

Date 20. 02. 1981

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator AKM. Alowddin (Lweddin) Trainee Investigator (if any) _____

Application No. 81-008(P) Supporting Agency (if Non-ICDDR, _____)

Title of Study Doeg Domestic Animal Project status:
Determine neonatal deaths
 New Study
 Continuation with change
 No change (do not fill out rest of form)

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
- Risks 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 involving the rights and welfare of subjects before making such change.

Alowddin
Principal Investigator

Trainee

81-008(P)
rec'd 25/2/87

SECTION I - RESEARCH PROTOCOL

1. Title: Does Domestic Animals Determine the Neonatal Deaths in Rural Bangladesh
2. Principal Investigator: AKM Alauddin Chowdhury
3. Co-Investigator: Md. Moshaddeque Hossain
4. Starting Date: When feasible
5. Completion Date: Three months after start
6. Total Direct Cost: US \$ 2,997.00
Incremental Cost US \$ 1,350.00
7. Scientific Programme Head:

This protocol has been approved by the "Disease Transmission Working Group."

*Signature of Scientific Programme Head:



Date:

20/2/1981

*This signature implies that the Scientific Programme Head takes responsibility for the planning execution and budget for this particular protocol.

8. Abstract Summary:

Tetanus of newborn is a major health problem of Bangladesh. Two ecological factors together probably are responsible for high neonatal tetanus deaths in Bangladesh. These are: (1) Domestic animals and the usage and disposal of manure in the proximity of the houses and (2) the delivery practice. This study will look at the relationship of proximity of domestic animals with a household and neonatal tetanus deaths of that household. This study will explore another risk factor of neonatal tetanus so that the immunization program can be efficiently utilised.

9. Reviews:

(a) Ethical Review Committee: _____

(b) Research Review Committee: _____

(c) Director: _____

(d) BMRC: _____

ABSTRACT SUMMARY - PARTICULAR ITEMS

1. Partial data collection needed at family level about the proximity of domestic animals and delivery care practice.
2. There is no risk - physical, psychological or social.
3. Does not arise.
4. Data will be published in aggregate and only the Investigators have the access to data.
5. A consent form to be filled for every household in case the respondent thinks of potential risk to the privacy of the family.
6. Interviews will be on domestic animals and delivery practice.
7. No individual benefit, however, overall benefit for the communities.
8. Births and Deaths registration data are required.

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objective: The study will look at the risk of neonatal tetanus and its association with the proximity of domestic animals and usage of their manure in rural Bangladesh.
2. Background: Tetanus of the newborn is a major health problem of Bangladesh. This is one of the leading causes of infant deaths in this country (McCord, 1980). This preventable disease attacks its neonate host in an environment of agrarian living conditions of Bangladesh. Manure from herbivorous domestic animals is considered to be responsible for the spread of tetanus infection. The epidemiologic cycle most often resulting in tetanus cases is manure from herbivorous domestic animals to soil to broken skin or to injury (Stecle, 1980). It is likely that soil, climatic conditions and animal living, foster the accumulation of widespread distribution of tetanus Bacilli (Marshall, 1968). Cows, goats and lambs live with very close proximity of Bangladesh abodes. Little importance is given to animal waste disposal. Moreover, cow-dung is used not only for agricultural purpose, but also for several domestic purposes. These are: (i) plastering of courtyard; (ii) plastering of mud floor of the houses; (iii) plastering of bamboo walls; (iv) making of cooking fuel, etc. All such works are done by females in bare hand.

All the babies are delivered at home. These home deliveries are done on straw mat on the floor of the houses which are generally of mud floor with no sanitary facilities. Birth attendants are neighbour relatives, dais or none.

In this agrarian rural society, the umbilical cord is cut either with old razor blade, or bamboo strip, or unsterile knife, etc. and cords are tied with old threads or sometimes left untied. Putting ashes or burned mud to the cut end of the cord is also common practice in Bangladesh.

Two ecological factors together may be attributed to be responsible for very high incidence of neonatal tetanus deaths in Bangladesh. These are: (1) Domestic animals and the usage and disposal of manure in the proximity of the houses and (2) Delivery practice.

Two studies in Bangladesh - one in Matlab (Chowdhury, 1974) and one in Companiganj (McCord, 1980) - showed landholding is not associated with infant deaths. Moreover, neonatal deaths are slightly higher in the biggest landholding group. These unusual findings are suggestive of a hypothesis that probably the biggest landholder have to keep more domestic animals in the household for the support of their land resulting in an increased risk of neonatal tetanus. One study in India showed that ownership of large animals is related to neonatal tetanus deaths (Smucker, 1980).

3. Rationale: There will be an attempt to pindown another risk factor of neonatal tetanus so that the immunization program can be planned more vigorously toward this risky group for an accelerated decline in neonatal mortality with allocated resources.

B. SPECIFIC AIMS

- (1) How the proximity of cowshed and the number of cows in the family is associated with neonatal tetanus?
- (2) How the domestic use of cow-dung is associated with neonatal deaths?
- (3) Define a domestic animal related pattern, determining the neonatal deaths.
- (4) To test the above pattern of neonatal deaths by incubation period and maternal immunization status.

C. METHODS OF PROCEDURE

To look at the relationship of proximity of domestic animals with the family and neonatal tetanus deaths, two kinds of data will be required: (1) DSS data for neonatal deaths and matched controls from post-neonatal deaths and surviving births and (2) Data relating to domestic animals and the use of their manure to be collected by a cross-sectional survey.

This will be a case-control study with two controls. Cases are the neonatal deaths, and controls are: (1) post-neonatal deaths; (2) surviving infant. For each neonatal death a post neonatal death and a surviving infant will be selected by mothers parity, village, and immunization status. 200 cases will be taken in each group. These families (600 altogether) will be interviewed for the collection of data relating domestic animals. These animals related data are to be collected retrospectively. For this, a questionnaire for interviewing the family will be used. Sample will be confined to only 1980 births and deaths. Informations about the actual distance of a cow-shed, number of cows and other animals will be collected. Use of cow-dung in domestic purposes and the frequency of such usage to be asked (Appendix 1). As the delivery practices is associated with neonatal deaths hence questions about delivery care practice of those particular births are also to be asked so that this factor can be controlled (Appendix 2).

Data Analysis

Animal related variables will be classified in two or three broad groups defining different level of exposure to tetanus infection. A neat definition can be possible by looking at the actual data. Odds ratio will be calculated by multidimensional classifications of the data.

Neonatal deaths will also classified by (1) within incubation period of tetanus (4 to 14 days: Black 1980) and after incubation period. The following Table will show the general plan by which data is going to be presented.

Table

Animal related factors	Immunization of mother	Delivery care	Neonatal deaths (cases)	Post neonatal deaths (Control I)	Survived Infant (Control II)	Odds ratio
High Risk	Yes	Good	n_1	c_1	d_1	$\frac{n_1 \sqrt{c_5 + d_5}}{n_5 \sqrt{c_1 + d_1}}$
	Yes	Bad	n_2	c_2	d_2	$\frac{n_2 \sqrt{c_6 + d_6}}{n_6 \sqrt{c_2 + d_2}}$
	No	Good	n_3	c_3	d_3	$\frac{n_3 \sqrt{c_7 + d_7}}{n_7 \sqrt{c_3 + d_3}}$
	No	Bad	n_4	c_4	d_4	$\frac{n_4 \sqrt{c_8 + d_8}}{n_8 \sqrt{c_4 + d_4}}$
Low Risk	Yes	Good	n_5	c_5	d_5	
	Yes	Bad	n_6	c_6	d_6	
	No	Good	n_7	c_7	d_7	
	No	Bad	n_8	c_8	d_8	

REFERENCES

- R.E. Black et al. Reduction of Neonatal Tetanus of Mass Immunization of Non-pregnant Women, Bulletin of World Health Organisation, 1980.
- F. M. Marshall. Tetanus of the Newborn, Advances in Pediatrics Vol. 15; 1968.
- C.W. McCord et al. Death rate, land and the price of rice '75-78. Evaluation unit report No. 04, Cristian Commission for Development in Bangladesh, 1980.
- C. M. Smucker et al. Neonatal Mortality in South Asia: The special role of Tetanus, Population Studies No. 2, Vol. 34; 1980.
- J.H. Steele, Chief Editor, CRC Handbook Series in Zoo Noses Vol. 2; 1980 CRL Publication.

SECTION III

A. DETAILED BUDGET

1. PERSONNEL SERVICES

<u>Name</u>	<u>Position</u>	<u>Percent of effort</u>	<u>Annual Salary</u>	<u>Project Requirements</u>
Dr. AKM Alauddin Chowdhury	Principal Investigator	10% for 3 months	US\$ 24,000/-	US\$ 600.00
Dr. Moshaddeque Hossain	Co-Investigator	20% for 3 months	\$ 2,315/-	\$ 120.00
	2(two) Health Asstt. (females)	100% for 2 months	\$ 2,224/-	\$ 742.00
	Coding Asstt.	100% for 1 month 10% overtime (provisional)	\$ 2,224/-	\$ 185.00 \$ 100.00*
		Sub-total		US\$ 1747.00

2. SUPPLIES AND MATERIALS

Ball pen, Pencil, paper etc. \$ 100.00*

3. EQUIPMENT

None

4. PATIENT HOSPITALISATION

None

5. OUTPATIENT CARE

None

6. ICDDR,B TRANSPORT

Matlab travel

4 trips to Matlab and Dacca return; speed boat. \$ 650.00*

7. TRAVEL AND TRANSPORTATION OF PERSONS

None

8. TRANSPORTATION OF THINGS

None

* Incremental Cost.

Project Requirements
Taka Dollars

9. RENT, COMMUNICATION AND UTILITIES

None

10. PRINTING AND REPRODUCTION

Memographs

\$ 500.00 *

11. OTHER CONTRACTUAL SERVICES

Computer time Use ICDDR,B Computer

12. CONSTRUCTION, RENOVATION AND ALTERATION

None

13. MISCELLANEOUS

None

* Incremental Cost.

B. BUDGET SUMMARY

<u>CATEGORY</u>	<u>TAKAS</u>	<u>DOLLARS</u>
1. Personnel Services	-	1,747.00
2. Supplies and Materials	-	100.00
3-5 Nil Items	-	-
6. ICDDR,B Transport	-	650.00
7-9 Nil items	-	-
10. Printing and Reproduction	-	500.00
11-13 Nil Items	-	-
		<hr/>
		Total cost:\$ 2,997.00
		<hr/>
		Total incremental cost: \$ 1,350.00
		<hr/>

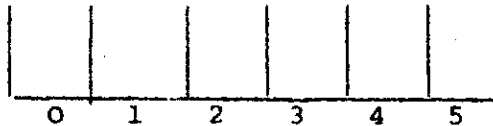
Village _____ Household/Bari _____

Name of woman _____ Census No. _____

Name of child _____ Census No. _____

Date of birth _____

1. How many cowsheds are here in this Bari?



2. Mention the number of cows in each of those cowsheds.

<u>Cowsheds serial No.</u>	<u>No. of cows</u>
1	
2	
3	
4	
5	

3. How many cows you own? _____

4. Distance of the place of delivery of the referred birth from the nearest cowshed _____.

5. Where do you dump the cowdung?

- i) By the side of cowshed
- ii) To a fixed place
- iii) Any where.

6. Distance of the place of delivery of referred birth from where cowdung is dumped _____.
7. What do you use while plastering the courtyard?
- i) Water with cowdung
 - ii) Water with cowdung & mud
 - iii) Water with mud
8. How often you plaster the courtyard? _____.
9. What was used for plastering the floor & wall of the house where the child was delivered?
- Floor _____
- Wall _____
- Not applicable _____
- (In case of mud floor and wall)
10. Do you use cowdung as fuel? Yes No
11. If yes, how do you prepare this?
- i) Sticking with jute wood
 - ii) Round ball.
12. Where do you dry this fuel? _____
13. The distance of this place from the house where the child was delivered: _____

Interviewer's Name: _____

Date of interview: _____

Village _____ Household/Bari _____
Name of mother _____ Census No. _____
Name of Child _____ Census No. _____
Date of birth _____

1. Where the delivery was done:

- i) Father's house
- ii) Father-in-laws house
- iii) Clinic
- iv) Hospital
- v) other.

2. Who was the Birth-attendant at the time of delivery?

- i) Dai
- ii) Relatives
- iii) Neighbours
- iv) Trained Dai

3. Which was the room where delivery was done:

- i) Bed room
- ii) Kitchen
- iii) Verandha
- iv) One extreme corner of Bed room
- v) Others

3a. Structure of the house

floor _____ wall _____ roof _____

4. The place where the delivery was done:

- i) Mud floor
- ii) Chatai (strawmat on mud-floor)
- iii) Coach

If Chatai used, was it

- i) new chatai
- ii) old chatai

5. Information about hand wash of the birth attendant.

- i) Hands were clean initially
- ii) Hands were washed by soap/soda just before delivery.

6. How the umbolical cord was cut by: _____

7. Was it cleaned initially? Yes / No

If not cleaned, how it was cleaned:

- i) wash only with water
- ii) wash with hot water
- iii) cleaned with soap/soda
- iv) others.

8. Was the umbolical cord lightened? Yes No

9. With what it was lightened?

- i) New tailoring thread
- ii) old cloths thread
- iii) others

10. Was anything used for dressing of cut end?

- i) ash
- ii) burnt soil
- iii) piece of old cloth
- iv) ash of burnt old cloth
- v) Jute leaves
- vi) nothing
- vii) other.

11. Any other thing was used?

Name of the Worker: _____

Date of interview: _____

CONSENT FORM

I am convinced that the proximity and care of domestic animal probably has some cause and effect relationship with deaths neonatum. In pursuit of investigating the idea, I do hereby extend my full cooperation with ICDDR,B staff for collecting the necessary information.

Signature of Thumb impression of respondent

Date _____

Signature of Worker: _____

সম্মতি পত্র

আমি অবজ্ঞাত হইলাম যে, গৃহপালিত পশু
পালন শ্রমিকের সাথে খুব ছোট-বাল্যের স্ত্রীর
সম্ভবতঃ একটি সমস্যা আছে। এই ধারণার
সূত্রে- প্রয়োজনীয় তথ্য প্রদান করে আর্থে সি ডি, ডি,
আর বি এর কর্মীদের সঙ্গে সহযোগিতা
করিতে আমি সম্মত হই।

স্বাক্ষর/ বৃদ্ধাশ্রমের ছাপ
তারিখ _____

কর্মীর স্বাক্ষর _____