Care in Rural East Pakistan. CRL Technical Report 1965.
10. Maloney, C, Aziz, K.M.S., and P. Sircar "Beliefs and Fertility in Bangladesh. Rajshahi University Press, 1980.
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SECTION III - BUDGET

A. DETAILED BUDGET

1. PERSONNEL SERVICES

<u>Name</u>	<u>Position</u>	<u>% Effort</u> <u># of days</u>	<u>Annual</u> <u>Salary</u>	<u>Project Requireme</u> <u>Taka</u> <u>Dollars</u>	
Najma Rizvi		50%	US\$25,000		
Senior Research Asstt.		5 mo.	Tk.24,000	10,000	
Junior Research Asstt. (3 available from Chandpur)		5 mo.	Tk.18,00	9,000	
Data Processing Asstt.		1 mo.	Tk.18,000	1,500	
Statistical Asstt. Computer Programme		1 mo.	Tk.31,605	2,634	
			Sub total =		

2. SUPPLIES AND MATERIALS

<u>I t e m s</u>	<u>Unit Cost</u>	<u>Amount Required</u>
Stationery, Pens, Pencils Clipboard		Tk. 3,000
Color Films and processing		Tk. 3,000
Xeroxing and mimeographing		Tk. 5,000

3. EQUIPMENTS

Spring Balance (1)	Tk. 8,000
Food Weighing Balance (2)	Tk. 5,120

4. LABORATORY EXPENSES

Blood test (50 children)	Tk. 200
Stool tests (50 children)	Tk. 300
PH tests for foods	Tk. 200

5. TRANSPORTATION

	<u>Amount Required</u>	
	<u>Taka</u>	<u>Dollars</u>
ICDDR,B Microbus with driver		
Dacca-Chandpur Rocket Fare (Twice a month for 6 mo. for 2)	Tk. 3,600	

B. BUDGET SUMMARY

<u>Category</u>	<u>Year 1</u>		<u>Year 2</u>		<u>Year 3</u>	
	<u>Taka</u>	<u>Dollars</u>	<u>Taka</u>	<u>Dollars</u>	<u>Taka</u>	<u>Dollars</u>
1. Personnel	23,134					
2. Supplies	6,000					
3. Equipment	13,120					
4. Laboratory Expenses	700					
5. Printing/Reproduction	5,000					
6. Communication	3,600					
Total	Tk.51,554					
Total	\$					

Conversion Rate \$

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