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REVIEW BOARD OF [illegible] Date 10.04.78

CRL

Principal Investigator Md. Shafiqul Islam Trainee investigator(if any) None

Application No 78-015 Supporting Agency(if Non-CRL) _____

Title of study Birth Care Practices and Infant Mortality in Teknaf - Analysis of Correlates.

Project status:
(x) New Study(Re-formulated protocol)
( ) 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 possibly 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 N. A
   d) Sensitive questions Yes No N. A
   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
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:
   ___ Until the 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 Board for review.

Agree to obtain approval of the Review Board on Use of Human Volunteers for any changes involving the rights and welfare of subjects before making such change.

MSalam
Principal Investigator

Trainee

Please return 2 copies of entire protocol to Chairman, Review Board on [illegible]

78-015
Recd 26/5/78

ABSTRACT SUMMARY

BIRTH CARE PRACTICES AND INFANT MORTALITY IN TEKNAF - ANALYSIS OF CORRELATES

Md. Shafiqul Islam

This protocol intends to study the influence of birth care practices (birth attendants, method of cutting and dressing of the umbilical cord) on infant mortality and the socio-demographic factors (Mother's age, sex of infant birth order, number of living and dead children, father's occupation and mother's education) which determind the relationship. Data for this work were generated from the routine registration of birth and death reports collected in the Teknaf Demographic Surveillance system effective July 1976. The survivors of the birth cohort of 1976 will be compared with the infants who died within one year of birth according to the aforementioned variables.

1. The study will involve about 1,800 live birth and 270 infant death reports which are already complete.

2. Not applicable (Data generated from routine reports).

3. Not Applicable

4. Data will be kept at personal care so that adequate confidentiality is maintained. No identifying information will be required to be quoted.

5. Not applicable

a. Not applicable

b. Not applicable

6. Not applicable (Data source is routine reporting system)

7. This kind of work will create social awareness of birth care practices, the factors and causes of infant mortality which may ensure welfare of mothers and infants.

8. Completion of this work will be based on the birth and infant death records which were already collected.

SECTION I - RESEARCH PROTOCOL

1. Title : Birth Care practices and Infant mortality in Teknaf Analyses of Correlates.

2. Principal Investigator : Md. Shafiqul Islam

3. Starting Date : May, 1978

4. Completion Date : October, 1978

5. Total Direct Cost : US $ 2731.00

6. Abstract Summary : (250 words or less)

This protocol intends to study the influence of birth care practices (birth attendants, method of cutting and dressing of umbilical cord) on infant mortality and the socio-demographic factors (Mothers age, sex of infant, birth order, number of living and dead children, father's occupation and mother's education , which determine the relationship. Data for this work were generated from the routine registration of birth and death reports (Appendix I) collected in the Teknaf Demographic surveillance system effective July 1976. The survivors of the birth cohort of July 1976 to June 77 will be compared with the infants who died within one year of birth according to the above mentioned variables.

7. Reviews (Leave blank)

a. Research Involving Human Subjects : _____

b. Research Committee : _____

c. Director : _____

d. BMRC : _____

e. Controller/Administrator : _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objective : This study attempts to relate birth care practices to infant mortality and analyse the factors that account for such a relationship.

2. Background : A preliminary estimate of Teknaf data of 1976 gave infant mortality rate of 148.0, neonatal and post-neonatal mortality rates were 75.0 and 73.0 respectively. It was found that about 97 per cent of the deliveries took place in home, attended mostly by relatives of women and the traditional birth attendants i.e. the untrained village dais. Doctors and nurses attended less that one percent and the rest births required no attendants. Unscientific methods of cutting and dressing of the umbilical cords were used by most birth attendants.

A study of infant rearing practices and beliefs by Dharam B. Sharma and U.C. Lahori (1977) among 250 urban and 300 rural mothers of Jammu Province revealed that 74 percent of the urban and 91 per cent of the rural deliveries were conducted at home most of them by midwives (83.0 percent in urban and 95.0 per cent in rural area respectively). The frequency with which unscientific instruments were used for clamping the umbilical cord (urban 19 and rural 69 per cent) was quite alarming. So also was the prevalent practice of treating the umbilical stump with either unconventional substance like, cowdung, ash, ghee etc. or nothing at all.

In a Sylhet Tea garden population a study was carried out in 1960 by Mackay (1962). This study showed prematurity as the major cause of death in the neonatal period accounting for 65 percent of the deaths and 10 per cent to gastrointestinal and respiratory infection. The author found an average survival time of 7 days. Respiratory infections accounted for 31 per cent and gastrointestinal infections for 27.6 per cent of post-neonatal deaths. Prematurity featured in this group but to a much less degree (20 per cent). The results showed an average survival time of 2 months and 20 days. Again, during the years 1967 to 1969 Mackay (1973) found in the same Tea garden population an overall infant mortality of 50.6 per 1000 live births. The neonatal rate

was 30.4 and the post-neonatal rate 20.2 . The author observed that the risks of death declined with age of infants. 77.8 per cent of the deaths occured in the first three months of life, 90.3 per cent in the first six months and only 9.7 per cent in the remaining six months. The principal cause of neonatal death was prematurity accounting for 60.7 percent of the deaths, cot deaths 6.7 per cent and conjenital deformation 5.9 per cent. The leading cause of post-neonatal death was infections of the bowel accounting for 42.2 per cent of deaths.

Anu Gupta, Kamlesh Chopra and Anita Khalil (1977) in a study of 247 neonates admitted over a period of twenty one months from January 1974 to September 1975 found tetanus neonatorum as one of the common causes of morbidity and mortality. There was higher prevalence of the disease in males and babies of rural community where deliveries were conducted at home by untrained dais. He found an overall mortality from tetanus neonaturum of 72 per cent. 98 per cent of all deliveries were conducted at home. The mortality was 80.7 per cent in neonates who presented with tetanus in the first 8 days of birth as compared to 39.3 per cent in babies who developed tetanus after 8 days of life. Unsterilized crude instruments were used to sever the cord : in 52 percent of cases the umbilical cord was cut by unsterilized blade. Other instruments used were knife, sickle and scissors.

According to a WHO chromicle (1976) infant mortality by age group showed considerable consistency. There was a pattern of high mortality rates among children born of mothers under 20 years of age. The rates declined in the 20-24 group and reached their lowest in the 25-29 group : they increased slightly in the 30-34 group and rather more in the 35 and over group. Moreover, the highest rates in all projects were roughly twice the lowest rates. Clearly the 25-29 years period was the most favourable in the maternal age span. For immaturity, the same pattern of high mortality rates in the under 20 group, particularly low rates in the 25-29 group, and increasing rates in older groups generally held true. With young mothers, the frequency of immature births may be greater because of biological conditions that interfere with the repenishment of reserves, such as inadequate development or shorter intergestational intervals. Also, such unfavourable factors as unwanted pregnancies, unstable marital unions, inexperience and lack of knowledge

and / or interest in prenatal and post-natal care may be more serious in this age group and thus pose an increased threat to the infant's survival. The correlation between infant mortality and birth order is clear : In the Latin American Projects and two North American ones where the relevant data were available there was a consistent pattern of increasing mortality rates with each subsequent product of pregnancy. The death rates among infants of the fifth or higher birth orders was more than double that for first products of pregnancy, reaching over 160 infant deaths per 1000 live births in EL Sulvador. With immaturity, the infant death rates in general rose progressively from low levels for first births to higher ones for the fifth and subsequent orders, doubling themselves in each of the three Latin American projects and almost trebling themselves in the North American ones.

Stockwell hypothesised (1962) that postneonatal mortality is much more sensitive to socio-economic variations. Further, Willie (1959) and Stockwell (1962) suggested that income seems to be the most important socio-economic variable related to infant mortality.

Markides and Barnes (1977) in their work during the years 1970 to 1974 in San Antonio, Texas showed a definite relationship between the total infant mortality rate and socio-economic status, the rates rises steadily from a low of 13.8 for the High SES group to about 20.8 for the Low SES group. While the relationship between neonatal mortality and SES is not as strong, it still exists. The strongest relationship is found between SES and postneonatal mortality : the postneonatal rate rises from 2.3 to 6.3 as SES decreases. It was found that infant mortality rates were much more sensitive to income differentials than to occupational and educational differentials.

3. Rationale : The analysis of the influence of birth care practices, the factors and causes of infant mortality will be an important contribution towards the evaluation of meternity and child health care facilities in rural Bangladesh.

B. SPECIFIC AIMS :

Specifically, the protocol addresses itself to the following questions :-

1. Are there variations in infant mortality rates by age and sex of infant, age of mother, no. of living / dead children, birth order and socio-economic status of the parents ?

2. Are there variations in birth care practises (birth attendant, cutting and dressing of umbilical cord) according to the aforementioned variables ?

3. Is there a relationship between birth care practices and infant mortality ?

4. Would the relationship (if any) persist after standardizing for age of mother, sex of infant, birth order, cause of death and socio-economic factors ?

C. METHOD OF PROCEDURE :

The records of births occuring in 1976 in Teknaf Surveillance area will be matched against the death records obtained for this cohort to segregate the infant deaths from the survivors. Based on this dichotomy, tabulations will be made both for the infant deaths and survivors according to the following characteristics.

1. Age of mother
2. Sex of the child
3. Birth order
4. Number of children born alive now dead
5. Number of living children
6. Total number of pregnancies
7. Occupation of father)
8. Education of mother) from census records.

Likewise, the birth care practices will be related to the aforementioned variables to avoid any spurious relationship. Then birth care practices will be related to infant mortality rates controlling for age, of mother, parity, socio-economic characteristics, sex of the child, and other variables which will be

deemed important in the course of analysis.

Finally, chi square tests and partial correlation analysis will be done to statistically validate the results attained.

D. SIGNIFICANCE :

The high infant mortality rate has been an important concern of public health administrators in Bangladesh. Between 1974 and 1976 in Matlab study area of CRL, the infant mortality rate fluctuated from 138 to 103. Infant mortality for Teknaf was 148 per 1000 births in 1976. By extricating the factors accounting for the high infant mortality and examining the birth care practices as they relate to the infant deaths, appropriate intervention measures could be undertaken with proper focus. Such knowledge would aid public health planners in preparing adequate programmes for the reduction of infant mortality.

E. FACILITIES REQUIRED :

Statistical Assistance will be required for approximately two months for sorting birth and death reports, and making necessary tabulations. Help of computer service may be required for tabulation of data.

F. COLLABORATIVE ARRANGEMENT :

None.

SECTION III - BUDGET

A. DETAILED BUDGET

1. PERSONNEL SERVICES

NAME	POSITION	Percent of effort or number of days	Annual Salary	PROJECT Requirements TAKA	DOLLAR
Md. Shafiqul Islam	Research Associate	88 days	43,372/-	14,849	
M.H. Munshi	Project Manager (Teknaf Dysentery)	10 "	36,384/-	1,400	
Trinidad Osteria	Investigator	5%	25,000/-		1250/-
M. Mizanur Rahman	Statistical Assistant (Teknaf)	20 days	14,606/-	1,124	
	1 Stasistical Assistant	22 "	9,720/-	823/-	
			Subtotal:	18,196	1250/-

2. SUPPLIES AND MATERIALS:

ITEM	UNIT COST	QUANTITY	PROJECT Requirements TAKA	DOLLAR
Pen, Ballpoint, Black	$ 0.15	4 Each		0.60
Refill, Black	$ 0.04	14 Each		0.64
Pencil, lead No. 1	$ 0.02	6 "		0.12
Pad, Octave	$ 0.16	2 "		0.32
Eraser, double, Oblong	$ 0.04	2 "		0.08
Clip, Paper, Gem	Tk. 3.75	1 Box	3.75	
Pad, foolscape, plain (100 sheet pad)	$ 0.36	2 Each		0.72
Pad, foolscape, lined (100 sheet pad)	$ 0.28	3 Each		0.84
		Subtotal	3.75	3.32

3. EQUIPMENT

None

4. PATIENT HOSPITALIZATION

None

5. OUTPATIENT CARE

Not applicable

6. CRL TRANSPORT

None

7. TRAVEL AND TRANSPORTATION OF PERSONS

None

8. TRANSPORTATION OF THINGS

None

9. RENT, COMMUNICATION AND UTILITIES

None

10. PRINTING AND REPRODUCTION

I T E M S	PROJECT REQUIREMENTS	
	TAKA	DOLLAR
Mimeography	1200/-	
Computer Service Charges	2400/-	
Cover Printing & Binding	800/-	
Xeroxing	200/-	
Special reproduction	100/-	
Sub-total	4700/-	-

11. OTHER CONTRACTUAL SERVICES

None

12. CONSTRUCTION, RENOVATION AND ALTERATIONS

None

B. BUDGET SUMMARY

	CATEGORY	YEAR-1		YEAR-2		YEAR-3	
		TAKA	DOLLAR	TAKA	DOLLAR	TAKA	DOLLAR
1.	Personnel	18196.00	1250.00				
2.	Supplies	3.75	3.32				
3.	Equipment	-	-				
4.	Hospitalization	-	-				
5.	Outpatient	-	-				
6.	C.R.L. Transport	-	-				
7.	Travel Persons	-	-				
8.	Transportation Things	-	-				
9.	Rent/Communication	-	-				
10.	Printing/Reproduction	4,700.00	-				
11.	Contractual Service	-	-				
12.	Construction	-	-				
	Total	22,899.75	1253.32				
	Total $	2730.72					

Say, $ 2731.00

Conversion rate $ 1.00 = Taka 15.50

REFERENCES

1. Anu Gupta, Kamlesh and Anita Khalil, Tetanus Neonatorum, Indian Pediatrics, 14(3), 1977, 211-213.
2. Dharam B. Sharma and U.C. Lahori. Some aspects of infant rearing practices and beliefs in the urban and rural areas of Jammu(kashmir), Indian Pediatrics, XIV (7), July 1977, 511-518.
3. D.M. Mackay. causes of death in a tea garden population, East Pak. Med. Journal, 6(2), 1962, 1-6.
4. D.M. Mackay, causes of infant mortality in a tea garden population, Bangladesh Med. journal, October, 1973 : 31-38.
5. Kyriokos S. Markides and Donna Barnes. A methodological note on the relationship between Infant mortality and socio-economic status with evidence from San Antonio, Texas, Social Biology, 24(1), 1977, 38-44.
6. Stockwell, E.G. Infant Mortality and socio-economic status. A changing relationship : Millbank Mem. Fund quart, 40, 1962, 101-111.
7. WHO chronicle, 30, 1976, 198-200
8. Willie, C.V. A Research note on the changing association between infant mortality and socio-economic status. Soc. Fore, 37, 1959, 221-227.

Appendix - 1.

T. D. P. Form 2

BIRTH REPORT

TEKNAF DYSENTERY PROJECT
(Cholera Research Laboratory, Dacca)

Sl. No.

Card [ ] (1)

Study No. [ ] [ ] (2—3)

Identification [ ] [ ] [ ] (4—6)

Name of Newborn : _____ Date : Day [ ] [ ] (7—8) Month [ ] [ ] (9—10) Year [ ] [ ] (11—12)

Litter Size : (13) Single [1] Twin [2] Triplet [3]

Result (14) : Miscarriage [1] Still birth [2] Live birth [3] Sex : (15) M [1] F [2]

Vill : [ ] (16) Para : [ ] [ ] (17 18) Census No. [ ] [ ] [ ] [ ] [ ] [ ] [ ] (19—25)

Information on Father :

Name : _____ Age [ ] [ ] (26—27) Census No. [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] (28—37)

Information on Mother :

Name : _____ Age [ ] [ ] (38—39) Census No. [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] (40—49)

Marital Status of mother at the time of delivery (50)

Married [2] Widowed [3] Divorced [4] Separated [5]

No. of living children : (51—52) [ ] [ ] Sons [ ] (53) Living with mother : Son [ ] (54) Daughter [ ] (55)
Excluding this birth)

No. of children born alive now dead: [ ] (56) Sons [ ] (57) No. of children born dead: [ ] (58)

Total no. of pregnancies : [ ] [ ] (59—60) No. of additional children wanted: [ ] (61)

Birth Attendant : (62) None [1] Mother [2] Mother-in-law [3] Grandmother [4]

Neighbouring women [5] Dai [6] Nurse [7] Doctor [8]

Other (specify) : [9] _____

Cutting of the umbilical cord : (63) Blade [1] Knife [2] Bamboosheet [3]

TDP Kit [4] Other Specify : _____ [5]

Dressing of the umbilical cord : (64) Nothing [1] Ash or Burnt earth [2] Tied with thread [3]

TDP Kit [4] Others : _____ [5]

Any delivery complication : [ ] [ ] (65—66) Specify : _____

Complication of the newborn : [ ] (67) Breathing or crying difficulty [1] Inability to suck [2]

Blue baby [3] Injured during birth [4] Birth defect [5] Others _____ (6)

Place of birth : Vill : _____ Para/P. O. _____ Thana _____ [ ] (68)

(If the place is not the usual residence of Mother)

Remarks : _____

Reported by : _____ FA Date _____ Verified by FSA _____

Appendix - I

T. D. P. Form 3

DEATH REPORT

TEKNAF DYSENTERY PROJECT

(Cholera Research Laboratory, Dacca)

Card

I. No.

Study No. (2—3)

Identification (4—6)

Name of deceased :

Date of death : Day (7—8) Month (9—10) Year (11—12)

True Age : Year (13—14) Month (15—16) Day (17—18) Sex : (19) M 1 F 2

Vill : (20) Para : (21—22) Census No. (23—29)

Education (30) Occupation : (31—32) Marital Status at death : (33)

Never married 1 Married 2 Widowed 3 Divorced 4 Separated 5

Describe events and symptom leading upto death

Causes of death as reported : (34—35)

Pneumonia	01	Diarrhoea : Acute	07	Malnutrition	13
Measles	02	Chronic	08	Drowning	14
Tetanus	03	Dysentery : Acute	09	Snake bite	15
Fever	04	Chronic	10	Tuberculosis	16
Murder	05	Delivery complications	11	Rabies	17
Suicide	06	Whooping cough	12	Killed by wild animal	18

Other not covered above (specify) 19

Treatment given by : (36) Licensed allopath 1 Allopath quack 2 Homeopath 3

Hakim/Kaviraj 4 CRL 5 No treatment 6 Other (specify)

No. of persons eating together : (37—38)

Place of death : Vill : Para/P. O. Thana (39)

(If the place is not the usual Residence of the deceased)

If age at death was 10 years or below, complete the following :

Occupation of Father/Head (40—41) Mother's census (42—51)

Mother's matrial status : (52) Married 2 Widowed 3 Divorced 4

Separated 5 Mother dead 6

The deceased was living with : (53)

Both parents 1 Father alone 2 Mother alone 3 Stepmother 4

Maternal relations 5 Paternal relations 6 Other (specify)

Remarks :

Reported by Date : Verified by . Date

F.A.