

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Bonita Stanton
Application No. 84-022(P)
Title of Study Assessing Risk Factors
Developing Xerophthalmia

Trainee Investigator (if any) John Clemens, Tajkera Khair
Supporting Agency (if Non-ICDDR,B) _____
Project status:
() New Study
() Continuation with change
() No change (do not fill out rest of form)

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Give 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.

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

Bonita Stanton
Principal Investigator

John Clemens Tajkera Khair
Trainee

SECTION I: RESEARCH PROTOCOL

1. Title: Assessing risk factors for developing xerophthalmia
2. Principal Investigator: Bonita Stanton
Co-Investigator: John Clemens, Tajkera Khair
3. Starting Date: 15 June, 1984
4. Completion Date: 14 December, 1984
5. Total Direct Cost: US\$500
6. Associate Director for CSR:
This protocol has been approved by the Community Services Research Working Group.

*Signature of Acting Associate Director for CSR: W.B.G.

Date: 17.05.84

*This signature implies that the Associate Director for CSR takes responsibility for the planning, execution and budget for this particular protocol.

7. Abstract Summary:

Vitamin A related Xerophthalmia appears to be a significant problem in urban Bangladesh. Identifying risk factors for xerophthalmia in this setting would potentially enable the development of a system for screening and delivering vitamin A to high risk patients that might be being missed by the current mass prophylactic distribution system.

8. Ethical Research Review Committee: _____

Research Review Committee: _____

Director: _____

SECTION II: RESEARCH PLAN

A. INTRODUCTION

1. Objective:

The overall aim of this project is to identify risk factors associated with the development of xerophthalmia in Dhaka city.

2. Background:

Vitamin A deficiency was estimated in the 1970's to be responsible for an estimated 17,000 new cases of blindness in Bangladesh per year¹. Since that time considerable attention has been focussed on assessing the vitamin A needs and delivery of Vitamin A to meet these needs in rural Bangladesh^{2,3}. However two papers examining children hospitalized for malnutrition^{4,5} and unpublished data from a nation survey by HKI⁶ have clearly indicated that the problem of vitamin A deficiency is probably at least as great in urban Bangladesh as in rural Bangladesh.

Risk factors potentially associated with the development of Vit. A induced xerophthalmia have been described in the above papers and in studies from other countries^{7,8,9}. Among the potential risk factors cited in these works were history of gastroenteritis, measles and other diseases, dietary intake, sex, breast feeding, overall nutritional status, age, knowledge of mother and socioeconomic status. The results however regarding these risk factors varied from study-to-study and country to country. Some, such as gastroenteritis, have only been suggestive in all studies.

The Urban Volunteer Program of ICDDR,B began delivery of Vit A to cases of xerophthalmia in February 1984. By government regulation, a physician must be present and only cases of xerophthalmia may be treated.

~~It is proposed that a case-control study of risk factors associated~~
with the development of xerophthalmia in Dhaka city be undertaken.

B. SPECIFIC AIMS

1. Identify risk factors associated with the development of xerophthalmia in Dhaka city.

C. MATERIALS AND METHODS

Cases will be all children <16 years of age residing in areas of Dhaka city in the cacheman area of Urban Volunteer Program. Children are pre-screened by the Urban Volunteers. On an appointed day the physician, one translator and one "interviewer" will go to the selected area to verify the diagnosis of xerophthalmia made by the Urban Volunteers. "Cases" will be enrolled in the study if they have (1) a verified diagnosis of xerophthalmia by the physician (night blindness or bitot spots, corneal xerosis, corneal keratomalacia, corneal ulceration or scars) and (2) the mother of the child is present so that the questionnaire may be completed. Controls will be randomly selected children preferably from the house next-door to the patient. If there are no children in the next home, then when possible, the next home or the same bari. Only one "case" from a family will admitted and a "control" may not come from a family with another child with xerophthalmia.

The questionnaire administered will have 4 parts; a brief physical exam by the phycian which will include age, sex and a determination of presence/absence and extent of xerophthalmia as well as other health indicators,

and 3 questionnaires to be administered by an interviewer "blinded" as to diagnosis. A profile of the child including recent illnesses (measles and diarrhoea) dietary recall of the last week with focus on Vitamin A containing foods which were offered and accepted, a profile of the family (number born, number alive, and number with xerophthalmia and SES indicators), and a questionnaire of maternal knowledge. Cases and controls will be recruited until 100 cases and 100 controls are obtained.

Analyses: All factors elicited will be compared between the two groups. Data regarding number of patients screened and areas will also be obtained in order to make prevalence determinations of xerophthalmia.

D. SIGNIFICANCE

Strategies for the prevention of xerophthalmia in Bangladesh remain controversial. The identification of specific risk factors for the development of xerophthalmia in Dhaka city would foster the development of a targeted Vitamin A distribution system.

E. FACILITIES REQUIRED

1. Office space - no additional
2. Laboratory space - no additional
3. Logistic support - none above current
Vit. A distribution schemes
4. Equipment - none

REFERENCES

- Rahaman MM. Periodical distribution of large doses of vital A in Bangladesh. Jakarta: WHO meeting on Vit A deficiency and xerophthalmia, 1980.
- Institute of Nutrition and Food Science. Nutrition Survey of Rural Bangladesh, 1975-76. Dhaka, 1977.
- Brown KH, et al. Failure of a large dose of vitamin A to enhance the antibody response to tetanus toxoid in children. Am J Clin Nutri 1980; 33: 212-77.
- Brown KH, et al. Xerophthalmia, protein-calories malnutrition and infections in children. J Pediatr 1979; 95: 651-56.
- Cohen, N. et al. Xerophthalmia in Urban Bangladesh. Acta Pediatr Scand 72: 531-536, 1983.
- Unpublished data, Cohen, N. et al.
- Vomen, M.A.P.C. et al. A global survey on xerophthalmia: Epidemiology and public health aspects, 1967.
- Mehurau, DS et al. Xerophthalmia in forder. American J. Clin Nutr. 17, 147, 1965.
- Kusin, J et al. Vit A deficiency in East Java, Indonesia. WHO meeting on Vit A Deficiency , 1980.

Abstract Summary

1. All children less than 16 years of age in the cacheman area will be eligible for inclusion in the study. The mother of the child must be present. Children with vitamin A deficiency will be treated regardless of whether or not they agree to participate.
2. Risks - none
3. NA
4. Names of patients will not be taken
5. NA
6. Interview will be in the home approximately 10 minutes.
7. Children will be screened for Vit. A deficiency and Vit. A deficiency cases will be treated. A potential algorithm will be worked out for delivery of Vitamin A to high risk groups.
8. No.

BUDGET

Project Requirement in US\$

1. <u>Personnel Services</u>	None
2. <u>Supplies and Materials</u>	
Paper and stationery, etc.	100.00
3. <u>Equipment</u>	None
4. <u>Patient Hospitalization</u>	None
5. <u>Outpatient Care</u>	None
6. <u>ICDDR,B Transport</u>	None
7. <u>Travel and Transportation of Persons</u>	None
8. <u>Transportation of Things</u>	None
9. <u>Rent, Communications & Utilities</u>	None
10. <u>Information Services</u>	None
11. <u>Printing and Reproduction</u>	None
12. <u>Other Contractual Services</u>	
Computer time for analysis	400.00
13. <u>Construction, Renovation, Alterations</u>	None
Total:	<u>US\$ 500.00</u>

Date: _____

Case # _____
Pt. name: _____

Pt. age: _____

Sex _____

Office Data Entrance

of children in family _____

of children with Vit. A def. _____

	<u>Present</u>	<u>Uncertain</u>	<u>Absent</u>
<u>Vit. A Def.</u>			
Night blindness	_____	_____	_____
Bitot Spot	_____	_____	_____
Keratomalacia	_____	_____	_____
Ulceration	_____	_____	_____
Scar	_____	_____	_____
<u>Malnutrition</u>			
Mild	_____	_____	_____
Moderate	_____	_____	_____
Severe	_____	_____	_____
<u>Vit. C Def.</u>			
Gums	_____	_____	_____
Bruseability	_____	_____	_____
Scabies	_____	_____	_____

PROFILE OF CHILD

P. n. _____
" _____
" _____

Medical

Did this child have

chicken pox in the last year _____
measles " " " " _____

How many days of diarrhea do you estimate child has had in last 2 months _____

Does your child have a chronic cough or TB _____

Has your child ever received a Vit. A capsule? _____

Child is the _____ child of _____ children born to this
mother.

Dietary

How many times in the last week did your child eat

green leafy veg.

pumpkin, carrot, papaya

eggs, wholemilk or cheese

How many meals a day does your child eat

Who eats before this child?

Is child breastfeeding? exclusively? partially?

If yes, are other children also breastfeeding?

If no, how old was child when stopped breastfeeding?

Knowledge Assessment of Mothers

Is night blindness a serious problem _____

What causes night blindness _____

What can you do to prevent or cure this problem? _____

What foods help prevent night blindness? _____

Patient # _____

Pt nos. _____

At Risk Children for Vitamin A Deficiency : FAMILY PROFILE

Socioeconomic

Who is major wage earner _____

Job/jobs of major salary earner _____

What is approximate monthly income of major salary earner _____

Monthly income of family _____

Number of people in household _____

Does father live with family? Yes/No

If no, Divorced? Lives with other wife?

Family Constellation : Children

Number of children in family total born total alive

Number of children <5 years _____

Number of alive males _____

Number of alive females _____