

Date 22 August 1991

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Circle the appropriate answer to each of the following. (If Not Applicable write NA).

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

Trainee

A-032070

[illegible]

**A STUDY OF RISK FACTORS OF PERINATAL
MORTALITY AMONG MOTHERS ATTENDING
SELECTED HOSPITALS OF DHAKA CITY.**

PROJECT PROPOSAL

**BANGLADESH INSTITUTE OF RESEARCH FOR PROMOTION OF
ESSENTIAL & REPRODUCTIVE HEALTH AND TECHNOLOGIES
(BIRPERHT).**

22 August 1991

SECTION I: RESEARCH PROTOCOL

1. Title : A study of risk factors of perinatal mortality among mothers attending hospitals of Dhaka city.
2. Principal Investigator(s):
Dr. Yasmin H. Ahmed
3. Co-Principal Investigator:
Dr. Shahida Tariq
Dr. Abdullah H. Baqui
3. Starting date : October 1, 1991
6. Completion date : December 31, 1992
7. Total direct cost: US \$ 9,985 (Taka 3,64,460)
8. Recommendations :

(A) National Institution
Signature of the Director
BANGLADESH INSTITUTE OF RESEARCH FOR
PROMOTION OF ESSENTIAL & REPRODUCTIVE
HEALTH AND TECHNOLOGIES (BIRPERHT).

(B) ICDDR, B

Halida Akhter

Abstract/Summary

Perinatal mortality is defined by WHO/UNICEF as mortality among fetuses weighing more than 1000 gms. before or during delivery and deaths occurring within first week of life. A number of studies have identified the rate and risk factors of perinatal mortality in different countries, including Bangladesh. However due to lack of consistent definition of perinatal mortality the findings of these studies are not comparable. This study is designed to identify the risk factors of perinatal mortality among pregnant women coming for antenatal care in selected urban centers of Dhaka city in conformity with WHO/UNICEF definition of perinatal mortality.

In addition, considering the need for competent health researchers in the country, the study proposes to train a representative of the Obstetrical and Gynecological Society of Bangladesh on research methodology, through active participation in the study. Exposure of young graduates/physicians to research methods in course of data collection will also contribute to development of research skills among selected doctors.

In order to meet the aforementioned research objectives, a prospective study will be conducted at the Azimpur Maternal and Child Health Training Institute, the ante-natal clinic of Sir Salimullah Medical College and Radda Barnen's MCH clinic. About 2095 women who report to these clinics at 24-28 weeks of pregnancy will be enrolled through a period of 6 months. They will be followed up as per the clinic's antenatal checkup schedule, and also at delivery and at 7 days postpartum. Information on delivery and at 7 days postpartum will be collected either at the hospital/clinic where the patient delivered the child, or at home. The total study will require fifteen months to be completed.

SECTION II : RESEARCH PLAN

1. AIMS OF THE PROJECT :

a) General aim :

The study aims to identify the risk factors of perinatal mortality in selected hospitals and clinics of the country, and in course of this, strengthen the capacity of the Obstetrical and Gynecological Society of Bangladesh for conducting research through transfer of technology. In addition the study will also enhance the capability of physicians working in the obstetrics department of selected hospitals in organizing and conducting research through exposure to and participation in various steps of this research.

b. Specific aims :

1. To determine maternal socio-economic, demographic and behavioural and health care factors which contribute to perinatal mortality.
2. To determine factors related to antenatal, at birth & postnatal care which affect perinatal mortality.
3. To identify foetal or infant conditions associated with perinatal deaths including foetal condition at birth (to be measured by APGAR score), infant feeding practices and morbidities leading to perinatal death.
4. To assess the relative risk of the maternal and foetal factors for perinatal mortality.

c. Significance :

Implementation of this project will help to enrich the research pool of the country in general, and that of the Obstetrical and Gynecological Society of Bangladesh in particular through transfer of technology. The study will yield a death case rate of perinatal mortality for the study sample. It may be mentioned that there is, as yet, no reliable estimate of perinatal mortality as per WHO/UNICEF definition. The identification of risk factors for perinatal mortality will help in future designing of strategies to reduce the incidence of perinatal mortality.

2. ETHICAL IMPLICATIONS:

The study involves collection of information from patient population through structured interviews. The interviews will be conducted by well trained clinic staff or by interviewers trained by the Principal Investigator.

Patients selected for enrollment into the study will be explained the purpose of the study, its methodology, and the time and type of cooperation required from them. They will be ensured that participation in the study is voluntary, and they may withdraw from the study at any time. Patients will also be assured that if they decide not to participate in the study, or withdraw from it, that decision will not in any way hamper their treatment or services they were receiving or will receive from the center. The above mentioned information will be contained in the introduction of the questionnaire, and will be read out and explained to every respondent.

The admission form will require 15 mins. to be completed. The follow-up forms will be completed in 10 minutes, and the forms for collection of information at delivery, and post partum, 15 mins. each. The admission and follow-up interviews will be administered during routine clinic visit. For collection of information at delivery, and post-partum patients will be visited at their homes/clinics by study interviewers. The study therefore will not involve any expenditure on the part of the patient and therefore there will be no monetary compensation to the patient from the study. However, the investigators recognize and acknowledge the time and effort expended by the respondent in helping interviewers complete the questionnaire.

3. BACKGROUND INFORMATION AND RATIONALE:

a. Background information

According to the WHO/UNICEF joint statement the term perinatal mortality includes both late foetal and early neonatal deaths. Late foetal deaths are those that occur before or during delivery of foetuses weighing 1000 gms or more. Where birth weight is unavailable the corresponding gestational age (28 weeks) or body length (35 cms crown heel) should be used to define the cut-off point. Early neonatal deaths are those that occur in the first week of life. The perinatal mortality rate is usually expressed as the rate of late foetal and early neonatal deaths among foetuses and infants weighing 1000 gms or more at birth, per 1000 live births (1).

A large number of studies have looked into the issues of perinatal mortality. The incidence of perinatal mortality has been found to vary over a wide range in countries where such studies were conducted. For example, an analysis of births and neonatal deaths to North Carolina, USA resident mothers for the cohort years 1968 through 1977 were analyzed. The mortality rate among babies with birth weights of 1000 gms or less was found to be 803/1000 live births and 696/1000 live births among whites and non-whites respectively (2). In another analysis of neonatal mortality, data for infants delivered between 1958 and 1969 at the University of Colorado Health Services Center; it was found that 57.4% of infants with birth weight between 500 gms to 999 gms, and 100% of those with birth weight less than 500 gms died (3).

In a population based longitudinal study on perinatal mortality conducted in Norway, it was shown that perinatal mortality decreases with increasing parity and increases with sibship size. These associations which are not noticeably affected by maternal age seem in part to operate through an association between parity, sibship size and birth weight (4).

Needless to say, the rates and proportions mentioned in these studies which were all conducted in developed countries will not apply to Bangladesh. Moreover, these studies have not used any consistent definition of perinatal mortality. For example, in the last study mentioned (4), perinatal mortality was defined as number of deaths among fetuses with a gestational age of 16 weeks or more plus the number of deaths occurring during first week of life per 1000 live births. The denominator included all live births and deaths of fetuses of gestational age 16 weeks or more. On the other hand, in the University of Colorado Health Center study (3), birth weight were classified in 500 gms categories and the gestational age in 3 weeks categories precluding the determination of any cut-off point for defining perinatal death.

These studies do lead us to conclude that:

- a. Perinatal deaths are important components of neonatal, and for that matter infant deaths; and
- b. Various factors including gestational age, birth weights, maternal parity and sibship size have important functions in determining the incidence of perinatal deaths.

Among the developing countries, a number of studies on perinatal deaths have been conducted in India. Again, these studies suffer from the essential deficiency of using varying definitions of perinatal death. Therefore the findings are not comparable. For example, a study of 1441 perinatal deaths at Associated Group of Hospitals in Bikaner, Rajasthan found a perinatal mortality rate 110.67/1000 live births. These deaths included intrauterine deaths after 20 weeks of gestation and from 20 weeks of gestation to 28 days of neonatal life (5). In another study conducted at KK Municipal Hospital in Bombay, the authors mention a perinatal mortality rate of only 29.9/1000 live births, but do not define perinatal mortality (6). Yet another study reported a rate of 77.22/1000 live births, but again, did not define perinatal mortality (7). We reviewed numerous other studies conducted in India, but none of these studies have used any consistent definition of perinatal mortality. However, in some of these studies, authors have indicated possible risk factors for perinatal mortality. These included extremes of maternal age, prematurity, low birth weight of the baby, obstructed labour, severe maternal anaemia, and other medical complications of the mother or child (5). Inferior quality of MCH care, extremes of maternal age and higher parity were mentioned in another study (7).

Among other developing countries, in Libya, a one year prospective study revealed a perinatal mortality rate of 27.5/1000 live birth, which was comparable to that of Kuwait (24.7/1000 live birth) and was less than that of Nigeria (86.9/1000 live birth) (8). In Hong Kong, a hospital based study revealed a perinatal death rate of 21.5/1000 live births. This study too did not define perinatal mortality (9).

In Bangladesh a hospital based study found the perinatal mortality rate to be 116.8/1000 live births. In this study too the perinatal period has not been clearly defined. Factors that have been mentioned to be associated with perinatal mortality include pregnancy and labour complications and smoking. (10, 11).

In Pakistan, a urban population based study estimated perinatal mortality rates by selected risk factors. (12-13). The risk factors that were identified included (Tables 1-6):

- (i) gravidity - the risk was greater among primigravida and among women with sixth or higher gravidity.
- (ii) age - the risk being greatest among teenage mothers and and mothers aged 35 years or more.
- iii) previous foetal loss - the risk being higher among women with history of foetal loss.
- (iv) antenatal care - the perinatal mortality rates were lower among women who had received antenatal care.
- (v) Socio-economic condition - perinatal mortality was higher among lower socio-economic group.

Table 1 : Pregnancy wastage rates as related to gravidity status of respondents

Gravidity status	Pregnancy wastage rates per 1000 conceptions at risk				Total pregnancy wastage
	Early fetal loss	Late fetal loss	Early neonatal loss	Perinatal loss	
1	140.5	62.2	38.9	98.7	236.4
2	80.0	17.3	31.4	48.2	135.2
3-5	124.6	27.7	21.0	48.2	169.2
6-9	157.7	27.8	32.0	58.9	221.6
10+	238.4	32.0	39.6	75.2	235.7

Source A.K. Awan(12)

Table 2 : Pregnancy wastage rates as related to age of respondents

Type of pregnancy wastage	Less than 20 years	Rate per 1000 conceptions			
		20-24 years	25-29 years	30-34 years	35 yrs and more
Early fetal loss	134.2	113.8	113.3	172.0	179.6
Late fetal loss	29.4	34.4	17.7	40.0	43.0
Early neonatal loss	44.6	32.5	24.9	21.5	37.2
Perinatal loss	72.7	65.8	42.2	60.7	78.6
Total pregnancy wastage	213.9	175.3	165.3	222.2	257.2

Source A.K. Awan(12)

Table 3 : Distribution of respondents in accordance with their past fetal loss status.

Past fetal loss status	No. of women	Percentage	Distribution
None	948	76.0	76.0%
One	189	15.2	21.0%
Two	72	5.8	
Three	18	1.4	
Four	9	0.7	
Five	6	0.5	3.0%
Six	5	0.4	
Seven or more	0	-	
Total:	1247	100%	

Source: A.K. Awan and M. Mubasher(13).

Table 4 : Pregnancy wastages and type by previous experience of fetal loss.

Type of pregnancy wastage	No history of previous fetal loss	History of one or two past fetal losses	History of or more past fetal losses
Early fetal loss	103.7	210.8	433.3
Late fetal loss	14.5	54.1	200.0
Early neonatal loss	26.0	41.2	-
Perinatal loss	40.2	93.1	200.0
Total pregnancy wastage	145.9	196.0	565.5

Source: A.K. Awan and M. Mubasher (13).

Table 5 : Pregnancy wastage rates as related to antenatal care

Type of pregnancy wastage	Rate per 1000 conceptions	
	Antenatal care given	Antenatal care not given
Early fetal loss	131.9	167.0
Late fetal loss	28.6	43.1
Early neonatal loss	28.8	33.2
Perinatal loss	56.6	74.9
Total pregnancy wastage	188.1	242.4

Source: A/K. Awan(4).

Table 6 : Pregnancy wastage rates as related to composite socio-economic status

Type of pregnancy wastage	Rate per 1000 conceptions	
	Higher socio-economic status	Lower socio-economic status
Early fetal loss	117.3	156.8
Late fetal loss	31.1	33.3
Early neonatal loss	18.6	38.5
Perinatal loss	49.1	70.5
Total pregnancy wastage	168.4	225.2

Source: A.K. Awan(5).

b. **Rationale**

The need for research capability development is a well recognized necessity in Bangladesh. There is dearth of capable researchers to develop well designed study protocols to answer specific research problems or questions, and effectively execute studies, analyze data and write up the findings. This has stunted research and development of research based policies and programmes in the sector of health and family planning. The medical graduates of our country who are in intimate contact with the problems existent in this sector through their profession do not have any exposure to the concept or modalities of research. As a result important health problems remain unidentified or unsolved. Side by side, these young physicians whose professional careers could be greatly promoted by acquirement of research skills remain away from this important field.

This study, which is designed to collect information on one of the vital lacunae of our knowledge on MCH has, as one of the primary objectives the development of skills in conducting and monitoring a research study protocol. The study will closely involve a representative of the Obstetrical and Gynecological Society of Bangladesh, who will remain associated with instrument development, study implementation, data collection, supervision, monitoring, data analysis and report writing of the study. This will generate the necessary research skills in the selected representative through transfer of technology. The research skill can be later drawn on to enable the Society to conduct its own studies and also to create its research pool.

The volume of published work on perinatal mortality in Bangladesh is very scarce. Internationally, a considerable number of studies have been conducted to determine the perinatal mortality rate and factors associated with or contributing to such deaths. However, these studies have used varying definitions of the perinatal period. For this reason, the findings from these studies are not comparable and may not be in conformity with the definition.

Considering the facts that

- (a) perinatal mortality is an important index of health care of a country;
- (b) the incidence of perinatal mortality is extremely high in Bangladesh, in fact, one of the highest in the world (117/1000 live births according to the hospital based study mentioned) and contributes a substantial proportion to infant mortality;

It is essential that a well designed study be conducted to identify the risk factors of perinatal mortality and assess its extent in selected hospital of Bangladesh.

4. METHODS:

a. Study Sites:

The study will be conducted in three centers which provide routine antenatal care services. These centers will be the Azimpur Maternal and Child Health Training Institute (MCHTI), the antenatal clinic of Sir Salimullah Medical College Hospital and the MCH clinic of Radda Barnen at Mirpur.

b. Methodology:

It will be a prospective study. All women who come to the selected centers during the study period at 24-28 weeks of pregnancy and are willing to come to the clinic regularly for follow up as per the normal schedule of antenatal care will be enrolled into the study. At admission data will be collected on relevant variables including expected date of delivery (EDD). Data on progress of pregnancy including information on medical and obstetrical examination will be collected at each follow up. In case a patient fails to return for follow up, home visits will be conducted to collect the relevant data.

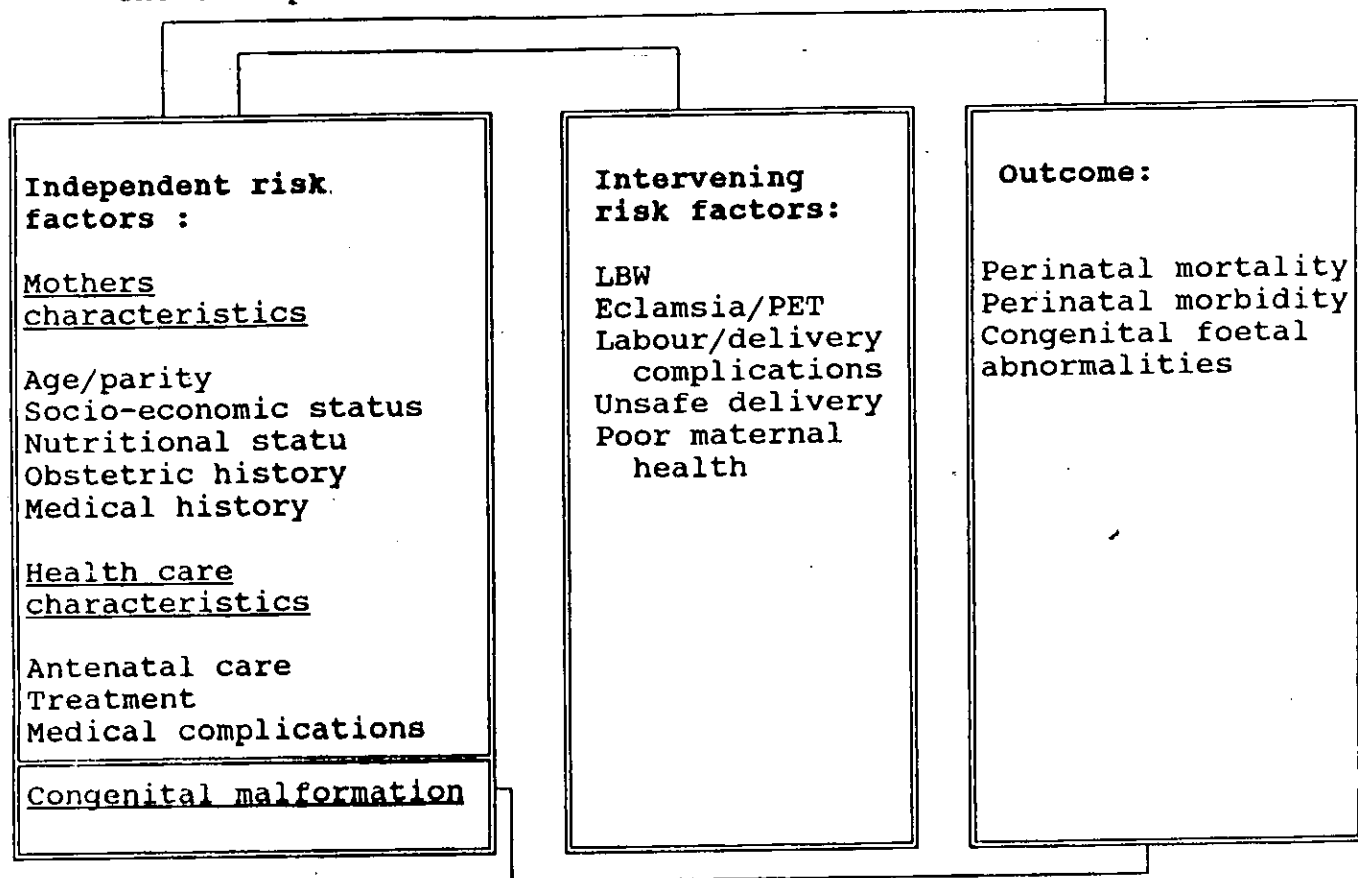
Information on pregnancy outcome and mode and conduct of delivery will be collected either through home visits (in case of home delivery) or by visiting the patient at the clinic/hospital/center where the patient may be admitted for delivery. At admission and at each follow up visit information will be collected from the patient regarding her intention as to where the delivery will be conducted, and she will be visited accordingly at her home/hospital/elsewhere. In case of those patients who deliver outside hospitals, efforts will be made to contact the person who conducted the delivery (e.g. TBA/female relation) to collect information on the delivery and condition of the newborn at birth. Another visit will be conducted at seven days post-partum at the place where the patient will be residing at that moment. Those patients who need home visits but reside outside a 10 mile radius of the respective clinic will not be followed up and will be excluded from analysis.

Perinatal death will be defined as per the WHO/UNICEF definition stated in page 4 of this proposal. Variables of interest for the mothers and infants in the study group will be compared for identification of risk factors.

c. Conceptual Framework:

Based on the literature review, the following conceptual framework is proposed:

The Conceptual Framework:



d. Variables:

Information will be collected on the following variables:

At admission:

A. Maternal socio-demographic characteristics: Age, education, socio-economic status (to be determined by certain proxy variables including monthly earning, employment, type of housing, sanitation) household size.

B. Obstetric History:

Gravidity, parity, sibship size, bad obstetric history, previous deliveries, previous perinatal or neonatal or infant deaths.

C. Medical history:

History of any concurrent medical disease with particular reference to anaemia, hypertension, diabetes mellitus, hepatic disease, renal disease, urogenital disease, cardiovascular disease.

D. Personal history:

Smoking habits, contraceptive use, previous breastfeeding practice.

E. Current Pregnancy:

Duration of pregnancy (from history & height of uterus), expected date of delivery, foetal condition blood pressure, weight, anaemia.

At follow ups:

Data will be collected on all the variables related to current pregnancy and management of any complications during antenatal visits.

At delivery:

At delivery, information will be collected on mode of delivery, place of delivery, person conducting the delivery, condition of new born at birth (subjective assessment of an attendant), birth weight (where available), breastfeeding.

At seven days post partum:

Information will be collected on foetal condition, maternal condition, breastfeeding.

e. Data Collection:

Patients will be enrolled into the study through the use of a selection criteria checklist. Data at admission, follow-ups, pregnancy outcome and delivery, and seventh day post-partum condition will be collected through structured forms. Another structured form will be used to record detailed current address of the patient and name and address of at least two alternate contact persons.

All the forms for a single patient will be filed in patient specific dossiers which will be maintained at the clinic. The forms will be administered by the clinic staff during their routine contacts with the patients.

f. Sample size:

The study will enroll pregnant women in the selected centers for a total of 6 months. Another 4 months will be required to complete follow up of all recruited women upto 7th post-partum day. Total duration for recruitment and follow-up period will be 10 months.

Considering the random sampling technique, the formula for calculation of sample size is,

$$n = \frac{1}{1-f} \left[\frac{(Z)_a^2 P(1-p)}{d^2} \right]$$

Where

n = required number pregnant women

z_a = The standard normal deviate set at 1.96 corresponding to the 95% confidence interval;

f = Expected proportion of lost-to-follow-up cases

p = Proportion of pregnant women attending antenatal clinic expected to experience perinatal mortality.

Table 7 lists the risk factors for perinatal mortality as identified in an urban population based study conducted in Pakistan, and referred to at pages 7-10 of this proposal. The table also shows the perinatal mortality rates among women exposed to the particular risk factor.

Table 7: Risk factors for perinatal mortality.

<u>Risk factors</u>	<u>Perinatal mortality/1000 pregnancies</u>
1. Age of the mother :	
<20 yrs	72.7*
>35 yrs	78.6*
(25-29 yrs)	(42.2)
2. Antenatal care	
Yes	56.6
No	74.9*

3. Gravidity

1	98.7*
2-5	48.2
6-9	58.9*
10 +	75.2*

4. Socio economic condition

High	49.1
Low	70.5*

Risk factors:

For the calculation of the sample size for this study, the 'p' has been considered to be 0.60, approximating the perinatal mortality rate of 56.6/1000 conceptions found among urban women receiving antenatal care in the Pakistan study.

Because the perinatal mortality rate is about 60 per 1000 pregnancies among those who have antenatal check up, P is 0.06 and 1-P=0.94. Assuming that 30% will be lost-to-follow-up or will deliver outside the geographical study limits f= 0.3 and d = degree of accuracy desired (set at 0.01).

$$\begin{aligned} \text{We have, } n &= \frac{1}{1 - 0.3} \left[\frac{(1.96)^2 (0.06) (0.94)}{(0.05)^2} \right] \\ &= 2166 \times 0.7 = 3095 \end{aligned}$$

Thus the sample must yield at least 3095 pregnant women.

Review of clinic records at MCHTI revealed that an average of 20 women at 24-28 weeks of pregnancy report to that center every day. The corresponding number at Sir Salimullah Medical College was 10 and at Radda Barnen clinic was 15. Antenatal services are available on 2 days of a working week. Therefore it is expected that a total of (2160 clients will be recruited during a study period of 6 months. 3095

g. Data Analysis:

- The case to perinatal death rate among the study sample will be determined.
- Differentials in perinatal mortality among the sample group will be examined by selected variables.

- c) The significance of these differences will be assessed through appropriate statistical tests.
- d) Risk factor analysis techniques such as multivariate logistics analysis (risk factor regression model) will be used to calculate odds ratio of each factor controlling for other factors.

R. WORK PLAN

Activities	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
BIRPERHT in house preparatory activities															
Training															
Client recruitment															
Client follow-up															
Interim report															
Data analysis															
Report writing															

5. OPERATIONAL DEFINITIONS:

PERINATAL MORTALITY:

Perinatal mortality includes both late foetal and early neonatal deaths. Late foetal deaths are those that occur before or during delivery of foetuses weighing 1000 gms or more. Where birth weight is unavailable the corresponding gestational age (28 weeks) or body length (35 cms crown heel) should be used to define the cut-off point. Early neonatal deaths are those that occur in the first week of life. The perinatal mortality rate is the rate of late foetal and early neonatal deaths among foetuses and infants weighing 1000 gms or more at birth, per 1000 live births.

(Source: World Health Organization Maternal care for the reduction of perinatal and neonatal mortality. A joint WHO/UNICEF statement, Geneva 1986.(1)

GESTATION :

If is defined as the period from the first day of the last menstrual period upto the delivery of the infant and denotes the duration of human pregnancy which on an average is about 280 days or 40 weeks.

GRAVIDITY :

A gravida is a woman who is or has been pregnant. With the first pregnancy she is a primigravida and with more than one a multigravida. Gravidity, therefore, refers to the number of pregnancies.

PARITY :

A para is a woman who has been delivered of a foetus or foetuses that have reached the stage of viability. Interpretations of the word "viability have varied between foetal weights of 400g (about 20 weeks of gestation) and 1,000g (about 28 weeks of gestation). Although the smallest surviving infant weighed 540g at birth, survival even at 700 or 800g is unusual. Attainment of a weight of 1,000g is therefore widely used as the criterion of viability. Parity means the number of foetuses weighing 1000g or more (about 28 weeks or more of gestation) delivered by a woman.

LBW (LOW BIRTH WEIGHT)

The value of 2,500g, arrived at arbitrarily, is accepted by most professional organizations and by the World Health Organization as the dividing point between "mature" and "premature".

NEONATAL DEATH

It is defined as death of a newborn infant within the first four weeks of life.

NEONATAL DEATH RATE

It is expressed as the number of neonatal deaths per 1000 live births.

INFANT MORTALITY RATE

It is defined as the number of infant deaths (under 1 year of age) per 1000 live births.

STILLBIRTH.

An infant with no heartbeat who neither breathes nor cries nor shows any other sign of movement is a **stillbirth**.

BAD OBSTETRIC HISTORY. (Ref. Lettenmaier, C, et al. 1988. "Mothers Lives Matter". Maternal Health in the Community, Series 1 No. 7).

A woman is said to have a bad obstetric history when she has a previous history of one or more of the following:

1. Haemorrhage
2. Stillbirth
3. Death of the baby within 48 hours
4. Prolonged/Obstructed labour
(Labour is prolonged if it lasts more than 16 hours in a primigravida & more than 8 hours in a multigravida).
5. Operative delivery
6. Retained placenta
7. Repeated abortion
8. Severe Oedema
9. Fits.

(Source : Hellman LM and Pritchard JA. Williams Obstetrics. Fourteenth edition. Appleton-Century-Crofts. New York, 1971).

6. FACILITIES REQUIRED:

The project would require clinic bases which provides regular antenatal, delivery and postnatal care services. These services are available at the MCHTI, Azimpur and Sir Salimullah Medical College Hospital. Antenatal and postnatal services are available at Radda Barnen's Clinic, which does not have delivering facilities. However, the study design has the provision for following up women who deliver outside these clinics.

7. COLLABORATIVE ARRANGEMENTS:

The study will be implemented by BIRPERHT in close collaboration of the Gynecological & Obstetrical Society of Bangladesh and ICDDR,B. One of the members of the Society will work side by side with the Principal Investigator and the Co-Investigator in designing instruments, implementing the study, data analysis and report writing, while the ICDDR,B person will provide technical guidance in preparing data collection instruments and in data analysis. The study will also require the collaboration of an obstetrician, and a pediatrician who will provide necessary technical guidance in development of questionnaires. The recommendations based on study findings will also use the collaboration of these two experts.

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SECTION III : BUDGET

A. PERSONNEL COSTS:

Sl. No.	Name	% Effort	No. of months	Monthly rate (Taka)	Budget required (Taka)
1.	Dr. Yasmin H. Ahmed*	20%	15	5000	15000.00
2.	Dr. Shahida Tariq*	25%	15	5000	18750.00
3.	Dr. Abdullah H. Baqui	5%	15	-	-
4.	Representative from Obstetrical & Gynaecological Society of Bangladesh	30%	15	5000	22500.00
5.	Interviewers 2 per center x 3 centers	100%	9	2500	1,35,000.00
6.	Honoraria for clinic contributors. Tk.1500 per center x 6 months x 3 centers				27,000.00
7.	Technical assistance				4,000.00
8.	Honoraria for TBAs Tk.10 per case x 600 cases				6,000.00
Sub-Total :					2,28,250.00

Sl. No.	Name	% Effort	No. of months	Monthly rate (Taka)	Budget required (Taka)
	B. SUPPLIES & MATERIALS:				10,000.00
	Computer accessories, papers				
	C. TRAVEL COST & TRANSPORTATION :				
	a. 3095 clients x 3 visits per client x 20% clients x Tk.30				55,710.00
	b. POL for study monitoring by PI & Co-PIs Tk.500 pm x 6 months				3,000.00
	D. RENT, COMMUNICATION, UTILITIES :				
	Rent: Tk.1000 PM X 15 M				15,000.00
	Communication: Tk.250 pm x 15 m				3,750.00
	Utilities :Tk.250 pm x 15 m				3,750.00
	E. OFFICE STATIONERY				2,000.00
	F. FORMS PRINTING				30,000.00
	Report printing				10,000.00
	G. TRAINING OF INTERVIEWERS				2,000.00
	H. CONTINGENCY				1,000.00
	GRAND TOTAL :				----- 3,64,460.00 =====
					US \$ 9,985.00

@ Tk.36.50 = 1 US \$

*This amount will be deposited in BIRPERHT account and will help support the specified staff's salary.

DRAFT

4/6/91

A STUDY TO ASSESS THE DETERMINANTS OF PERINATAL MORTALITY

ADMISSION FORM

I. INTRODUCTION: Assalamoalaikum; We have come on behalf of an organization working to promote the health of mother and children through research. We are conducting a study to find out the problems which infants have at birth or soon after birth. In this connection, we would like to ask you some questions on your current pregnancy, and also ask your doctor how you are doing now. We intend to follow you up as you come for antenatal checkups, and find out about the health condition of both you and your child at delivery and after seven days of delivery. Your participation in the study is completely voluntary, and you may withdraw from the study any time you want. Your decision will, in no way affect the services you are presently receiving from the center. All information divulged by you will be kept strictly confidential and will not be used for purposes other than this study.

II. PATIENT IDENTIFICATION:

1. Center name _____
2. Center number _____
3. Client's name _____
4. Husband's name _____
5. Date of admission

--	--	--	--	--	--

Day Month Year
6. Client order no.

--	--	--	--
7. Patients address : (Please Complete Client's Detailed Address form.)

III. BACKGROUND CHARACTERISTICS:

8. Current age (completed years)

--	--
9. Education (completed years)

--	--
10. Husband's education (completed years)

--	--
11. Husbands occupation

--

- | | |
|-----------------|-------------------------|
| 1 - Service, | 5 - Unemployed |
| 2 - Business | 6 - Not stated |
| 3 - Day labour, | 7 - Other specify _____ |
| 4 - Cultivation | |

12. Total No. of household members
(excluding servants)
13. Approximate total expenditure of
last month (in Takas)
14. Type of Housing
 1 - Pucca
 2 - Semi-pucca
 3 - Shanties
 7 - Other specify _____
15. Water supply:
 1 - Tap water
 2 - Tube well
 3 - Deep tube well
 4 - Well
 5 - Pond
 6 - River/Streams
 7 - Others specify _____

IV PRESENT MENSTRUAL HISTORY

16. Date of onset of last menses (LMP)
 Day Month Year
17. Expected date of delivery
 Day Month Year

V OBSTETRIC HISTORY

18. Total no. of pregnancies
19. Total no. of live births
20. Total no. still birth
(after 28 weeks of pregnancy)
21. Total no. of abortion/miscarriage/MR
(before 28 weeks of pregnancy)
22. Total no. of children who died within
7 day of delivery & reasons
 1. _____
 2. _____
23. Total no. of living children
24. History of congenital abnormality among any
of the children born
 1 - Yes, 2 - No.

25. History of Caesarean section ☐
(how many)
26. History of forceps delivery ☐
(how many)
27. History of prolonged/obstructed labour ☐
1 - Yes, 2 - No
28. History of placenta praevia/ APH ☐
1 - Yes, 2 - No.
29. History of PET/Eclampsia ☐
1 - Yes, 2 - No.

VI MEDICAL HISTORY

30. Diabetes mellitus ☐
1 - Suffers from diabetes mellitus
2 - Has family history of diabetes mellitus
3 - Had gestational diabetes
4 - None of the above
5 - Combination, specify. _____
31. Heart disease ☐
1 - (Yes (specify)
2 - No.
32. Liver disease ☐
1 - Yes (specify)
2 - No.
33. Hypertension ☐
1 - Yes
2 - No.
34. Respiratory disease ☐
1 - Yes
2 - No.

VII PERSONAL HISTORY

35. Height of patient (in cms.) - ☐
9999 = not recorded
36. Smoking ☐
1 - Yes, 2 - No.
37. Other use of tobacco ☐
1 - Yes, specify
2 - No.

VIII. PREVIOUS DELIVERIES

38. Information of last two deliveries
(excluding current pregnancy)

Serial No.	Time of birth (How many years back)	Any antenatal visit 1-yes * (Give reasons) 2-No	Place of delivery 1-Home 2-Hospital/ Clinic 3-Others **	Delivered by 1- Doctor 2- Nurse/FWV 3- Trained TBA 4- Untrained TBA/Dai 5- Female relative 7- Others*** specify
I Last Pregnancy				
II Last but one Pregnancy				

* Reasons for 'yes' column B--

** Specify others in column C--

*** Specify others in column D--

39. When did you first come for antenatal checkup during this pregnancy
Day Month Year

40. Why have you decided to come for antenatal checkups ?
Verbatim _____

41. Where do you intend to deliver this baby,
1 - Home
2 - Hospital/clinic (specify (skip Q 32.)
7. Other, specify

42. Who will deliver this baby
1 - Trained TBA
2 - Untrained TBA/Dai
3 - TBA (training status unknown)
4 - Female relative
7 - Other, specify ----

ANTENATAL FOLLOW-UP FORM

I. STUDY IDENTIFICATION

1. Center name _____
2. Center number
3. Clients order number
4. Clinical follow-up number
5. Date of follow-up
Day Month Year
6. Any change in address within next two months
1 - Yes
2 - No
If Yes, please record in green detailed address form

II. PRESENT MEDICAL COMPLAINTS

(1 - Yes, 2 - No.)

A. Respiratory system

7. Difficulty in breathing
8. Cough (for more than 4 weeks)
9. Fever (for more than 4 weeks)

B. Cardiovascular system

10. Breathlessness on slight exertion
11. Palpitation
12. Dependent oedema
13. Headache/dizziness

C. Breasts

14. Tenderness in breasts
15. Any lump in breasts

D. Urinary System

16. Frequency of micturition
17. Burning sensation during micturition
18. Haematuria
19. Pain in renal angle

III. GENERAL EXAMINATION (999 = not recorded)

20. Weight of patient (in kg.) -
21. Oedema of foot
0 - Absent 2 - Moderate
1 - Mild 3 - Severe
22. Blood pressure Systolic
(in mm Hg.) -----
Diastolic
23. Jaundice
1 - Present, 2 - Absent
24. Haemoglobin estimation (in gms/dl)
25. Urine sugar
1 - Present
2 - Absent
26. Urine albumin
1 - Present 2 - Absent
27. Whether tetanus injection taken
1 - Yes
2 - No
28. Number of doses taken

IV. CLINICAL EXAMINATION

29. Duration of pregnancy (in weeks)
(Height of fundus) -----

30. Presentation of foetus

- 1 - Vertex
- 2 - Breech
- 3 - Face
- 4 - Brow
- 5 - Shoulder
- 6 - Cord prolapse
- 7 - Others
- Specify -----

31. Foetal movements

- 1 - Present
- 2 - Absent

32. Foetal heart sounds

- 1 - Present
- 2 - Absent

V. INTENDED PLACE OF DELIVERY

33. Where does the patient intend
to deliver this baby

- 1 - Home
- 2 - Hospital/clinic
- 7 - Other, specify -----

34. Who will attend the delivery

- 1 - Doctor
- 2 - Nurse/FWV
- 3 - Trained TBA
- 4 - Untrained TBA/Dai
- 5 - Female relatives
- 7 - Other, specify

Complete name and detailed address of person
who will attend this deliver :

CONFINEMENT/DELIVERY FORM

I. STUDY IDENTIFICATION

1. Center name _____
2. Center number
3. Clients order number
4. Date of follow-up
Day Month Year
5. Any change in address within next two months
1 - Yes
2 - No
If Yes, please record in green detailed address form

II. DESCRIPTION OF PRESENT LABOUR/DELIVERY

6. Actual date of delivery
Day month Year
7. Mode of delivery
1 - Normal vaginal delivery
2 - Vaginal delivery after trial
3 - Vacuum extraction
4 - Breech extraction
5 - Forceps
6 - Caesarean section
7 - Destructive procedure
8 - Other, specify _____
8. Place of delivery
1 - Home
2 - Hospital/clinic
3 - Others, specify
Complete name & address of place of delivery -----

9. Who attended the delivery
1 - Doctor
2 - Nurse/FWV
3 - Trained TBA
4 - Untrained TBA/Dai
6 - Female relatives/neighbours/friends
7 - Other (specify) _____

Complete name and detailed address of person
who attended this delivery :

III. FOETAL OUTCOME

10. Number of Newborns

11. Death of Newborn

- 0 - No death
- 1 - Stillbirth
- 2 - Within 24 hours of delivery
- 3 - Within 2-7 days of delivery

12. Whether child cried soon after birth

- 1 - Yes, 2 - No

IV. MEDICAL INFORMATION ON DELIVERY

(Interviewer :
Please collect the following information from records/
person who attend this delivery)

13. Any complication of pregnancy

- 1 - PET
- 2 - Eclamptic fit
- 7 - Other complication (specify) _____
- 8 - No complication

14. Third stage of labour

- 1 - Normal
- 2 - Postpartum haemorrhage
- 3 - Retained placenta

15. Weight of newborn in gms.
(9999 = not recorded)

16. Abnormalities

- 1 - Present, specify _____
- 2 - Absent

Who attended the delivery
- Doctor
- Nurse/Midwife
- Trained TB
- Untrained
- Other (specify) _____

POST-PARTUM FOLLOW-UP FORM

I. STUDY IDENTIFICATION

1. Center Name _____
2. Center Number
3. Clients order Number
4. Clinical follow-up number
5. Date of follow-up
Day Month Year

II. MEDICAL COMPLAINTS

7. Any bleeding per vagina
1 - Yes
2 - No
8. Any lochial discharge without
foul-smell per vagina
1 - Yes
2 - No
9. Any lochial discharge with foul-smell
per vagina
1 - Yes
2 - No
10. Any pain in lower abdomen
1 - Yes
2 - No
11. Onset of menses
1 - Yes
2 - No (Skip to Q 13)
12. Date of onset of menses
Day Month Year

III. CLINICAL EXAMINATION (Please skip to section V if not done)

13. Anaemia ☐
0 - Absent 2 - Moderate
1 - Mild 3 - Severe
14. Jaundice ☐
1 - Present, 2 - Absent
15. Blood pressure Sys.
 dias
(in mm Hg)
16. Temperature of patient
(in celsius)
17. Sugar in urine ☐
1 - Present
2 - Absent
18. Albumen in urine ☐
1 - Present
2 - Absent
19. Involution of uterus ☐
1 - Complete
2 - Incomplete

IV. PER VAGINAL EXAMINATION (Please skip to section V if not done)

20. Position of uterus ☐
1 - Anteverted
2 - Retroverted
21. Shape of uterus ☐
1 - Normal
2 - Abnormal
22. Pain on pressure ☐
1 - Present
2 - Absent

V. STATUS OF NEWBORN

23. Condition of newborn ☐

- 1 - Alive and healthy
- 2 - Alive and not healthy
specify _____

3 - Death within 7 days

4 - Death within 8 to 14 days

Specify cause of death _____

24. How soon after childbirth was baby
put to breast. ☐ ☐
(in hours) 88 = NA

25. Any bottle feeding ☐
1 - Yes, 2 - No,
8 - NA