Attachment 1.

Library A-00013

Date ~~April 5 1993~~ MAY 18, 1993

(FACE SHEET) ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Gretchen Antelman

Trainee Investigator (if any) _____

Application No. 93-018

Supporting Agency (if Non-ICDDR,B) _____

Title of Study Determinants of Birth weight, Gestational Age, and Perinatal mortality

Project status:
(X) 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).

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 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 NA
   (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 NA
5. Will signed consent form be required:
   (a) From subjects — Yes (No) Verbal consent
   (b) From parent or guardian (if subjects are minors) — Yes (No) NA
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
   NA 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.

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

Gretchen Antelman
Principal Investigator

_____
Trainee

ENTERED 2 1 JUN 1993

Title: Determinants of Birth Weight, Gestational Age, and Perinatal Mortality Among the Urban Poor in Dhaka, Bangladesh

Principal Investigator: Gretchen Antelman

Co-Investigators: Shams El Arifeen
Selina Amin
Abdullah Baqui

Starting Date: July 1, 1993

Completion Date: January 31, 1995

Total Direct Cost: $93,000

Funding Source:

Program Head: Dr. R. Bradley Sack, Associate Director, Community Health Division, ICDDR,B

Protocol approved by R. Bradley Sack
Signature, Program Head / Date

Abstract Summary

Perinatal mortality is a sensitive indicator of maternal health status prior to and during pregnancy. Birth weight is the single most important predictor of neonatal survival. Bangladesh has among the highest incidence of poor perinatal outcome in the world. Perinatal mortality is estimated to be 75 per 1000 live births and 40-50% of all live births have a birth weight less than 2500 grams. The incidence of intrauterine growth retardation and preterm delivery are unknown. The determinants of perinatal mortality and low birth weight among the urban poor in Bangladesh have not been documented.

This prospective study will measure the incidence of perinatal mortality, low birth weight, and preterm delivery. The aim is to identify the maternal, perinatal and socioeconomic determinants of perinatal outcome. A cohort of women (n=1395), identified early in pregnancy, will be visited two times prenatally, within 72 hours after birth to obtain the infant's birth weight and a gestational age assessment using a standardized test of signs of gestational maturity, and twice after the first seven days to assess perinatal survival, and maternal prenatal and perinatal health. Structured household interviews during the prenatal and postpartum visits will measure risk factor variables. Anthropometric measurements (height, weight, arm, head circumference) of the mother will be taken prenatally and immediately postpartum.

The research will be conducted with the Urban Health Extension Project, ICDDR,B over a period of approximately 19 months and the total direct cost is estimated to be $93,000.

Reviews:

(I) Research Review Committee: **April 14, 1993**

(II) Ethical Review Committee:

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A. Introduction

Goal and Objectives

The goal of this study is to generate information from which recommendations can be formulated for interventions aimed at improving maternal and neonatal health in the urban slums of Dhaka, Bangladesh.

The specific objectives are:

(1) To estimate the incidence of perinatal mortality, low birth weight, intrauterine growth retardation, and preterm delivery.[1]

(2) To identify factors related to perinatal mortality, intrauterine growth retardation, and preterm delivery.

(3) To estimate the attributable risk percent of selected factors found to be related to perinatal mortality, preterm delivery, and intrauterine growth retardation.

Background

Definitions: Perinatal Mortality and Low Birth Weight

Perinatal mortality and low birth weight are both sensitive public health indicators of maternal and infant health. Perinatal survival and birth weight are largely conditioned by the health and nutritional status of the mother; and birth weight is one of the single most important determinants of infant survival (Kramer, 1987; Kumar et al., 1987; McCormick, 1985; Victora et al., 1987; WHO, 1980). Risk factors for perinatal mortality are lack of antenatal care, maternal age (<16 or >35), smoking, low socioeconomic status, low birth weight, and unsafe delivery care practices (Barros et al., 1986; Bartlett et al., 1991; Edouard, 1985; Fauveau et al., 1990; Mavalankar et al., 1991; Mostafa et al., 1991). Risk factors for low birth weight are maternal age, high parity, female

[1] These estimates will be biased toward lower incidence rates due to unavoidable study limitations. These limitations are: (a) some respondents will be referred by study interviewers for medical care when necessary, and if they receive medical intervention because of this study's referral, their pregnancies may result in better perinatal outcomes than if they had not been referred to medical interventions by study interviewers; (b) some respondents may choose not to participate in the study, and if this decision is related to the likelihood (or result) of a poor pregnancy outcome, the incidence estimates will be underestimated. An additional limitation is related to the measurement of perinatal mortality which requires that the respondent be capable of accurately telling the interviewer how many weeks gestation she was before a stillbirth (to determine whether she had carried for 28 completed weeks).

infant gender, smoking, and poor maternal nutritional status prior to, and during pregnancy (Berkowitz 1981; Ferraz et al., 1988; Kramer, 1987).

Perinatal mortality is defined as late fetal or early neonatal death (>=28 weeks gestation through 7 days after birth). It is a standard health indicator of and child health because it is affected by both antenatal risk factors such as maternal age or use of prenatal care, as well as intrapartum risks which can be harmful to both mother and infant, such as sepsis, prolonged labor, or malpresentation (Edouard, 1985; MotherCare Matters, 1991).

Low birth weight (LBW) is defined as a weight below 2500g at birth. An infant's birth weight is determined by the length of gestation and the rate of growth in utero. Therefore, low birth weight can be due to preterm delivery, intrauterine growth retardation, or a combination of both. Intrauterine growth retardation (IUGR) has various definitions, but one widely recognized definition is a birth weight less than the 10th percentile of birth weight for gestational age, according to a sex-specific fetal growth chart (Read et al., 1984).

There are two important gaps in our knowledge of the determinants of low birth weight. The first is caused by the scarcity of "conclusive" studies on LBW in developing countries. The majority of LBW studies done in developing countries are based on unrepresentative hospital-based populations. Many studies do not have sufficient sample sizes to detect associations between known risk factors and low birth weight. Furthermore, the factors known to be related to preterm delivery in developing countries are largely unidentified (Kramer, 1987).

The second gap is caused by the lack of clarity in defining LBW due to shortened gestation versus LBW due to poor intrauterine growth. Since birth weight is such a strong predictor of neonatal survival, it is compelling to focus on that measure alone (Susser et al., 1972). However, several studies have shown that preterm infants are at greater risk of death than growth retarded infants (Lubchenco et al., 1972; McCormick, 1985; Starfield et al., 1982; van den Berg, et al., 1966). Thus, the incidence of LBW as a health indicator is more useful if the proportions of preterm/LBW and IUGR/LBW also are known.

Villar and Belizan (1982) analyzed existing data on LBW from around the world and showed that the proportion of infants who are LBW due to growth retardation, as opposed to preterm delivery, is much higher in developing countries than in developed countries. They concluded that in countries where the incidence of LBW was relatively high (e.g. above 10%), the proportion of LBW infants who were growth retarded was about twice that of LBW infants due to preterm delivery (i.e. 65-80%). In countries where the incidence of LBW was low (5-10%), the reverse was true, and the majority of all LBW infants were delivered preterm, and not growth retarded.

The authors concluded that the incidence of preterm birth around the world was relatively stable, but the incidence of IUGR was much higher in developing countries. Therefore, in comparison with developed countries, the increased incidence of LBW in developing countries was primarily due to fetal growth retardation.

This conclusion deserves re-examination given the variability in Villar and Belizan's own data (1982), as well as other studies that do not support it. Two studies of South Asian countries have found that preterm delivery accounts for nearly 50% of all LBW infants (Hort, 1987; Mavalankar, 1992). These studies indicate that the determinants and incidence of preterm delivery vary across populations. Undue concentration on LBW due to IUGR can detract important attention to the especially high risk groups of infants who are delivered preterm.

Incidence of Perinatal Mortality and LBW

The estimated annual number of perinatal deaths occurring in developing countries is seven million (MotherCare, 1990). Incidence of perinatal mortality have been dramatically reduced during the last 40 years in developed countries, but developing countries do not show similar trends. It is generally recognized that infant mortality rates have declined faster than perinatal mortality rates in developing countries. This is because recent efforts to improve child survival have predominantly affected late neonatal and post-neonatal survival (Edouard, 1985).

The World Health Organization has estimated that 21 million infants with LBW were born in 1979, nearly 20% of all births worldwide. But the incidence of LBW is not evenly distributed around the globe. Over 90% of the world's LBW infants are born in developing countries, and two-thirds of all LBW infants are born in Middle South Asia (India, Pakistan, Bangladesh). Incidence of LBW in parts of India and Bangladesh may be as high as 50% of all live births (WHO, 1980). Patel (1989) found that the incidence of LBW was 50% in Calcutta, India. In comparison, only 5% of all births are LBW in developed countries (WHO, 1980).

The extent of perinatal mortality or LBW has not been documented in the urban slum populations of Bangladesh. One study in rural Matlab of Bangladesh estimated a perinatal mortality rate of 75 for every 1000 live births (Fauveau et al., 1990). Other studies done with hospital-based populations and in rural communities of Bangladesh have documented a high incidence of low birth weight (Canosa 1989, Hort 1987). Huque and Hussain (1991), using a hospital population, excluded certain high risk groups of women (based on medical and demographic characteristics), and still found an incidence of low birth weight over 40%. Hort (1987) identified significant seasonal variation in birth weights, consistent with the cost of rice.

Canosa (1989) found important differences in birth weight between socioeconomic status (SES) and urban versus rural residence. The overall mean birth weight was 2593g, and the incidence of low birth weight at 45.4%. But among the low SES/rural dwellers, the incidence of LBW was over 70% of all births, and over 80% of all these LBW infants had intrauterine growth retardation. Among the high SES/urban dwellers, the incidence of LBW was less than 24% and about 50% of these LBW infants had IUGR. Thus, low birth weight appears to be strongly associated with socioeconomic status in Bangladesh. Among the poorer classes, a substantial portion of the increased incidence of LBW appears to be due to IUGR, though the proportion of LBW/preterm births remains high even in the higher SES groups.

In 1989, a pilot study on LBW and gestational age was conducted in the Urban Volunteer Program's (UVP) sample area which, as the precursor program, overlaps the Urban Health Extension Project (UHEP) area. The purpose of the study was to test the feasibility of collecting birth weight and gestational age data in the home. Using volunteers to inform the UVP of any delivery, a total of 33 newborns were examined within 72 hours. The mean birth weight was 2600g and mean gestational age 38.5 weeks. Twenty-seven percent of all babies examined were LBW (Uzma et al., 1991). Though the mean birth weight is consistent with prior studies in Bangladesh, the low percentage of LBW is surprising and probably indicates a bias in the sample of births. One explanation for this bias is that volunteers tended to notify the UVP of healthier births. Thus, babies with birth weights below 2500g who were sickly or did not survive the early neonatal period were less likely to be included in the pilot sample. The mean weight of 2600g can be explained by the fact that newborns of weight around 2500g have much greater chances of surviving than newborns with weights below 2000g. It is this group that is probably under-represented in the pilot sample.

Rationale

Perinatal mortality and low birth weight are very high in Bangladesh, yet the few studies available are generalizable only to a rural population, or a highly select group of women who deliver in hospitals. There have been no community-based studies of the urban poor in Bangladesh. Preliminary data from the UHEP (Baqui et al., 1993) reveal rates of infant mortality in the urban slums (about 142/1000 live births) that are higher than the national average of 111 deaths per 1000 live births (1987 national estimate). Almost 13% of all infant deaths in the urban slums were due to LBW, and 6.3% of deaths were due to asphyxia, which is a complication associated with prematurity.

Information on the types of medical and delivery care services utilized by pregnant women in the urban slums is entirely lacking. It is known, however, that many women do not attend antenatal

care or use trained delivery providers to deliver their babies (UHEP, 1992). The prevalence and attributable risk of other prenatal risk factors such as poor maternal nutritional status, indoor smoke exposure, and genital tract infections also is unknown.

This study will provide needed information on the incidence and determinants of perinatal mortality and LBW in this population in order to plan health services. But the study also can make a unique contribution to the literature on risk factors for poor pregnancy outcomes because it focuses on factors that either deserve further study, such as cooking or passive smoke exposure and symptoms of genital tract infection, or risk factors that may play a unique role in severely disadvantaged populations, such as maternal nutritional status and use of antenatal and delivery care.

B. Specific Aims

Description

To meet the first objective of this study, the incidence of perinatal mortality, low birth weight, IUGR and preterm delivery will be estimated. The prevalence of known and hypothesized risk factors for poor perinatal outcomes also will be estimated. The degree of association between the risk factors investigated and poor perinatal outcomes will be described by the odds ratio adjusted for the presence of other confounding factors (using logistic regression). The prevalence estimates and adjusted odds ratios for each risk factor will be used in a combined measure of attributable risk, which estimates the percentage of the "disease" that could be eliminated if the given risk factor were eliminated.

Hypothesis Testing

The following are hypothesized:

(a) Low maternal nutritional status, passive tobacco or cooking smoke exposure, and lack of antenatal care utilization by a qualified practitioner will be associated with intrauterine growth retardation, preterm delivery, and perinatal death.

(b) Symptoms of genital tract infection during pregnancy will be associated with preterm delivery.

(c) Delivery with an untrained attendant will be associated with perinatal death.

Justification of Hypotheses

Prior research on risk factors for LBW and perinatal mortality has consistently identified young maternal age, primiparity, prior poor pregnancy outcome, and low socioeconomic status (Berkowitz 1981; Fauveau et al., 1990; Kramer, 1987). Although the proposed research will measure these factors and test for associations with poor pregnancy outcome, the hypothesis testing is limited to risk factors that are either (a) less certain and deserve further investigation, or (b) are particularly relevant to the health of this population, and other similarly disadvantaged populations. To assess the independent contribution of the risk factors of interest, other risk factors known to be associated with pregnancy outcome in other populations will be considered potential confounders.

Nutrition

Several studies have shown that indicators of poor maternal nutritional status prior to and during pregnancy, such as short height, low pre-pregnancy weight, or poor weight gain, are risk factors for poor perinatal outcome (Adair et al., 1991; Kramer, 1987; Krasovec and Anderson, 1991; Pebley et al., 1985; Tripathi et al., 1987; Winikoff et al., 1981). Experimental studies have demonstrated that nutritional supplementation during pregnancy among low socioeconomic status or malnourished groups improves birth weight (Lechtig et al., 1975; Prentice et al., 1983; Stein et al., 1978; Villar et al., 1988).

Women in Bangladesh have exceedingly poor non-pregnant nutritional status, and poor weight gain during pregnancy. One study found that almost 75% of women weighed less than 43 kg at pregnancy termination (Huffman, 1987). Another estimated the mean weight gain during pregnancy to be less than 5 kg (Krasovec, 1989). A recent study of the urban slum population in Dhaka found that the mean weight of non-pregnant women was 41.8kg and mean height 149 cm. Over 71% of the women weighed below 45kg and 40% weighed below 40kg.

Few studies have looked at how nutrition affects pregnancy outcomes in populations with such poor nutritional status. One interesting and important question is whether relatively small differences in nutritional status, in populations where almost all women would be considered to have below adequate nutrition, are associated with pregnancy outcome. Another reason to take anthropometric measures of nutritional status is to identify the appropriate cut off points of key measures for assessing perinatal risk in this population.

Smoke Exposure

Tobacco use during pregnancy has repeatedly been documented as a cause of poor fetal growth and preterm delivery (Harger et al., 1990; Kramer, 1987; Wainright, 1983; Nasrat et al., 1986). Some studies have found evidence that passive smoke exposure is damaging to the infant (Lazzaroni et al., 1990; Malloy et al., 1988). The prevalence of maternal smoking in Bangladesh has not been reported, and is expected to be quite low. However, a pilot study of adolescents in the urban slums reported that about 20% did smoke cigarettes (UHEP, 1992). Passive smoke exposure could also be significant if the woman is frequently around members of the household who smoked.

Few studies have looked at the effect of indoor cooking smoke on pregnancy outcomes, yet biomass fuels produce smoke containing some toxic materials which are similar to tobacco smoke (de Koning et al., 1985). One study in India found evidence of an association between indoor cooking smoke and LBW (Mavalankar, 1992). Since women are responsible for cooking, a poorly ventilated stove and cooking area could put pregnant women at risk. Crowded living conditions could put pregnant women at risk of smoke exposure from more than their own households as well. Tobacco smoke exposure is associated with perinatal death and preterm delivery, as well as low birth weight, therefore, this study hypothesizes that cooking smoke exposure is associated with IUGR, preterm delivery, and perinatal mortality.

Antenatal and Delivery Care

Both medical care during pregnancy and safe delivery practice have been shown to be associated with better outcomes (Islam et al., 1982; Ferraz et al., 1990; Rahman, 1982). In developing countries, where a larger proportion of pregnancies are high risk due to poor maternal nutritional status, prior poor pregnancy outcome, and other factors, the effect of the quantity and quality of antenatal care is still unknown (Kramer, 1987). However, researchers have concluded that antenatal care is one of the risk factors for poor perinatal outcomes that is most amenable to change (Ferraz and Gray, 1990). Further studies on antenatal care in developing countries should focus on the content of care, and attempt to control for the reason antenatal care is sought, since women with complications may be more likely to seek care than healthier women.

Genital Tract Infection

The prevalence of genital tract infections in Bangladesh is estimated to be very high. Wasserheit (1989) found that over 20% of women of child-bearing age reported symptoms of reproductive tract infections, and almost 70% of these symptomatic women had clinical or laboratory evidence of infection. Many researchers have found some evidence to support the hypothesis that maternal genital tract infection is a risk factor for LBW and preterm delivery (Kramer, 1987; de Schryver and Meheus, 1990).

Further epidemiologic research on the effects of genital tract infections is needed in developing countries, and is appropriate in Bangladesh where the prevalence of symptoms is high and medical treatment is low (Bakketeig, 1984; Kramer, 1987). There is also a possibility of an interaction between infection and unsafe delivery practices, since the two factors combined could promote intrapartum infections in the mother or neonate.

Other Factors of Interest

Other risk factors of interest are nutritional intake (and beliefs), and general morbidity during pregnancy such as symptoms of anemia, diarrhoea, or injuries. These risk factors are not included in the hypotheses because either prevalence is expected to be quite low, or the risk factor's measurement too imprecise. However, descriptive statistics will be collected for future investigations--both to obtain more accurate prevalence estimates, and to identify any trends or crude associations with poor perinatal outcome.

Nutritional status during pregnancy is directly related to both caloric and micronutrient intake, but may be indirectly related to the social status of women in the household. Recent ethnographic research reported that in traditional households, women ate after the men, and sometimes after the whole family. This often deprived women of the more nutritious foods, such as meat, fish or vegetables, which can be in short supply (Blanchet, 1991). In fact, this research found evidence that malnutrition among pregnant women occurred at all socioeconomic levels, partly because of unequal food distribution within the household.

Blanchet (1991) also reported that many pregnant women do not believe that they need to increase their food intake during pregnancy. Other ethnographic research in India and Bangladesh has supported this finding (Blanchet, 1984; Nichter et al., 1983). If women do believe that they should change their diet during pregnancy, it is unknown what kind of foods are preferred, or believed to be compatible with pregnancy. If certain nutritious and available foods are routinely avoided by

pregnant women, these beliefs could potentially be related to poor nutritional status and poor pregnancy outcome.

Women with deficient diets are at risk of being anemic, and anemia has been related to increased risk of LBW and maternal postpartum mobidity and mortality (Kramer, 1987; MotherCare 1990). Anemia leading to chronic fatique, pallor of skin or nailbeds, and cravings to eat non-food substances will be captured in this study by maternal reporting of those symptoms of anemia; laboratory diagnosis will not be done.

Few studies have looked recently at how diarrhea during pregnancy could affect fetal outcome, but one study in rural Bangladesh found a very high incidence of stillbirth among women hospitalized for diarrhea (Hirschhorn et al., 1969). Though treatment for diarrhea has become more widespread since then, it is still one of the major causes of morbidity and mortality in Bangladesh.

Finally, the relatively high risk of physical injury to women of childbearing age, both intentional and unintentional, could be a significant risk factor for perinatal mortality. Research on maternal mortality found that 9% of pregnancy-related deaths were caused by violence or injury (Fauveau et al., 1988a). In a survey of women of reproductive age, 12% of deaths occurring were due to injuries, mostly unintentional injuries or suicide (Fauveau et al., 1988b). A third study found that the incidence of death due to violent injuries among reproductive age women varied by age. It was highest (47 per 100,000) among women age 15-24, and lowest (11 per 100,000) among women 35-44. Among the highest risk group, the proportion of deaths due to injuries was almost 20% (Fauveau et al., 1989). Prior research studies on mortality due to violence or injuries provides only a clue to the potentially high incidence of non-fatal injuries.

C. Methods and Procedures

Study Population and Study Site

The Urban Health Extension Project (UHEP) operates in the slums of five *thana* of Dhaka. The UHEP has drawn a representative sample of households from these five *thana* in order to establish the Urban Surveillance System (USS), which monitors vital and demographic events occurring in each selected household, and periodically collects data on socioeconomic status, health, and health care utilization. The USS visits each household at three month intervals to collect and update information. The date of the last menstrual period (LMP) is collected at each three month visit, so all pregnancies in the USS sample should be identified between 4 and 16 weeks LMP.

The target population includes all pregnant women in selected clusters of the five *thana* who carry their pregnancy beyond the 28th week. The study sample will include all pregnant women who (a) are identified by the USS, (b) meet the target population criteria of residence and length of gestation, (c) agree to participate, and (d) remain at/near their residence in Dhaka for the delivery (i.e. delivery at their home, a relative's home, or a clinic/ hospital). Women who return to their village to deliver will be excluded.

Study Design

This is a prospective observational study. In this population, where the majority of women do not deliver in clinics or hospitals, birth weight or gestational age cannot be assessed in a timely manner unless the pregnancy is identified prospectively, and some arrangement can be made in advance for immediate notification of delivery.

Furthermore, anthropometric measures of maternal nutritional status in this population can only be obtained in a prospective cohort study because prenatal records rarely exist. Therefore, the prospective design, though more costly than other designs, is the only option.

Variables

Operational definitions of dependent and independent variables are described in Appendix A. Most variables will be collected directly by this study through anthropometric measurement, interviewer observation (e.g. type of cooking stove and area), and questionnaire. Identifying information on women who become pregnant will be obtained from the USS, and some household socioeconomic status data will be used from the USS. Though determination of cause of perinatal death is not an outcome variable examined by this study, information on cause of early neonatal deaths will be available through the USS' "verbal autopsy" which is completed for every registered death in the USS households (not for stillbirths).

Several variables will be collected as continuous variables, and later categorized according to appropriate criteria based on the literature, and/or the distribution of the data (e.g. age). Other variables will be collected on ordinal scales or according to nominal categories (e.g. presence/absence of a characteristic or condition, type of symptoms, etc.).

Table 1. Dependent Variables

Outcome Variable	Definition	Method
Perinatal death	Stillbirth occurring >=28 completed weeks of gestation or early neonatal death occurring <=7 completed days after birth.	Perinatal death will be defined by LMP in the case of stillbirths, and by completed days since birth in the case of live births (at 24 hour intervals from estimated time of delivery). When LMP is not available, the participant will be asked whether she was more or less than 7 months pregnant at termination.
Birth weight	Measured by a portable beam balance scale called the "Detecto Doctor's Infant Scale." This scale should be accurate to at least the nearest 10 grams.	Birth weight should be measured within the first 72 hours after birth. Each mother will be given a light cloth of standard weight (a "gumcha") to wrap the infant in for weighing; the final weight will be adjusted for the weight of the cloth. Scales will be set to zero and calibrated with a standard weight before each weighing.
Gestational age	Capurro method, modified from Dubowitz' gestational age assessment examination of the newborn.	The Capurro (1978) method, a modified version of the Dubowitz method (1970) has been chosen for its simplicity and proven applicability and validity in the field. The Capurro method uses only six signs of newborn maturity: skin texture, ear form, breast size, plantar creases, the scarf sign, and head lag. Each sign is rated on a 3-4 point scale corresponding to a certain number of points ranging from 0-24. All points are summed to a base of 200 and the total equals the estimated number of days of gestation.

Validity of Birth Weight

All infants lose weight in their first few days after birth, and initial weight loss is proportionately greater among low birth weight infants than normal birth weight infants (Dancis et al., 1948). The amount of weight loss is estimated to be from 5-15% of body weight at birth over the first four to seven days (Shaffer et al., 1987). Studies have noted considerable individual variation, however.

Though a birth weight is most accurate immediately after birth, the 72 hour limit was chosen as a feasible and still valid field measure of birth weight in Bangladesh. Preliminary birth weight data from clinic/hospital births in Matlab Bangladesh have shown that variation in birth weight over the first four days of life is less than 4%, and the greatest decline occurs within the first 24 hours (A. deFrancisco, 1992).

To estimate the bias of taking weights as late as 72 hours after birth, a sub-sample of infants who are successfully weighed within the first 24 hours will be visited again at 72 hours for another

weighing. These longitudinal measurements will provide information on the pattern of weight changes over the first three days, and whether the patterns vary by initial birth weight. The data also will help to estimate the amount of bias in the rest of the sample, and to adjust obtained weights if necessary. Infants who are not weighed within 72 hours still will be visited, weighed and examined, but may be excluded from some analyses.

Validity of Gestational Age

Since the LMP dates reported by some women may be inaccurate, gestational age assessments based on newborn maturity are a more standard and reliable measure for this study. This method has been successfully used in clinical and field settings in developing countries (Ferraz et al., 1990). Its main advantage is its simplicity, both for the respondent because it takes less time, and for the assessor because it requires far fewer signs to learn to rate.

Evaluating signs of newborn physical and neurological maturity can only approximate an infant's gestational age because maturation in utero does not occur at the same rate for all fetuses. Nevertheless, the variability in newborn maturity for each gestational age is small enough so that postpartum assessments serve as a valid approximation of length of gestation (Ballard, 1979; Dubowitz, 1970). Some misclassification bias is introduced by using postpartum assessments of maturity in preterm and postterm infants. Alexander (1990) has shown that among preterm infants, gestational age is overestimated by these assessments, and among postterm infants gestational age is underestimated.

Table 2. Independent Variables

Variable Construct	Specific Measures
Pre-pregnancy maternal "endowment"	• Prior stillbirth, preterm delivery, LBW, or perinatal death • Parity • Maternal age • Interpregnancy interval
Maternal nutritional status	• 2nd trimester weight, height and arm circumference • 4 week weight gain velocity between 24-32 weeks gestation • Postpartum weight and arm circumference • Maternal report of eating behaviors • Maternal report of foods eaten in last week
Health modifying/controlling behaviors	• Number and timing of antenatal care visits • Content of antenatal care and type of provider • Content of other medical care and type of provider • Reason medical treatment sought • Medications taken during pregnancy
Prenatal/intrapartum risk factors	• Illness symptoms during pregnancy • Injury during pregnancy • Exposure to cooking or tobacco smoke, or tobacco use • Perinatal morbidity
Maternal socioeconomic status	• Education • Employment • Household income (# persons living in household) • Presence of husband in the household • Material possessions
Delivery care	• Where delivered • Level of training of who attended delivery • Complications of delivery • Specific behaviors of delivery attendant
Early neonatal infant care	• Breastfeeding status • When breastfeeding started • Other liquids given besides breast milk • Medications given, treatment sought for infant illness

Data Collection

Trained interviewers will conduct all interviews and assessments. The birth notification system and questionnaires will be piloted on women who have recently given birth in the project area and are not likely to be pregnant again during the enrollment year.

Interviewers will be trained at Azimpur Maternity Hospital, the Salimullah Medical College (Mitford hospital) and/or Shishu Hospital on anthropometric and gestational age assessments. To test reliability at training and periodically each month, all interviewers will assess the gestational age of several babies of varying weights in a hospital. The first measure of inter-rater agreement between interviewers will be the intraclass correlation coefficient (Fleiss, 1981). This requires that each rater's estimate be categorized into one- or two-week gestational age intervals. The intraclass correlation coefficient provides a measure of agreement between several raters for categorical data. The second method of reliability testing is the Kappa statistic which compares pairs of interviewers, and requires categorizing the gestational age estimates into two (i.e. <37 weeks vs. >=37 completed weeks) or more groups (Fleiss, 1981). The kappa describes the amount of agreement between any two interviewers, adjusting for agreement due to chance alone.

The points of data collection are the following:

(a) Second trimester (26-28 wks LMP): The woman gives informed consent to participate in the study. A short interview about pregnancy history, employment during pregnancy, and actvitity level is completed; maternal weight, height and arm-circumference is obtained.

(b) Third trimester (30-32 wks LMP): Maternal weight and arm-circumference is obtained. An interview about exposure to cooking smoke and eating behaviors during pregnancy is completed.

(c) Within 72 hours postpartum: The participant is interviewed about perinatal outcome, breastfeeding, health status during pregnancy, and delivery care and complications/events. Birth weight, length, head and arm circumference and gestational age is taken.

(d) Seven to nine days postpartum: Assessment of perinatal survival, and maternal weight and arm-circumference.

(e) Two weeks postpartum: Participant is interviewed about antenatal care attendance, and content of care.

Enrollment of Participants and Follow-up Logistics

A pregnant woman should be identified by the USS system within the first 16 weeks of the pregnancy. The interviewer will visit the woman between the 26th and 28th week of pregnancy to describe the study, enlist the woman's participation, give a short interview, and take the first set of anthropometric measurements.

The UHEP office will be notified of a participant's delivery from a family member or "reporter" designated by the participant at the enrollment interview. Each participant will be given a "referral card" which includes her name, study number, household address (or location), and expected date of delivery. Both she and the interviewer will decide on a household member who will be able to notify the UHEP field office of the delivery. If no household member appears to be capable of notifying the community reporter (e.g. working full time, reluctant to travel outside the house, only children in household), then a close friend or neighbor who lives nearby will be selected by the participant for assistance with notification.

A community volunteer has been assigned by UHEP in selected clusters according to UHEP's applied research program design. In these clusters, the volunteer will be utilized as a backup reporter. She will be encouraged to report all births in her neighborhood to the field office, in addition to the designated family reporter for those births. This backup system of reporting in the clusters where a UHEP volunteer resides will ensure maximum reporting of births, despite some duplication of reporting.

The designated reporter will be encouraged to report the delivery immediately after birth by bringing the referral card to the nearest field office him/herself. A schedule will be arranged with project staff to keep the office open to reporters on weekends. Directions to the office and daily office hours will be printed on the referral card. If the delivery occurs after office hours, the reporter will be instructed to bring the card in the next morning. The time and date of the delivery (if known), and when the reporter notified the office will be recorded on the referral card.

All designated household notifiers will be invited to visit the office ahead of time in order to know where it is located and to emphasize the importance of their role as reporter. At the second prenatal visit, the interviewer will spend time explaining this procedure again to both the woman and family designate, motivating them to comply. The household member or reporter who notifies the office will receive travel reimbursement for the familiarizing, and reporting visit to the office.

If a woman cannot be visited within 72 hours of birth, all measurements still will be taken. It is expected that in the case of stillbirth or early neonatal death, a birth weight will not be obtainable

because the office will not be notified in time to visit before burial. This is an unavoidable bias in a study of this nature.

Prior data from the USS show that the majority of births occurred in the woman's own home. However, births that occur in other homes (e.g. a relative's), or in a clinic or hospital in Dhaka, must still be followed-up. To facilitate following births that occur in local medical centers, the principal investigator will send a letter notifying all administrators and chief physicians about the nature and purpose of the study. We will meet with the directors of each medical center to clarify any questions or apprehensions they may have about the study, and to encourage them to measure the birth weight of the infant if possible. This initial contact with the medical centers should reduce administrative barriers to our contacting the participant during her hospital stay if her health permits.

Sampling and Sample Size

A representative sample (N=8300-8500) of all households in the five *thana* was selected using a multistage cluster sampling method. Sample clusters of 20-55 households were defined and these clusters were the sampling units, comprising the frame from which a random cluster sample was drawn. Every household in a randomly selected cluster is enrolled in the USS.

The following sample size calculations are presented for the hypothesized risk factors for perinatal mortality. Since LBW, preterm delivery and IUGR are expected to be more common outcomes than perinatal mortality, the sample sizes estimated for perinatal mortality should be sufficient for the other two outcomes.[2]

Parameters	α=.05	probability of Type I error; corresponding Z_α= 1.96
	ß=.20	probability of Type II error; corresponding $Z_ß$=.84
	P_1	proportion of perinatal deaths, given absence of risk factor
	P_2	proportion of perinatal deaths, given presence of risk factor
	r	ratio of "unexposed/exposed"
	P	$[P_1 + rP_2]/(r + 1)$
	Q	1-P
	n'	sample size of "exposed" group, uncorrected
	n	sample size of "exposed" group, corrected
	N	(r+1)n, which is the total sample size needed

[2] The two assumptions made to justify not calculating sample size for each hypothesized association are (1) the prevalence of exposure to each hypothesized risk factor for each of these other outcomes is not lower than 15%, and (2) the strength of the association between each hypothesized risk factor and each of the other outcomes of interest is comparable to the strength of association between the risk factors included in the sample size calculations and perinatal mortality.

The minimum detectable level of increased risk is estimated to be 2.0 for each risk factor, the perinatal mortality rate is assumed to be 65/1000, and the sample size calculations are for two-tailed tests.

The following formula from Fleiss (1981, pg. 45) is applied:

$$n' = \frac{(z_{\alpha/2}\sqrt{(r+1)\bar{P}\bar{Q}} + z_{\beta}\sqrt{rP_1Q_1 + P_2Q_2})^2}{r(P_2 - P_1)^2}$$

Where,

$$n = n' + \frac{r+1}{r|P_2 - P_1|}$$

Table 3. Sample size estimates for different independent variables, where perinatal mortality is the dependent variable.

Risk factor (estimated prevalence in study cohort)	% Deaths among unexposed (P_1)	% Deaths among exposed (P_2)	Required # in exposed group (n)	Required sample size (N)	Study Power Given N=1139
Maternal postpartum weight < 40 kg (40%)	4.6	9.2	421	1053	85.9%
Smoke exposure during pregnancy (30%)	5.0	10.0	322	1073	85.2%
Antenatal care not received (60%)	4.0	8.0	768	1280	78.7%
Unsafe delivery practice (50%)	4.3	8.6	557	1114	84.1%

These sample size estimates are highly dependent on the prevalence of the risk factor in the population, the perinatal mortality rate, and the strength of association. The rarer the risk factor, and the lower the perinatal mortality rate, the harder it becomes to identify a crude association of at least RR=2.0 with this sample size. There is no data on this population describing the prevalence of exposure to the above risk factors, except a recent study on maternal nutritional status, which did show that 40% of all non-pregnant women were below 40kg (Baqui, 1993).

Based on preliminary data from the USS, an estimated 2034 pregnancies would be recorded over 12 months. All pregnant women who are identified by the USS should be screened for eligibility. However, based on estimates of the proportion of women who will be unable or unwilling to fully participate, a completed sample size of N=1139 is anticipated.

This estimate takes into account attrition due to refusals (5%), ineligibility (6%), and out-migration (23%), resulting in a sample of 1395 pregnant women who carry beyond 28 weeks gestation. Out of these 1395 births, an estimated 15% will not be successfully visited within 72 hours of pregnancy termination. Taking into account further attrition and possible late refusals postpartum, a total of 1139 women will have fully participated (i.e. having been visited within 72 hours of delivery and having completed the three postpartum interviews). See appendix B for a justification of these estimates.

A completed sample size of N=1139 should be sufficient to test the associations between risk factors in Table 3 and perinatal mortality, as well as the risk factors of interest for LBW and preterm delivery.

Data Management and Analysis Plan

All questionnaires and assessments will be reviewed by the investigator for completeness and accuracy. When possible, an interviewer will return to the field to clarify answers, or collect missing information. After editing, the data will be entered into a database. Range and consistency checks will be programmed into the data entry program to improve accuracy. Data will be periodically "cleaned" by running frequencies to identify outliers.

Stage I: Descriptive Statistics and Classifying/Recoding Data

Descriptive statistics (mean, median, variance, frequency tables) will be examined to assess the distribution characteristics of the dependent and independent variables. Some of these variables will then be recoded and/or grouped into categories for bivariate analysis as appropriate. Estimates of rates and proportions will be expressed within 95% confidence intervals.

Stage II: Crude and Adjusted Bivariate Analysis

Bivariate associations will be identified using the chi-square test. The t-test will be used to compare means of continuous dependent measures of two independent groups (Daniel, 1987). Some adjusted bivariate associations or interactions will be estimated by stratifying the data on potential confounding characteristics (Schlesselman, 1982). Confidence intervals around odds ratios and relative risk estimates will be calculated using Woolf's method (Kahn and Sempos, 1989).

Stage III: Multivariable Analysis Using Regression Modeling

Regression techniques will be used to identify important determinants of each dependent variable outlined in this study. Regression models can simultaneously control several confounding factors and include interaction terms, providing estimates of the independent effect of variables of interest (Kleinbaum et al., 1988).

For perinatal mortality, logistic regression will be used; linear and logistic regression will be used to predict gestational age and birth weight (defining these outcomes on a continuous scale and dichotomously as preterm delivery and LBW). Several different models will be built to determine whether each of the four to five hypothesized variables are related to the three dependent variables. The first part of regression analysis is concerned with assessing the affect of confounding variables on the relationship between the hypothesized independent variables and the dependent variables. The second part of regression analysis is an exploration of pathways of influence of independent variables.

Part 1--Example: To assess whether exposure to cooking smoke is related to perinatal mortality, the selected measure of exposure will be entered first into a regression equation, and potential confounders subsequently entered. These may include socioeconomic status, use of antenatal or delivery care, and nutritional status. A variable will be considered a potential confounder if it is related to the exposure (cooking smoke) and to the outcome (as determined in stage II bivariate analysis). If the beta cooefficient (which corresponds to an odds ratio) is changed by the presence of the confounding variables in the model, it can be interpreted that exposure to cooking smoke is not an independent risk factor for perinatal mortality; it is confounded by the other variables in the model. The amount of change required in the beta coefficient to determine whether there is confounding is not subject to a statistical test of significance, however, if the independent variable was significantly related to the outcome before entering confounders and becomes non-significant after confounders have been entered, then the presence of confounding is quite clear.

Part 2:--Example: Assuming that cooking smoke has been determined in prior analysis stages to be a risk factor for LBW, this part of analysis would attempt to determine whether the effect of cooking smoke exposure is "mediated" by weight gain velocity (i.e. smoke causes LBW by slowing the rate of weight gain in the second/third trimester). The analysis question to be tested is whether smoke exposure is "confounded" by weight gain velocity and the methods of analysis are then similar to those in part 1. If the effect of cooking smoke exposure on LBW is reduced after weight gain velocity has been entered into the

regression equation, then it can be concluded that smoke exposure effects LBW through reduced weight gain in the second/third trimester.

Stage IV:

The prevalence of risk factors in the community, and the incidence of all outcomes of interest, can be estimated from this study since it follows a cohort of all eligible pregnant women in a probability sample representative of the urban slums of Dhaka. Therefore, adjusted attributable risks can be calculated from the adjusted odds ratios estimated by logistic regression, and the prevalence of the risk factor in the community. This measure can be interpreted as the estimated amount of reduction in the incidence of the outcome if a given risk factor could be eliminated. The attributable risk percent will be calculated for all statistically significant determinants of each outcome of interest (Kahn and Sempos, 1989).

Ethical Implications

This study does not involve any invasive measures, or prescribing different treatment protocols to sample groups. However, it does require the collection of sensitive health information, and the handling of potentially fragile and sickly infants. This leads to three potential ethical problems.

The first ethical problem is the identification of serious health problems, for which the study itself prescribes no specific treatment. If a study interviewer is told about, or observes symptoms of serious maternal or infant morbidity, she will refer these women or their families to the nearest appropriate medical facility. A collaborative agreement will be made with specialists at Dhaka's Salimullah Medical College (Mitford hospital) to receive referrals. When a referral is made to Salimullah, the interviewer will give the woman a referral card that identifies her as part of this study. The interviewer will report all referrals made to her supervisor who will ensure that they are followed-up. Women who do not seek medical attention after a referral is made will be motivated to do so by the interviewer, or her superivisor, and accompanied to the medical facility if necessary.

The second ethical problem is related to taking a birth weight and doing a gestational age assessment on preterm or sickly infants. To minimize any risk of hypothermia, the infants will be wrapped in a warm cloth for weighing. Interviewers will be trained to complete the gestational age assessments without unwrapping the infant entirely. If the infant needs an immediate referral for emergency care, the interviewer will forego any physical assessment or maternal interview and offer to take the mother and infant to the hospital.

The third ethical problem is the confidentiality of the information gathered in this study. Much of it is sensitive and personal, involving a woman's reproductive behaviors and health. To protect each participant's privacy, interviewers will only conduct the interviews alone with the woman, unless the participant herself invites other family members to listen.

Informed Consent and Confidentiality

Each questionnaire will be numerically coded, with the identification register kept locked in the UHEP office. Questionnaire codes will be recorded on a master sheet where the name of the interviewee and location of the house are noted. All data entry will use the code number for identification. All staff and interviewers will be counseled about the sensitive nature of some of the information collected, and on the need for strict confidentiality of records.

Informed consent will be obtained from each participant verbally by the interviewer. The interviewer will first explain the purpose of the study, requirements of participation, and risks and benefits to the participant. The majority of this population is unable to read, so a verbal consent is reasonable. However, a written copy of the informed consent form will be given to each participant for reference and documentation.

D. Significance

This proposed research is important for four reasons. First, it will provide epidemiologic estimates of the incidence of LBW, preterm delivery and perinatal mortality for the urban poor in Bangladesh. Such important baseline data will be useful in the evaluation of health programs for this population.

Second, it will provide information to make program recommendations to improve maternal and child health services and interventions in the urban slums of Dhaka. Priority areas for training of antenatal and delivery service providers will be identified, and appropriate educational/motivational activities will be designed according to the risk factors identified by this study. Health intervention programs can be made more cost-efficient by focusing on the amenable risk factors that contribute substantially to poor pregnancy outcomes in this community.

Third, the prospective study design allows (a) the measurement of bias due to attrition; (b) prospective measures to be taken of maternal nutritional status, birth weight, gestational age and assessments of newborn maturity; and (c) different analytical questions to be defined and answered

simultaneously (i.e. because data will not be limited to "cases" and "controls" selected on predefined criteria).

Fourth, this proposed study will contribute to the literature on determinants of maternal and perinatal health in urban populations of developing countries.

E. Facilities Required

The UHEP's office and photocopy facilities are sufficient. Bathroom scales for adults and birth weight scales will be purchased. Infant length boards and maternal height measuring sticks will be designed and built locally. Arm circumference measuring tapes will either be purchased or homemade. The budget (Appendix C) includes money for equipment, supplies, and a computer.

F. Collaborative Arrangements

An agreement will be made with specialists from Salimullah Medical College (Mitford hospital) in obstetrics/gynecology and pediatrics so that referrals can be made from project staff when necessary, or if a woman asks for medical care. These specialists will review all training materials, and assist in developing a decision-making protocol to help interviewers make appropriate referrals to the hospital.

Collaboration between the principal investigators of the two other related studies on the same cohort of pregnant women and their infants has been ongoing. One of these other studies proposes to examine maternal postpartum morbidity and decision-making about a delivery care provider, another study proposes to examine the role of birth weight on infant mortality.

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APPENDIX E: STUDY TIMELINE

ACTIVITY	STUDY MONTH 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19
Hire and train interviewers	----------
Enrollment	----------
Data collection	----------
Computer programming for data entry	--------
Questionnaire codebook developed	--------
Coding and data entry	----------
Data cleaning	----------
Data analysis	----------
Report writing and dissemination of findings	----------

Responsibilities of Investigators and Project Staff

Principal Investigator 1: Has ultimate responsibility for all aspects of study design, methodology and accountability to ICDDR,B review, UHEP director and research director. Develops computerized tracking system to manage enrollees.

Research co-investigators (Selina Amin; Shams el Arifeen): Assists in hiring and training of interviewers; communicating with collaborating and non-collaborating hospitals and clinics (where subjects may be referred for care, and where subjects may deliver); codes questionnaires for data entry; supervises the Field Research Officer; writes reports and articles on progress of study and findings. Liases with UHEP staff to secure necessary materials for locating potential participants (maps), and purchasing necessary equipment and supplies. Translates questionnaires and consent forms into Bengali.

Co-investigator (Abdullah Baqui): Provides technical assistance and epidemiological consultation. Holds weekly meetings with study investigators to facilitate integration with the UHEP program and problem-solve with technical or logistical issues. Assists in writing findings and publications.

Field Research Officer: Manages field logistics of project which includes the following activities: Assists with training of interviewers. Copies blank questionnaires and other forms and distributes to field offices, monitors money spent out of field offices on travel. Reviews and edits all completed questionnaires. Accompanies interviewers to field on selected interviews to ensure standard quality of interviews, and for reliability testing.

Liases with the USS interviewers and receives reports of pregnant women from USS. Manages computerized tracking data on enrollees and their due dates for delivery and visits. Generates reports to interviewers on who to follow-up and when, and generates reports to investigators on total number enrolled, completed, etc.

Assists in coding questionnaires for data entry.

Interviewer: Participates in all training and reliability sessions. Conducts all 5 interviews, and anthropometric assessments. Reviews and edits interviews after completion, and returns to the house to make correction if necessary.

Programmer: Programs computer for data entry, and assists in some programming for data cleaning and analysis if necessary.

Data entry assistant: Enters data after coding. Runs basic frequency tables for data cleaning, and summarizing.

APPENDIX C: BUDGET

	UNIT COST/JUSTIFICATION	YEAR 1	YEAR 2 + 10%[1]	SUB-TOTALS
STAFF				
Co-Investigator	(To be determined)			
Co-Investigator (on staff)	625/mo for 19 mos @ 50%	3,741	2,197 + 220	6,158
Field Research Officer	379/mo for 19 mos	4,548	2,653 + 265	7,466
Programmer	2.83/hr for 320 hrs	571	335 + 34	940
Data entry assistant	237/mo for 15 mos @ 50%	2,240	1,315 + 132	3,687
Interviewers in field	237/mo for 150 person mos[2]	22,397	13,154 + 1,315	38,866
Interviewers in training	237/mo for 12 person mos	2,844		2,844
				59,961
TRAVEL				
Notifiers of delivery	3.75/delivery @ n=1395(1.5)	4,944	2,903 + 290	8,056
Interviewer visits	1.00/visit @ 8307 visits	5,233	3,074 + 307	8,614
Missed visits/emergency visits to hospital	1.00/visit @ 8307(30%)=2492	1,570	922 + 92	2,584
Investigator/Supervisor visits	1.00/visit @ 8307(15%)=1246	785	461 + 46	1,292
				20,546
FIELD EQUIPMENT/SUPPLIES				
Gumcha to wrap baby	1.00 ea @ n=1395	879	516 + 52	1,447
Birth weight scale	500.00 ea @ qty 6	3,000		3,000
Maternal weight scales	30.00 ea @ qty 6	180		180
Other anthropometric equipment	50.00 ea set @ qty 6	300		300
				4,927
EXPENSES/SUPPLIES				
Photocopy	.05 ea @ 50,000 pp	1,575	925 + 93	2,593
Computer and supplies	1 PC, discs, surge protector	4,000		4,000
Other office supplies	papers, pencils, etc.	1,000		1,000
				7,593
SUB-TOTAL DIRECT				93,027
Indirect overhead	32%			29,769
TOTAL				122,796

[1] The total study is for 19 months, with 12 months in year 1 and 7 months in year 2. Thus, year 1 costs are usually 63% of the total costs, unless the item is purchased at the beginning of the study, or in the case of interviewer training costs which occur in year 1 only.

[2] These 150 person months includes 12 different interviewers hired over a period of 16 months. See appendix D for staff justification.

Abstract Summary for ERC

Protocol: Determinants of Birth Weight, Gestational Age, and Perinatal Mortality Among the Urban Poor in Dhaka, Bangladesh

The purpose of this study is threefold. First, to determine the incidence of perinatal mortality, low birth weight (LBW), intrauterine growth retardation (IUGR), and preterm delivery in an urban slum population of Bangladesh. Second, to test several hypotheses about the relationship between suspected risk factors for poor perinatal outcome in this population.[1] And third, to estimate the contribution of known risk factors for poor perinatal outcome to the extent of poor perinatal outcome observed in this population (the attributable risk percent).

The methods and procedures used by this study are summarized in the following points, as specified by the Committee in Attachment 1a.

1) The required subject population of this study is pregnant women. The participants will be able to give voluntary informed consent. Data will, however, also be collected on the weight, gestational age, length and arm circumference of the subjects' live born neonates. Informed voluntary consent to conduct this assessment of the infants will be obtained from the mother (and father if he is present during the first postpartum interview when these measures are scheduled to be taken).

2) This study poses no physical risks to the mother. Since the interviews deal with sensitive information about a woman's reproductive history and health, there are social and psychological risks to the mother (and her family) if the data are not kept confidential. There are no alternative research methods, however, besides interviewing the mother. There is no foreseeable likelihood of any legal risks to the participants' of this study, as no questions asked relate to the legal status (e.g. illegal behaviors) of a woman or her family.

3) To minimize risks to the mother, interviews will not be done in the presence of others, unless the participant has consented to or requested their presence. See paragraph (4) for a description of how confidentiality of the data will be maintained, and how each respondent's anonymity will be established on data records. Interviewing a mother soon after a perinatal death poses potential psychological risk to the mother; interviewers will be instructed to reschedule the interview if the mother prefers to wait.

There are no physical, psychological or social risks to the infant. All infants will be wrapped in a cloth of known weight to prevent any cooling of the infant during weighing. Anthropometric assessments pose no physical risk to infants.

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[1] The specific hypotheses are: (1) Is (a) poor maternal nutritional status, (b) passive exposure to tobacco or cooking smoke, or (c) lack of antenatal care utilization by a qualified practitioner, related to increased risk of perinatal mortality, intrauterine growth retardation, and preterm delivery in this population? (2) Are symptoms of genital tract infection during pregnancy related to increased risk of preterm delivery in this population? And (3) Is delivery with an untrained attendant related to increased risk of perinatal mortality in this population?

4) Every interview, upon completion, will be filed by a unique identifying number and kept in a locked cabinet. Only study staff with job responsibilities related to data collection will be allowed access to the cabinet storing completed interviews. The respondent's name will not be on the filed interviews, but will be on a cover sheet attached to the uncompleted interview (to facilitate the interviewer in finding the household and designated participant).

A separate list linking each respondent's name to her study ID number will be held by the principal investigator and field managers. When a respondent has completed an interview, her name and address will be removed, leaving only the unique identifier to distinguish her interviews from another respondent's and linking the interviews together.

Data entered onto the computer will not include the names or addresses of the respondents, but will include the unique identifier. All name and address sheets that have been removed from the completed interviews will be retained by the investigator in a locked cabinet. Only the investigator will have access to this material.

5) Potential participants will be identified by the Urban Health Extension Project's Urban Surveillance System (USS), which monitors at three-month intervals all vital and demographic events occurring in each selected household. The date of the last menstrual period (LMP) is collected at each three month visit, so all pregnancies should be identified before 16 weeks LMP by USS interviewers who will then notify the investigator of the woman's name, age, LMP and household location.

An interviewer assigned to a designated area will visit the eligible woman in her home to introduce herself and describe the study. The interviewer will discuss the purpose, requirements, and risks/benefits of the study with the pregnant woman. Since most women are illiterate and not accustomed, or comfortable with signing forms, a woman's verbal agreement to participate will be considered sufficient consent. The interviewer will act as a witness to the woman's verbal consent. A copy of the consent form in Bengali will be given to the woman however.

(a) NA--consent will be obtained.
(b) NA--information will not be withheld from a subject.
(c) The attached consent form states that the subject's confidentiality will be protected. Compensation and/or treatment is not provided by this study for any invasion of privacy. There are no physical risks incurred by the subject or her neonate in this study. The consent form states that referral for treatment will be provided and the research protocol states that all referrals will be followed-up and participants motivated to seek care when necessary (e.g. by accompanying them to the hospital when necessary).

6) All interviews will take place in the woman's own home. The following is an outline of the timing, content, and time required of each visit:

(a) Second trimester (24-28 wks LMP): Enrollment discussion and informed consent obtained. Interview about pregnancy history, employment and current activity level is completed; maternal weight, height, head and arm-circumference is measured **(30 minutes required).**

(b) Second-Third trimester (28-32 wks LMP): Maternal weight and arm-circumference is measured. Interview about exposure to cooking smoke and eating behaviors during pregnancy is completed **(30 minutes).**

(c) Within 72 hours postpartum: Interview about perinatal outcome, breastfeeding, maternal morbidity during pregnancy and postpartum, and delivery care and complications/events. Infant birth weight, length, head and arm circumference and gestational age is taken **(90 minutes).**

(d) Seven to nine days postpartum: Assessment of perinatal survival; maternal weight and arm-circumference is taken **(< 15 minutes required for this portion of interview).** NOTE: This visit also will include an interview about infant health and breastfeeding for a related study of birth weight and infant mortality. (Total time required of the visit is 30 minutes, if the woman is participating in both studies).

(e) Fourteen to Eighteen days postpartum: Interview about antenatal care attendance, content of care, and health during pregnancy **(30 minutes required for this portion of interview).** NOTE: This visit also will include an interview about maternal postpartum morbidity, health care seeking behaviors during pregnancy, and opinions/attitudes of delivery care providers for a related study of postpartum morbidity and maternal decision-making about delivery care providers). (Total time required of women participating in both studies is 90 minutes).

7. The only benefit to participation in the study is medical referral when necessary. All women who are referred will be given an identifying card (and accompanied by an interviewer if necessary) so that they are received and cared for in a timely manner.

This study is important because it can provide population-specific information to public health programs in Dhaka city that could help them to shape program recommendations for improving perinatal outcome. The prevalence and attributable risk of all hypothesized factors, as well as other known prenatal risk factors, will be determined to inform planners of health services.

This study also can make a contribution to the literature on risk factors for poor pregnancy outcomes, particularly preterm delivery, because it focuses on factors that either deserve further study, such as cooking or passive smoke exposure and symptoms of genital tract infection, or risk factors that may play an important role in severely disadvantaged populations, such as maternal nutritional status and use of antenatal and delivery care. Furthermore, it can contribute to the international literature on poor perinatal outcome in developing countries, especially in urban settings.

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH, BANGLADESH (ICDDR,B)

URBAN HEALTH EXTENSION PROJECT

Verbal consent form for participation in the research study:

Determinants of Birth Weight, Gestational Age and Perinatal Mortality Among the Urban Poor in Dhaka, Bangladesh

The Urban Health Extension Project at ICDDR,B (Cholera Hospital) is conducting a special study on women who have babies delivered in Dhaka.

The purpose of the study is to find out more about women in Dhaka who are having babies, and to find out more about the health of the mother and the baby after delivery. We want to do this by asking you some questions before and after your delivery. The questions will be about your health during this pregnancy and delivery, and about the health of your baby after the delivery.

If you agree to participate in the study, I would like to ask you a few questions today about your current activities and prior pregnancies. Then we will measure your weight, your height, and your arm size now so that we understand better the nutrition of pregnant women. I will come back after one month to check your weight again, and also to ask a few more questions. I will visit as soon as possible after your delivery to see how you and your baby are doing. Then I will visit you two more times in the next few weeks.

There is no possibility of harm coming to you or your newborn as a result of participating in this study. If, during our visits, we find that you or your baby is not well, we will help you obtain treatment by referring you to a nearby hospital.

We know that some of the questions we will ask you about your health, pregnancy, and family will be personal. Therefore, we will keep all of your answers secret. That is why this questionnaire does not have your name written on it.

If there are any questions which you do not want to answer, that is okay. Even if you decide not to answer the research questions, you will always be able to use the services at the Cholera Hospital as usual. If you have any questions about the study, you can contact the principal investigator, Gretchen Antelman, or the Urban Health Extension Project, at the telephone number 600003 (or through the staff at the nearest UHEP field office--see your "referral card" for the location).

Do you agree to participate?

_____ _____/_____/_____

Signature of Interviewer Date of Consent

_____

Signature of Principal Investigator

INTERNATIONAL CENTRE FOR
DIARRHOEAL DISEASE
RESEARCH, BANGLADESH

Phone : 600171-78
Telex : 675612 ICDD BJ
Fax : 880-2-883116
Cable : Cholera Dhaka
Mail : GPO Box 128, Dhaka-1000
Bangladesh

Urban Health Extension Project

"বাংলাদেশের ঢাকা নগরীর দরিদ্রদের মধ্যে গর্ভবিস্হার বিভিন্ন পরিনামের কারন সমুহ" গবেষনায় অংশগ্রহনের জন্য মৌখিক সম্মতি পত্র ।

আরবান হেল্থ এক্সটেনসন প্রজেক্ট আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্রে (কলেরা হাসপাতালে), ঢাকা শহরে যে সব মহিলাদের বাচ্চা হয়েছে, তাদের উপর একটি বিশেষ গবেষণা চালাচ্ছে ।

এই গবেষণার উদ্দেশ্য হচ্ছে, শহরের যে সব মহিলাদের বাচ্চা আছে, তাদের ও বাচ্চা হবার পর মা ও বাচ্চার স্বাস্হ্য সম্মন্ধে আরো ভালভাবে জানা । আপনার বাচ্চা হবার আগে ও পরে আপনাকে কিছু প্রশ্ন করে আমরা এই কাজ করতে চাই । আপনার বর্তমান গর্ভবিস্হা সম্পর্কে এবং বাচ্চা হওয়ার সময় ও বাচ্চা হবার পর আপনার এবং বাচ্চার শরীর কেমন আছে সে সম্মন্ধে প্রশ্ন করা হবে ।

আপনি যদি এই গবেষণায় অংশ নিতে রাজী থাকেন, তাহলে আজকে আপনার বর্তমান কাজকর্ম এবং পুর্ববর্তী গর্ভবিস্হা সমুহ সম্পর্কে কিছু প্রশ্ন করতে চাই । এখন আমি আপনার ওজন, উচ্চতা ও হাতের মাপ নেব । যাতে একজন গর্ভবর্তী মহিলার পুষ্টি সম্পর্কে আমি আরো ভালভাবে বুঝতে পারি ।

একমাস পর আমি আবার আপনার ওজন নিতে আসব । তখন আপনাকে আরো কিছু প্রশ্ন করবো । বাচ্চা হওয়ার পর যত তাড়াতাড়ি সম্ভব আপনাকে ও আপনার বাচ্চাকে দেখতে আসব । পরবর্তী কয়েক সপ্তাহে আমি আরও দু'বার আপনাকে দেখতে আসব ।

পর পাতা-২

আমাদের এই গবেষণায় অংশ নিলে আপনার ও আপনার বাচ্চার কোন আঘাত পাওয়ার সম্ভাবনা নেই । কিন্তু আপনাকে দেখতে আসার সময় আপনি বা আপনার বাচ্চা অসুস্থ্য থাকলে আমরা আপনাকে নিকটবর্তী হাসপাতালে চিকিৎসার জন্য পাঠানোর ব্যবস্থা করবো ।

আমরা জানি যে আপনার স্বাস্থ্য, ও গর্ভবিস্থা পরিবার সম্মন্ধে আমরা যে সব প্রশ্ন করবো, তার কিছু প্রশ্ন খুবই ব্যক্তিগত । সেজন্য আপনি যা বলবেন তা খুবই গোপন রাখা হবে । এই জন্যই প্রশ্নমালায় আপনার নাম থাকবে না ।

এমন কিছু প্রশ্ন যদি থাকে যা আপনি উত্তর দিতে না চান তাতে কোন অসুবিধা নাই । আপনি এই গবেষণার প্রশ্নগুলোর উত্তর না দেওয়ার সিদ্ধান্ত নিলেও আপনি সব সময়ই যথারীতি কলেরা হাসপাতালের স্বাস্থ্য সেবা ব্যবহার করতে পারবেন । এই গবেষণা সম্পর্কে যদি আপনার কোন প্রশ্ন থাকে তাহলে আপনি মূল গবেষক অথবা আরবান হেল্থ একসটেনশন প্রজেক্ট এর সাথে ৬০০০০৩ নম্বরে যোগাযোগ করতে পারেন (অথবা আপনাকে দেয়া কার্ডে উল্লেখিত আমাদের নিকটবর্তী দপ্তরের মাধ্যমে) ।

আপনি কি এই গবেষণায় অংশগ্রহণ করতে রাজি আছেন ?

সম্মতি গ্রহণকারীর স্বাক্ষর

সম্মতির তারিখ

মূল গবেষকের স্বাক্ষর

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH, BANGLADESH (ICDDR,B)

URBAN HEALTH EXTENSION PROJECT

Written consent form for participation in the research study:

Determinants of Birth Weight, Gestational Age and Perinatal Mortality Among the Urban Poor in Dhaka, Bangladesh

We have been asking you several questions about your pregnancy and your baby for this study.

In order to understand how your health was during your pregnancy, we are required to ask you some questions now about your gynecological health during the time that you were pregnant.

If you agree to answer some simple questions right now, please sign below.

_____ _____/_____/_____

Signature of Respondent Date of Consent

_____ _____/_____/_____

Signature of Interviewer Date of Consent

PROJECT FRAMEWORK

Determinants of Birth Weight, Gestational Age, and Perinatal Mortality Among the Urban Poor in Dhaka, Bangladesh

Objective: To estimate the incidence of poor perinatal outcome, and the effects of poor maternal health and nutrition, smoke exposure, and lack of medically trained antenatal and delivery care on perinatal outcome in this population.

Activities/Output	Indicators of achievement	How indicators can be quantified/assessed	Assumptions
Design study, write and review protocol and budget, develop questionnaires, locate appropriate equipment (e.g. birth weight scale), obtain approval from ICDDR,B for research.	- Study protocol completed and approved. - Draft questionnaires ready for pilot testing. - Equipment for study selected and ordered.	- Study begins.	- Review boards are satisfied with the study design. - Appropriate, affordable, and feasible equipment is available.
Develop pilot test protocol, and implement the pilot test of the design and questionnaires.	- Pilot test protocol completed and pilot test implemented. - Necessary modifications made to design and questionnaires.	- Written report detailing how pilot test was implemented and what changes were made to study plan.	- Sufficient staff, equipment, and participants (e.g. pregnant women) can be mobilized during the pilot test phase.
Hire and train interviewers.	- Training materials completed. - Hiring completed.	- Sufficient staff hired and trained. - Reliability in gestational age, birth weight, infant length, and arm circumference measurements tested and adequate.	- Sufficient applicants with qualifications. - Interviewer ability to learn and demonstrate consistency and accuracy in taking measurements, and administering questionnaires.

Activities/Output	Indicators of achievement	How indicators can be quantified/assessed	Assumptions
(1) Recruitment of pregnant women to participate in the study. (2) Notification of each participant's delivery soon afterward by either a family member, a UHEP volunteer, or a designated "notifier" from the neighborhood.	- Adequate percentage of all pregnant women identified who qualify for the study agree to participate. - Participants are followed-up as long as they remain in Dhaka for their delivery and can be located. - Adequate percentage of deliveries are reported to the UHEP field office within 3 days.	- A high percentage (>90%) of eligible women agree to participate in the study. - Loss to follow-up of participants who have agreed to participate and remain in Dhaka is low (<10%). - A high percentage of deliveries are reported within 3 days (90%).	- Women in the UHEP slum areas look favorably on UHEP and ICDDR,B and will be willing to cooperate with little personal gain. - Women who move away during their follow-up will notify the field office, or be traceable by a neighbor or family member. - The family member, UHEP volunteer, and notifier will be willing to act promptly in notifying the field office of any delivery as soon as possible.
Supervision of field activities and monitoring of data quality.	- Collaborating investigators and field supervisors hold regular meetings to review progress and problems in the study or in the data collected. - Regular meetings held with project interviewers. - Periodic reliability testing of interviewers' measurements conducted.	- Quality of data (e.g. completeness and accuracy) remains high throughout the study.	- Management meetings, interviewer meetings, and reliability testing and re-training are interesting and productive.
Questionnaire coding.	- Standardized codebook in use by coders. - Questionnaires coded soon after completion and editing (within 1 week).	- Codebook (and case definitions) available in final technical reports for review.	- Open-ended questions can be meaningfully coded.

Activities/Output	Indicators of achievement	How indicators can be quantified/assessed	Assumptions
Data entry and cleaning.	- Data entry program written to include range and consistency checks. - Frequency tables and cross-tabulations printed out and checked for outliers and illogical data.	- Technical report on data management and cleaning available for review.	- Most data entry or interviewer errors will be evident from questionnaire editing, data entry checks, and data cleaning.
Data analysis and dissemination of findings and recommendations.	- Descriptive and analytic research questions addressed in analysis. - Estimation of biases due to non-participation, loss to follow-up, or measurement bias completed. - Generalizability of findings to target populations of urban slum dwellers described by demographic profile of participants.	- Descriptive report describing who participated, who did not participate or was lost, and what is the incidence of poor perinatal outcomes. - Analytical report on the determinants of each specific poor perinatal outcome measured in this study. - Summary report emphasizing public health implications and recommendations for health programs in the urban slums. - All reports will be adapted to reach a wider international audience through peer-reviewed scientific and public health journals.	- Technical ability to analyze data. - Collaboration with and technical advice from experts at ICDDR,B and academic institutions.

Papers to be written based on above research:

(1) The incidence and determinants of low birth weight among the urban poor in Dhaka, Bangladesh.

(2) The incidence and determinants of perinatal mortality among the urban poor in Dhaka, Bangladesh.

(3) Maternal health and pregnancy outcomes in the urban slums of Dhaka: A priority for "Child Survival."

(4) More on specific risk factors of interest depending on data results (e.g. "Maternal nutritional status and eating behaviors..."; "Antenatal and delivery care utilization...").

(5) One paper discussing the risk factors for growth retardation and preterm delivery, addressing possible differences in risk factors for proportionately versus disproportionately growth retarded newborns (might be combined with LBW paper in (1)).

APPENDIX A: OPERATIONAL DEFINITIONS OF INDEPENDENT VARIABLES

Variable	How treated in Analysis (Type)	Measurement and Definition
Prior poor pregnancy outcome	Binary (yes/no). Ordinal (# of prior poor outcomes).	History, based on maternal self-report, of prior stillbirth or miscarriage, preterm delivery ("too early birth"), LBW ("smaller than usual"), or perinatal death.
Parity Gravidity	Binary (primipara/multipara). Ordinal (# of prior live births/pregnancies).	History, based on maternal self-report, or number of prior live births and pregnancies.
Maternal age	Ordinal categories according to distribution of data. Continuous (# of years).	History, based on maternal self-report (may be taken from USS database).
Interpregnancy interval	Ordinal categories according to distribution of data. Continuous (# of months).	History, based on maternal self-report (may be verified against from USS database).
Maternal nutritional status	Ordinal categories according to distribution of data. Continuous (as measured).	Anthropometric assessment of 2nd trimester weight, height and arm circumference, 4 week weight gain velocity between 24-32 weeks gestation, and postpartum weight and arm circumference.
Maternal nutritional behaviors	Categorical (yes/no) or other response categories depending on question.	Maternal self-report on beliefs about how much a pregnant woman should eat; how much respondent has been able to eat during this pregnancy; kinds and amounts of food eaten in past week; and whether respondent eats with husband and family or eats after others have finished.
Antenatal care utilization	Ordinal categories based on either total number of routine visits, or content of examinations and care received. Scale score based on combination of relevant measures such as timing, frequency, content, and provider qualifications.	Maternal self-report on the number and timing of antenatal care visits; the content of antenatal care and type of provider. Must examine data before determining details of a scale which takes into account both the timing and frequency of ANC, as well as quality/content of care (e.g. were certain procedures performed, was woman counseled about basic health during pregnancy, what were the qualifications of the provider).
Other medical care utilization	Categorical based on types of treatment received or medications taken. Scale score developed according to medical advisor's assessment of danger to fetal health.	Maternal self-report on the content of other medical care received, reason sought, type of provider, and any medications taken during pregnancy. An expert medical opinion will assist in interpreting the potential danger of some locally available medications and treatments.

Variable	How treated in Analysis (Type)	Measurement and Definition
Prior poor pregnancy outcome	Binary (yes/no). Ordinal (# of prior poor outcomes).	History, based on maternal self-report, of prior stillbirth or miscarriage, preterm delivery ("too early birth"), LBW ("smaller than usual"), or perinatal death.
Prenatal /intrapartum morbidity	Binary (presence/absence). Categorical (type of illness/complication).	Maternal self-report of illness symptoms, injuries or complications experienced during pregnancy. Severity measured by number of bed days may be used as part of some case definitions. Symptoms assessed will be: blood pressure (if measured and self-reported by respondent), diabetes (if diagnosed previously and self-reported by respondent), convulsions, vaginal bleeding, consciousness after delivery, vaginal discharge or urine problems, pain or tenderness in legs, heart problems, vomiting, edema, headaches /dizzy spells /visual disturbances, diarrhea, respiratory tract infections, general assessment of health and activity level, and physical injury. Specific definitions of each of these categories of illness symptoms will be determined according to the medical advisor's assistance.
Prenatal exposure to cooking/tobacco smoke	Binary (smokes/doesn't smoke). Categorical according to amount smoked, or estimated number of hours per day exposed to passive cooking or tobacco smoke.	Maternal self-report on questions about her own smoking behaviors during pregnancy, estimated number of hours per day she is exposed to others smoking cigarettes, and estimated number of hours per day she is exposed to cooking smoke from biomass fuels (type of fuel used may be examined separately, controlling for hours of exposure).
Maternal socioeconomic status	Binary (literate/illiterate; employed outside home/not employed outside home; earning own income/not earning own income; presence/absence of husband in household). Categorical (# of years of education; amount of own income; amount of household income; types of material possessions in household). Scale score developed according to a few key elements found to be related to pregnancy outcome (e.g. education, indicators of respondent's independence or "empowerment," and wealth of household as measured by income and assets).	Maternal self-report of educational level and skills (literacy, additional training received), current employment and employment just prior to pregnancy, earnings from employment or other income-generating activities, household income (controlling for # persons living in household), presence of husband in the household. USS collects information on material possessions, money borrowing history and status, and other related data elements such as type of latrine and material house is made of.

Variable	How treated in Analysis (Type)	Measurement and Definition
Prior poor pregnancy outcome	Binary (yes/no). Ordinal (# of prior poor outcomes).	History, based on maternal self-report, of prior stillbirth or miscarriage, preterm delivery ("too early birth"), LBW ("smaller than usual"), or perinatal death.
Delivery care	Categorical based on location of delivery or level of training of attendant (ordinal). Categorical based on content of care controlling for provider type/qualifications (e.g. were basic elements of safe delivery kit used, what interventions or examinations were done, what medications were given).	Maternal self-report on location of delivery and who attended. Complications and specific procedures will also be determined through maternal self-report. Data, if available, from interviews with the local midwives (dai) for the collaborating study on maternal morbidity also will be used to supplement and/or verify maternal self-reported information.

APPENDIX B: COMPLETED 12 MONTH SAMPLE SIZE

The following table shows how the cohort of potential and participating pregnant women move through the study's visits during their pregnancy. It begins with USS identification of a woman's pregnancy, and ends with the third postpartum visit approximately 2 weeks after delivery.

The target population is all pregnant women in the USS area who carry beyond the 28th week LMP and deliver in Dhaka. However, women are actually enrolled in the study before the 28th week in order to get necessary anthropometric measures. Women also are enrolled regardless of any stated plan to deliver outside of Dhaka in order to collect as much information as possible about these births, and in case they do deliver in Dhaka.

Weeks LMP	**USS Contact/ Study Visit**	**A: Attempts to visit a household** **R: Reached household to enroll or interview** **C: Completed visit-- successfully enrolled or interviewed.**	**Losses**	**Assumptions**
4-16 wks	USS identifies 2050 pregnancies.	Not enrolled yet.	Unknown % pregnancies never identified[1] due to: • Purposely not reported (possible reasons are that the woman may plan to abort or the pregnancy is illegitimate). • Pregnant woman of 28-30 wks LMP who recently in-migrated was not registered with the USS until after delivery.	• USS surveillance of 8300 households. • USS identifies .245 pregnancies per household during the study year. See note[2]
24-28 wks	Enrollment Visit.	A: 2034 HH R: 86% of 2034 = 1749 C: 92% of 1749 = 1609	• 14% "net out-migration" • 3% refusal 5% miscarriage/abort	• Based on estimated 3% "net out-migration" per month and maximum of 5 months between USS identification and enrollment visit.[3] • USS interviewers have reported no refusals, so 3% initial refusal for this study is a conservative assumption. A miscarriage rate of 7% per year is estimated, with 5% occuring before 24 weeks LMP (see data in note 2).
28-32 wks	2nd Prenatal Visit.	A: 1609 R: 97% of 1609 = 1561 C: 97% of 1561 = 1514	• 3% "net out-migration" • 1% refusal 2% miscarriage/abort	• 3% * 1 mo. • Late refusals and remaining 2% of miscarriages prior to 28 wks.

Weeks LMP	USS Contact /Study Visit	A: Attempts to visit a household R: Reached household to enroll or interview C: Completed visit--successfully enrolled or interviewed.	Losses	Assumptions
32-42 wks	72 hr Postpartum Visit.	A: 1514 R: 94% of 1514 = 1423 C: 98% of 1423 = **1395** C < 72 hrs: 85% of 1395 = **1186** C > 72 hrs: 15% of 1395 = 209	• 6% "net out-migration" • 2% refusal • 15% late notification of delivery (mothers and infants will still be assessed, but may be dropped from sample in some analyses due to invalid anthropometric data.)	• 3% * 2 mos. • late refusals • A more educated estimate can be ma after the pilot tes notification system.
34-45 wks	Two Postpartum Visits at 7-10 dys and 14-18 dys PP.	C < 72 hrs n = 1186 A: 1186 R: 97% of 1186 = 1150 C: 99% of 1150 = **1139** C > 72 hrs n = 209 A: 209 R: 97% of 209 = 203 C: 99% of 203 = 201	• 3% "net out-migration" • 1% refusals	• 3% * 1 mo. • late refusals

In sum,

	N	%
Pregnancies identified by USS	2034	100.0
Lost to out-migration	459	22.6
Lost to refusal/late refusal	109	5.3
Ineligible	119	5.8
Late follow-up after delivery (incomplete)	209	10.3
Complete participation	1139	56.0

And the breakdown of participation and loss of the target population:

Target population [(2034 id) - (459 out-m) - (119 inel)]	1456	100.0
Lost to refusal/late refusal	109	7.5
Late follow-up after delivery (incomplete)	209	14.3
Complete participation	1139	78.2

1. The total % of pregnant women that are never identified who will end up actually carrying beyond 28 wks LMP and delivering in Dhaka is very low, and not expected to be an important source of potential bias. However, most of these "missed" women will eventually be captured by the USS, and study interviewers will

be able to assess demographic characteristics and conduct follow-up interviews about risk factor exposure and delivery care.

2. The USS currently surveys approximately 8300 households (HH). In 1991, the USS recorded 783 live births in 4600 HH. The ratio of pregnancies recorded by the USS to live births is based on 1991 data from approximately 6 months. These data were:

	#	%
Induced miscarriage:	10	1.5
Spontaneous miscarriage:	32	4.9
Single still birth:	26	4.0
Single live birth:	450	69.0
Twin live birth:	2	0.3
Out-migration:	132	20.2
TOTAL	652	

Thus, the ratio is 652/452 = 1.44 and [(783 LB * 1.44)/4600 HH] * 8300 HH = 2034 pregnancies identified.

3. "Net out-migration includes the following groups: (1) women who return to their home village to deliver; (2) women who move away from Dhaka with their families; (3) women who move away from the USS area and cannot be located; and (4) in-migration of pregnant women and their families to the USS area, and who are registered by the USS before 28 weeks LMP.

"Net out-migration" is estimated to be 3% per month, 14% over 5 months, and about 30% over 12 months. Using the formula:

$$P_n = P_0(e^{rt})$$

where:
P_n = population after n months
P_0 = population at starting month
e = base of natural logarithm
r = rate of net decrease in population per month
t = number of months

then:

$$P_n = 100(e^{-.03*12})$$

Solving for P_n, there will be 70 people remaining in the population after 12 months for every 100 in the population at starting time "0." This estimate is consistent with the 1991 data which showed 20.2% of USS pregnancies were recorded as "out-migrated" in 1991 (see note 2).

APPENDIX D: STAFFING JUSTIFICATION

Enrollment Visit			
Status of Potential Participant	**Number**	**Interview and editing time, plus 1 hour travel**[1]	**Worker time spent in hours**
Out-migrated	285	1.00	285
Refused/Ineligible[2]	140	1.50	140
Completed	1609	2.00	3218
Return to correct (5%)	80	1.25	100
TOTAL HOURS			3743
Interviewers needed for each of 12 study months for this visit:[3]			2.23

2nd Prenatal Visit			
Participant Status	**Number**	**Interview and editing time, plus 1 hour travel**	**Worker time spent in hours**
Out-migrated	48	1.00	48
Refused/Ineligible	47	1.25	59
Completed	1514	1.75	2652
Return to correct (5%)	70	1.25	95
TOTAL HOURS			2852
Interviewers needed for each of 12 study months for this visit:			1.70

[1] This travel time includes locating the household, and having to return another day to a proportion of households because the woman was not home, or unable to complete the interview.

[2] "Refused/Ineligible" includes late refusals and miscarriages.

[3] A total of 35 hours per week and 48 weeks per year are assumed for each interviewer. This allows for sick days, holidays, in-service training, and staff meetings. The calculations are: 35(48)=1680 hours/year or 1680/12=140 per month.

The total interviewers needed on staff per study month to complete all enrollment interviews over a period of X months of enrollment is calculated: Total hours/140/X months = Y.

72 Hour Postpartum Visit[4]			
Participant Status	**Number**	**Interview and editing time, plus 1 hour travel**	**Worker time spent in hours**
Out-migrated	91	1.00	91
Refused/Ineligible	28	1.50	42
Completed	1395	3.00	4185
Return to correct (5%)	70	1.50	105
TOTAL HOURS			4423
Interviewers needed for each of 13 study months for this visit:			2.43

7-10 Day Postpartum Visit[5]			
Participant Status	**Number**	**Interview and editing time, plus 1 hour travel**	**Worker time spent in hours**
Out-migrated	0	NA	0
Refused/Ineligible	0	NA	0
Completed	1395	1.75	2441
Return to correct (5%)	70	1.25	88
TOTAL HOURS			2529
Interviewers needed for each of 13 study months for this visit:			1.39

14-18 Day Postpartum Visit			
Participant Status	**Number**	**Interview and editing time, plus 1 hour travel**	**Worker time spent in hours**
Out-migrated	0	NA	0
Refused/Ineligible	0	NA	0
Completed	1395	3.00	4185
Return to correct (5%)	70	1.50	105
TOTAL HOURS			4290
Interviewers needed for each of 13 study months for this visit:			2.36

[4] For this and remaining postpartum visits, all participants will be visited, regardless of the timing of birth notification. That is, even if an interviewer was unable to visit within 72 hours after birth, the woman will still be interviewed according to this schedule.

[5] To ensure adequate staffing, we must assume that there will be no out-migration or refusals in the first few weeks postpartum.

APPENDIX D: STAFFING SPREADSHEET BY STUDY MONTH

Visit	Study Months							
	1	2	3	4	5	6	7	8
Enroll	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23
2nd Prenatal		1.70	1.70	1.70	1.70	1.70	1.70	1.70
72 hrs PP		1.22	2.43	2.43	2.43	2.43	2.43	2.43
7-10 dys PP			.70	1.39	1.39	1.39	1.39	1.39
14-18 dys PP			1.18	2.36	2.36	2.36	2.36	2.36
TOTAL	2.23	5.15	8.24	10.11	10.11	10.11	10.11	10.11
TRAINED STAFF NEEDED IN FIELD[6]	3	6	9	12	12	12	12	12

Visit	Study Months							
	9	10	11	12	13	14	15	16
Enroll	2.23	2.23	2.23	2.23				
2nd Prenatal	1.70	1.70	1.70	1.70	1.70			
72 hrs PP	2.43	2.43	2.43	2.43	2.43	2.43	1.22	
7-10 dys PP	1.39	1.39	1.39	1.39	1.39	1.39	1.39	.70
14-18 dys PP	2.36	2.36	2.36	2.36	2.36	2.36	2.36	1.18
Total	10.11	10.11	10.11	10.11	7.88	6.18	4.97	1.88
TRAINED STAFF NEEDED IN FIELD	12	12	12	12	9	6	6	3

[6] There are three field offices, and should be a minimum of 1 interviewer in each field office. Interviewers will be added to staff in multiples of three to equally cover each field office. This arrangement will be evaluated during the study if data show that the field offices handle significantly different participant loads.

The staff needed does not account for a lead time of at least 2 weeks for training.

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH, BANGLADESH (ICDDR,B)

URBAN HEALTH EXTENSION PROJECT

ENROLLMENT INTERVIEW
(28 Weeks of Pregnancy)

[COMPLETE FOLLOWING FACE SHEET INFORMATION PRIOR TO INTERVIEW]

Stratum No: _____ Cluster No: _____ Structure No: _____

Household No: _____ Mother's USS ID No: _____

Date: ___/___/___ Interviewer: _____

Head of Household's Name: _____

Woman's Name: _____

Address: _____

Age: _____ LMP: ____/____/____ (dy mo yr) EDD: ____/____/____ (dy mo yr)

List persons present
during interview: _____

SECTION I. PREGNANCY HISTORY

1101. Have you ever been pregnant before?

Yes 1
No ..... 2 [GO TO Q1103a]

1102a. How many times have you been pregnant?

_____ times

1102b. How many children have you given birth to, that are alive now [including children not living with you]?

_____ children

1103a. Have you ever been pregnant and had a miscarriage [within 7 months of pregnancy]?

Yes 1
No ..... 2 [GO TO Q1104a]

1103b. In total, how many miscarriages have you had?

_____ miscarriage(s)

Now I am interested in talking to you about any problems you have had with your past pregnancies. [IF PRIMIPARA, GO TO Q1201]

1104a. Have you ever given birth to a baby who cried or showed any sign of life, but only survived a few hours or days?

Yes 1
No ..... 2 [GO TO Q1105a]

1104b. How many of these types of births?

_____ early neonatal deaths

1105a. Have you ever given birth to a boy or girl (either alive or dead) who was born earlier than usual, that is, after 7 months but before 9 months of pregnancy.

Yes 1
No ..... 2 [GO TO Q1106a]

1105b. How many of these types of births?

_____ too early birth(s)

1106a. Have you ever given birth to a boy or girl (either alive or dead) who was born smaller than usual?

Yes 1
No ..... 2 [GO TO Q1107]

1106b. How many of these types of births?

_____ too small birth(s)

1107. When did your previous pregnancy end?

_____ months ago

1108. Where was that baby delivered?

At home 1
Hospital/clinic 2
(name_____)
Parent's home 3
(Dhaka____ Village____)
Other relative's home 4
(Dhaka____Village____)
Other _____ 5
Miscarriage ?

1109. Who delivered the baby?

Relative 1
Untrained dai 2
Trained birth attendant 3
Doctor, nurse, midwife 4
Self 5
Other 6
Miscarriage ?

1110. Is the child alive now?

Yes ..... 1 [GO TO Q1113]
No 2

1111a. Was the child born alive?

Yes 1
No ..... 2 [GO TO Q1112]

1111b. How old was the baby when he/she died?

< 24 hrs after birth 1
> 24 hrs and < =7 dys 2
> 7 dys old (specify age _____) 3

1111c. What was the cause of death? (PROBE FOR SYMTOMS SURROUNDING DEATH, SUCH AS: convulsions, poor feeding/sucking, fever skin rash, abnormal breathing, cough/wheeze, diarrheoa, malnutrition/wasting)?

_____

_____

_____

1112. Just during or after the birth, did the child show any sign of life, such as taking a breath or crying?

Yes 1
No 2

1113a. Were there any problems with the delivery or postpartum?

Yes 1
No ..... 2 [GO TO Q1114]

1113b. What kind of problems with the delivery?

_____

1114. Did you have any other complications with any of your previous pregnancies?

Yes 1
No ..... 2 [GO TO Q1201]

030783

1115. Describe any complications which have occurred in other pregnancies.

_____

SECTION II: CURRENT PREGNANCY DELIVERY INFORMATION

1201. Do you know where you will deliver your baby?

Home 1
Hospital/Clinic 2
(name _____)
Parent's home 3
(location _____)
Other relative's home 4
(relationship/location
_____)
Other 5
(specify _____)
Don't know yet 6

1202. Who will assist you at the time of delivery?

Relative 1
Trained Dai 2
Untrained Dai 3
Dai (unknown training) 4
Doctor, nurse, midwife 5
Self 6
Other 7
Don't know yet 8

SECTION III. MATERNAL ANTHROPOMETRIC MEASURES

Now I would like to measure your height, weight and arm. This is very simple and quick. Nothing I do will make you uncomfortable.

1301. Maternal Anthropometrics:

Weight: _____ kg Arm Circumference: _____ mm

Height: _____ cm

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH, BANGLADESH (ICDDR,B)

URBAN HEALTH EXTENSION PROJECT

SECOND ANTENATAL INTERVIEW
(32 Weeks of Pregnancy)

[COMPLETE FOLLOWING FACE SHEET INFORMATION PRIOR TO INTERVIEW]

Stratum No: _____ Cluster No: _____ Structure No: _____

Household No: _____ Mother's USS ID No: _____

Date: ___/___/___ Interviewer:_____

Head of Household's Name: _____

Woman's Name: _____

Address: _____

Age: _____ LMP: ___/___/___ EDD: ___/___/___
dy mo yr dy mo yr

List persons present
during interview: _____

SECTION I: MATERNAL WEIGHT AND ARM CIRCUMFERENCE

I'll start with taking your weight and arm circumference today. Then, I'd like to ask you a few more questions. This is a short visit; only about 15 minutes today.

2101a. Weight: _____ kg

2101b. Arm Circumference: _____ cm

SECTION II: EATING DURING PREGNANCY

2201a. Do you think pregnant women should take usual, more than usual, or less than usual amount of food?

Usual amount ..... 1 [GO TO Q2202]
More than usual 2
Less than usual 3
Don't know ..... 4 [GO TO Q2202]

2201b. Why do you think that? _____

2202. Have you actually been eating the usual amount, more than usual, or less than the usual amount of food during this pregnancy?

Usual amount 1
More than usual 2
Less than usual 3

2203a. During this pregnancy, have you been eating special foods for pregnancy that you normally would not eat if you were not pregnant?

Yes 1
No ..... 2 [GO TO Q2204]

2203b. What foods are you eating now for your pregnancy?

_____

2204a. During this pregnancy, have you avoided eating certain foods because you are pregnant?

Yes 1
No ..... 2 [GO TO Q2205]

2204b. What foods do you avoid eating because of your pregnancy?

_____

2205. During your pregnancy, have you been able to eat enough to keep hunger away?

Yes, usually 1
Sometimes 2
No, not usually 3

2206. Have you been able to take a snack between meals when you are hungry?

Yes, usually 1
Sometimes 2
No, not usually 3

2207. How many times per week/month have you eaten fish (meat,...) since you became pregnant?

Fish ..... _____ wk/mo
Meat ..... _____ wk/mo
Milk/eggs ..... _____ wk/mo
Dal ..... _____ wk
Vegetables ..... _____ wk
Yellow Fruit ..... _____ wk
Bread ..... _____ wk
Rice ..... _____ wk

2208. At what time during the day do you usually eat your snacks and meals?

_____ am/pm _____ am/pm
_____ am/pm _____ am/pm
_____ am/pm _____ am/pm

2209a. Were you pregnant during the last Ramadan?

Yes 1
No ..... 2 [GO TO Q2210]

2209b. Did you fast during that Ramadan month?

Yes 1
No 2

2210a. During this pregnancy, have you ever wanted to eat something that people do not usually like to eat?

Yes 1
No ..... 2 [GO TO Q2301]

2210b. What did you want to eat? _____

2210c. Did you actually eat something that people do not usually eat (what)?

_____

SECTION III: ACTIVITY LEVEL DURING PREGNANCY AND EMPLOYMENT

2301a. During this pregnancy, have you been carrying heavy things (such as water, clothes, your children, garbage, etc.) a lot?

Yes 1
No ..... 2 [GO TO Q2302]

2301b. What kind of things have you been carrying?

_____

2301c. How far do you have to carry them?

_____

2301d. How many times a day/week do you carry them?

_____

2302a. During this pregnancy, have you had to walk long distances?

Yes 1
No ..... 2 [GO TO Q2303]

2302b. How far do you have to walk?

_____

2302c. How many times a day/week do you have to walk this far?

_____

2303a. During this pregnancy, have you been staying up a lot at night (for working, caring for children, etc.)?

Yes 1
No ..... 2 [GO TO Q2304]

2303b. How many hours of sleep do you usually get per day?

_____

2303c. How many nights per week do you have to stay up late, or get no sleep?

_____

2304a. During this pregnancy, have you been employed outside the home?

Yes 1
No ..... 2 [GO TO Q2305]

2304b. What kind of job was this?

_____

2304c. How many hours a week do/did you work?

_____ hours

2305a. During this pregnancy, have you had any work that requires that you stand up for long periods of time?

Yes 1
No 2

2305b. How long did you have to stand up?

_____

2305c. How many times a week did you have have to stand for long periods?

_____

SECTION IV: SMOKE EXPOSURE

Now I'd like to ask you some questions about your cooking area.

2401. Where is the place where you cook located?

Inside the house 1
Adjoining the house 2
Away from house 3

2402. Is the cooking area enclosed by a roof or walls?

Enclosed by roof 1
Enclosed by roof
and walls 2
Open 3

2403. Does the cooking area fill up with smoke when someone is cooking?

Always 1
Sometimes 2
Rarely 3
Never 4

2404. Do your eyes ever burn from smoke while you are near the stove(s)?

Always 1
Sometimes 2
Rarely 3
Never 4

2405. Do you ever have trouble catching a breath while you are near the stove(s)?

Always 1
Sometimes 2
Rarely 3
Never 4

2406. What kind of fuel do you use most of the time in your cooking stove(s)? [CHECK ONLY ONE. IF SEVERAL FUELS USED EQUALLY, NOTE THIS IN MARGIN].

Gas 1
Kerosene 2
Wood, leaves, twigs 3
Cow-dung 4
Garbage 5
Rags/clothes 6
Other _____ 7

2407. How many hours per day do you spend cooking, or working near a burning stove in the cooking area?

_____ hrs near cook smoke

2408. Does your household fill up with smoke from other families' cooking?

Yes 1
No 2

2409. How many hours a day would you say that your house is smoky from cooking?

_____ hrs smoke in house

2410a. Does anyone who lives in this household smoke cigarettes?

Yes 1
No ..... 2 [GO TO Q2411]

2410b. Counting all the people who smoke in this household, how many hours per day ~~are you near them when they are smoking?~~ do they smoke around you? (cigarettes)

_____ hrs near cig smoke

2411. Have you ever smoked cigarettes or a pipe?

Yes 1
No ..... 2 [GO TO Q2501]

2412a. Have you ever smoked any cigarettes during this pregnancy?

Yes 1
No 2

2412b. Have you ever smoked a pipe during this pregnancy?

Yes 1
No 2

2412c. How many cigarettes have you smoked per day (or week) during this pregnancy?

_____ cigs per day/week

2412d. How many times have you smoked a pipe per day (or week) during this pregnancy?

_____ pipe smokes per day/week

SECTION VI: OBSERVATION OF COOKING AREA

[INTERVIEWER OBSERVES COOKING AREA AND ANSWERS THE FOLLOWING QUESTIONS]

2501. Describe where the cooking area is located in the household. What rooms is it nearby?

_____

2502. How many cooking pits or burners are there?

_____

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH, BANGLADESH (ICDDR,B)

URBAN HEALTH EXTENSION PROJECT

FIRST POSTPARTUM INTERVIEW
(Within 72 hours postpartum)

[COMPLETE FOLLOWING FACE SHEET INFORMATION PRIOR TO INTERVIEW]

Stratum No: _____ Cluster No: _____ Structure No: _____

Household No: _____ Mother's USS ID No: _____

Date: ____/____/____ Interviewer:_____

Head of Household's Name: _____

Woman's Name: _____

Address: _____

Age: _____ LMP: ____/____/____ EDD: ____/____/____
dy mo yr dy mo yr

List persons present
during interview: _____

SECTION I: INFANT OUTCOME

3101a. What day was your baby delivered?

_____ days ago

3101b. What time of the day did you deliver?

_____ am/pm

3102. Was it a boy or a girl?

Boy 1
Girl 2

3103. How is the baby now? (Can I see him/her?)

Alive 1
Dead 2

3104a. Was the baby born normal, or was there something physically wrong with the baby's head, body or limbs?

Looked normal ..... 1 [GO TO Q3105]
Malformation injury 2

3104b. What was wrong with the baby? _____

3105a. Were there bruises or marks of injury on the baby's body after birth?

Yes 1
No ..... 2 [SEE NOTE]

3105b. Can you describe where the bruises or marks were, and what they looked like?

_____

[IF BABY LIVING, GO TO S/II, Q3201; IF DEAD, ASK 3106 AND CONTINUE]

3106. Was the baby born alive? That is, did the baby show any signs of life, like crying or taking a breath?

Yes ..... 1 [GO TO Q3107]
No ..... 2]GO TO Q3116]

M/END: MODULE ON EARLY NEONATAL DEATH

3107. Did the baby fail to breathe, cry or suckle normally during the first day (hours) after birth?

Yes 1
No 2

3108a. Did you put the baby to breast before he/she died?

Yes 1
No ..... 2 [GO TO Q3109]

3108b. How soon after birth did you put the baby to breast?

_____ hrs after birth

3109. Was the baby limp or unconscious during the first few days (or hours) after birth?

Yes 1
No 2

3110. Was the baby's body abnormally cold after birth?

Yes 1
No 2

3111. Did the baby have a fever at all since birth?

Yes 1
No 2

3112a. Did the baby have any other illness/symptoms after birth?

Yes 1
No ..... 2 [GO TO Q3113]

3112b. Please describe. _____

_____

3113. What do you think the baby died from?

_____

3114a. Did you receive any treatment or medicine for your baby before he/she died?

Yes 1
No ..... 2 [GO TO Q3115]

3114b. Who gave you the treatment or medicine? _____

3114c. What kind of treatment or medicine did you get? _____

_____

3115. How many hours or days after birth did the baby die?

_____ hrs _____ days after birth

3116. Was the baby born smaller than usual?

Yes 1
No 2

[GO TO SECTION III, Q3301]

M/SB: MODULE ON STILLBIRTH

3116. How would you describe what the baby looked like?

_____

3117. Was the baby smaller than usual?

Yes 1
No 2

3118a. Did the baby have an unusual color?

Yes (specify _____) 1
No 2

3118b. Did the baby have an unusual smell?

Yes (specify _____) 1
No 2

[GO TO SECTION III, Q3301]

SECTION II: INFANT WELL-BEING AND BREASTFEEDING

3201. How would you describe your baby's health in general? Would you say he/she is in excellent, good, fair, or poor health?

Excellent 1
Good 2
Fair 3
Poor 4

3202. Is the baby sucking well?

Yes 1
No 2

3203a. Is the baby alert and active?

Yes 1
No 2

3203b. Did the baby cry normally when he/she was first born?

Yes 1
No 2

3204. Does the baby have a fever?

Yes 1
No 2

3205a. Have you put the baby to breast yet?

Yes 1
Not yet ..... 2 [GO TO Q3301]
Will not breastfeed ..... 3 [GO TO Q3301]

3205b. When did you first give him/her breastmilk?

_____ hrs after birth

3205c. Have you fed him/her anything besides breastmilk? [PROBE FOR: sugar water, animal milk].

Sugar water 1
Animal milk 2
Infant formula 3
Other _____ 4
Nothing 5

SECTION III. INFANT ASSESSMENT AND ANTHROPOMETRY

This examination of the baby is very simple and quick. Nothing I do will hurt the baby, or make him/her uncomfortable.

3301. Infant birth weight: _____ grams

3302a. Infant length: _____ cm

3302b. Infant head circumference: _____ cm

03. INFANT GESTATIONAL AGE ASSESSMENT

kin exture	Thin, gelatinous 0	Thin, smooth 5	Smooth, medium thickness, superficial peeling 10	Slight thickening, superficial cracking and peeling of hands and feet 15	Thick and parchment like 20
Ear orm	Pinna flat and shapeless (stays folded) 0	Incurving of part of edge (slightly curved, soft with slow recoil) 9	Partial incurving of whole of upper pinna (well-curved, soft but ready recoil) 16	Well-defined incurving of pinna (formed and firm with instant recoil) 24	
Breast ize	No breast tissue 0	Diameter < 0.5 cm 5	Diameter 0.5 - 1.0 cm 10	Diameter > 1.0 cm 15	
Plantar reases	No creases 0	Faint red marks over anterior 1/2 5	Definite red marks over anterior 1/2, indentations over anterior 1/3 10	Indentations over anterior 1/2 15	Deep indentations over more than anterior 1/2 20

carf ign	(stick figures to be drawn in) 0	6	12	18	
lcad ng	0	4	8	12	

SECTION IV. CURRENT HEALTH AND DESCRIPTION OF LABOR AND DELIVERY

I will ask you some questions about your health during this pregnancy, and since your delivery. Then I would like to talk to you about your labor and delivery.

3401. How would you describe your health today?

Excellent 1
Good 2
Fair/but normal 3
Fair/but not well 4
Poor 5

3402. Where was your baby delivered?

Marital home 1
Hospital/clinic 2
(name_____)
Parent's home 3
(Dhaka_____Village____)
Other relative's home 4
relation_____
(Dhaka_____Village____)
Other_____ 5

3403a. Were you transferred to another location to deliver after your labor had started?

Yes 1
No ..... 2 [GO TO Q3404]

3403b. Where did you start your delivery? _____

3403c. Where were you transferred to?_____

3404a. Who was the main person who delivered the baby?

Relative _____	1
Untrained dai	2
Trained birth attendant	3
Doctor/nurse/midwife	4
Self	5
Other	6

3404b. Did anyone else participate in the delivery (e.g. was anyone called in to cut the cord, or for complications)?

Yes	1
No	2 [GO TO Q3405]

3404c. Why was this person called?_____

3405. Who cut the umbilical cord?

Primary person delivering baby	1
Other _____	2

3406. What was used to cut the umbilical cord?

Razor blade	1
Knife	2
Bamboo	3
Thread	4
Other _____	5

3407a. Was the [cutting instrument] cleaned?

Yes	1
No	2 [GO TO Q3408]
DNK	9 [GO TO Q3408]

3307b. How was the [cutting instrument] cleaned?

_____

3408. What was used to tie the cord?

Cloth strips already in house 1
Thread already in house 2
Ties/thread bought especially for the delivery 3
Ties/thread brought by delivery provider 4
Other _____ 5

3409a. Were the ties/thread cleaned?

Yes 1
No ..... 2 [GO TO Q3410]
DNK ..... 9 [GO TO Q3410]

3409b. How were they cleaned?

_____

3410. What was put on the umbilical cord stump after cutting?

_____

3411. What item did you lie on for delivery?

Clean cloth 1
Clean plastic 2
Clean mat 3
Clean straw 4
Bare floor 5
Unwashed cloth 6
Other _____ 7

3412a. Did the [delivery provider] wash her hands before the delivery?

Yes 1
No ..... 2 [GO TO Q3413]
DNK ..... 9 [GO TO Q3413]

3412b. What did she use to wash her hands?_____

3413a. Did the [delivery provider] put her fingers inside of you during labor?

Yes 1
No ..... 2 [GO TO Q3414]

3413b. How many separate times did she examine you this way?

_____ times

3413c. When she first examined you inside with her fingers, was this before or after your water broke?

Before water broke 1
After water broke 2

3414. Did the [delivery provider] put her fingers inside of you after delivery?

Yes 1
No ..... 2 [GO TO Q3415]

3415a. Did the [delivery provider] make any other examinations or checks of your condition during labor or since delivery?

Yes 1
No ..... 2 [GO TO Q3416]

3415b. Can you describe what she did? _____

_____

3416. How long were you pushing before the baby came out?

< 1/2 hour 1
1/2 to 1 hour 2
> 1 hour 3

[IF GREATER THAN 1 HOUR, HOW LONG? _____]

3417a. How long after your water broke did the delivery occur?

< 12 hours 1
12 to 24 hours 2
> 24 hours 3

[IF GREATER THAN 24 HOURS, HOW LONG? _____]

3418. Do you think that your labor and delivery was normal? [RECORD UNPROMTED ANSWERS FIRST, THEN PROMPT FOR RESPONSES TO EACH CONDITION].

		Self Response	Prompted
a.	It was normal/no problem Yes ..... 1 No 2	____	____
b.	Took too long Yes ..... 1 No 2	____	____
c.	Water broke too early Yes ..... 1 No 2	____	____
d.	Too much pain Yes ..... 1 No 2	____	____
e.	Too much bleeding Yes ..... 1 No 2	____	____
f.	Afterbirth did not come quickly Yes ..... 1 No 2	____	____
g.	Tearing of perineum Yes ..... 1 No 2	____	____
h.	Convulsions Yes ..... 1 No 2	____	____

i. Other _____

Yes 1
No ..... 2 ____ ____

j. Baby was in wrong position

Yes 1
No ..... 2 ____ ____

3419. What position did the baby come out in?

Head first 1
Feet first 2
Shoulder first 3
Other (specify_____) 4

3420. Was the umbilical cord wrapped around the baby's neck?

Yes 1
No 2

3421a. Were you referred to another place for any emergency care or treatment?

Yes 1
No 2

3421b. Did you receive any special treatments for the problems described above?

Yes 1
No ..... 2 [GO TO Q3501]

3421c. Who treated you? _____

3421d. Where did you go? _____

3421e. What treatment did you receive? _____

SECTION V: MATERNAL ~~AND~~ MORBIDITY

Now I want to ask you about specific problems which might have required special treatment.

A. Convulsions

3501a. Did you ever have convulsions before, during or after delivery

Yes 1
No ..... 2 [GO TO Q3502]

3501b. When did you have these convulsions?

Before delivery 1
During labor/delivery 2
After delivery 3

3501c. Did you take any steps to seek treatment for the convulsions?

Yes 1
No ..... 2 [GO TO Q3502]

3501d. Who treated you? _____

3501e. Where did you go? _____

3501f. What treatment did you receive? _____

B. Vaginal Bleeding

3502a. Did you have vaginal bleeding during your pregnancy?

Yes 1
No ..... 2 [GO TO Q3503]

3502b. When during your pregnancy did the bleeding occur?

First 3 months 1
Second 3 months 2
Last 3 months 3
Throughout pregnancy 4
Last month of preg only 5

3502c. How much did you bleed?

Like the heaviest
days of menstruation 1
More than just spotted
but not heavy 2
Spotted only 3

3502e. How many separate episodes during your pregnancy did you notice bleeding?

_____ times

3502f. How many days altogether during your pregnancy did you have vaginal bleeding?

_____ days

3502g. Did you ever have to stay in bed or curtail activities because of bleeding?

Yes 1
No ..... 2 [GO TO Q3502i]

3502h. How many days did you stay in bed, or couldn't do normal activities because of bleeding?

_____ days

3502i. Did you take any steps to seek treatment for vaginal bleeding?

Yes 1
No ..... 2 [GO TO Q3503]

3502j. Who treated you?

_____

3502k. Where did you go? _____

3502l. What treatment did you receive? _____

3503a. Do you think you bled more than normal during labor, delivery or postpartum?

Yes 1
No ..... 2 [GO TO Q3503e]

3503b. When during your labor, delivery or postpartum did bleed more than normal?

During labor 1
Postpartum 2
During labor
and postpartum 3
Other _____ 4

3503d. Why do you think that your bleeding was more than normal? [PROBE FOR: how frequently rags or sari changed].

_____

3503e. Have you sought, or did you receive, any special treatment for the bleeding?

Yes 1
No ..... 2 [GO TO Q3504]

3503f. Who treated you? _____

3503g. Where did you go? _____

3503h. What treatment did you receive? _____

C. Placenta

3504a. How long after the birth was it when the placenta came out?

Within 1/2 hour 1
>1/2 but <2hours 2
>2 hrs (how long:____) 3

3504b. Were there any special measures taken to help the afterbirth come out?

Yes 1
No ..... 2 [END]

3504c. Who treated you? _____

3504d. Where did you go? _____

3504e. What measures were taken? _____

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH, BANGLADESH (ICDDR,B)

URBAN HEALTH EXTENSION PROJECT

7 DAY POSTPARTUM INTERVIEW

Stratum No: _____ Cluster No: _____ Structure No: _____

Household No: _____ Mother's USS ID No: _____

Date: ___/___/___ Interviewer:_____

Head of Household's Name: _____

Woman's Name: _____

Address: _____

Date of birth: ___/___/___ Target date of visit: ___/___/___

List persons present
during interview: _____

SECTION I: INFANT WELL-BEING AND BREASTFEEDING

4101. How is the baby today? (Can I see him/her?)

Alive 1
Dead ..... 2 [GO TO Q4201]

4102. Is the baby alert and active?

Yes 1
No 2

4103. How would you describe your baby's health in general? Would say he/she is in excellent, good, fair, or poor health?

Excellent 1
Good 2
Fair 3
Poor 4

4104. Is the baby sucking well?

Yes 1
No 2

4105. Does the baby have a fever?

Yes 1
No 2

4106a. Did the baby have any other illness/symptoms after birth?

Yes 1
No ..... 2 [GO TO Q4107]

4106b. Please describe. _____

_____

4107a. Have you put the child to breast yet?

Yes 1
Not yet ..... 2 [GO TO Q4201]
Will not breastfeed ..... 3 [GO TO Q4201]

4107b. When did you first give him/her breastmilk?

_____ hrs after birth

4107c. Have you fed him/her anything besides breastmilk? [PROBE FOR: sugar water, animal milk].

Sugar water 1
Animal milk 2
Infant formula 3
Other _____ 4
Nothing 5

SECTION II: EARLY NEONATAL DEATH

4201. When did the baby die?

_____ hrs _____ days after birth

4202. Was the baby born smaller than usual?

Yes 1
No 2

4203. Was the baby limp or unconscious during the first few days (or hours) after birth?

Yes 1
No 2

4204. Was the baby's body abnormally cold after birth?

Yes 1
No 2

4205. Did the baby have a fever at all since birth?

Yes 1
No 2

4206a. Did the baby have any other illness/symptoms after birth?

Yes 1
No ..... 2 [GO TO Q4207]

4206b. Please describe. _____

_____

4207. What do you think the baby died from?

_____

4208a. Did you receive any treatment or medicine for your baby before he/she died?

Yes 1
No ..... 2 [GO TO Q4209]

4208b. Who gave you the treatment or medicine? _____

4208c. What kind of treatment or medicine did you get? _____

_____

4209a. Did you put the baby to breast before he/she died?

Yes 1
No ..... 2 [GO TO Q4301]

4209b. How soon after birth did you put the baby to breast?

_____ hrs after birth

SECTION III: MATERNAL SMOKING (RELIABILITY CHECK)

4301a. Does anyone who lives in this household smoke cigarettes?

Yes 1
No ..... 2 [GO TO Q2411]

4301b. Counting all the people who smoke in this household, how many hours per day are you near them when they are smoking?

_____ hrs near cig smoke

4301. Have you ever smoked cigarettes?

Yes 1
No ..... 2 [GO TO Q4201b]

4301a. Have you ever smoked any cigarettes during this pregnancy?

Yes 1
No ..... 2 [GO TO Q4301b]

4301b. Have you ever smoked a pipe during this pregnancy?

Yes 1
No 2

4301c. How many cigarettes have you smoked per day (or week) during this pregnancy?

_____ cigs per day/week

4301d. How many times have you smoked a pipe per day (or week) during this pregnancy?

_____ pipe smokes per day/week

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH, BANGLADESH (ICDDR,B)

URBAN HEALTH EXTENSION PROJECT

THIRD POSTPARTUM INTERVIEW

(14-18 days postpartum)

[COMPLETE FOLLOWING FACE SHEET INFORMATION PRIOR TO INTERVIEW]

Stratum No: _____ Cluster No: _____ Structure No: _____

Household No: _____ Mother's USS ID No: _____

Date: ____/____/____ Interviewer: _____

Head of Household's Name: _____

Woman's Name: _____

Address: _____

Date of Birth: ____/____/____ Target Date of Visit: ____/____/____

List persons present
during interview: _____

SECTION I. HEALTH DURING PREGNANCY

A. Symptoms of Anemia

5101a. During this pregnancy, have you felt more tired than usual?

Yes 1
No 2

5101b. Have you noticed that you had white spots under your fingernails during this pregnancy?

Yes 1
No 2

5101c. Has you been told that your face or skin has looked paler than usual during this pregnancy?

Yes 1
No 2

B. Visual Disturbances

5102a. Have you noticed any of the following problems with your vision during your pregnancy?

Night blindness

Yes 1
No 2

5102b. Fuzzy vision Yes 1
No 2

5102c. Seeing double Yes 1
No 2

[IF NO VISUAL PROBLEMS, GO TO Q5103]

5102d. Did you have any of these problems before pregnancy?

Yes, it was the same 1
Yes, but it was different 2
_____
No 3

5102e. Have your sought treatment for any of these visual problems?

Yes 1
No ..... 2 [GO TO Q5103]

5102f. Who treated you? _____

5102g. Where did you go? _____

5102h. What treatment did you receive? _____

_____

C. Water Retention

5103a. Did your face swell up during your pregnancy?

Yes 1
No ..... 2 [GO TO Q5104]

5103b. When during your pregnancy did your face swell?

First 3 months 1
Second 3 months 2
Last 3 months 3
Throughout pregnancy 4
Last month of preg only 5

5103c. Did your feet or legs swell up during your pregnancy?

Yes 1
No 2

[SKIP TO Q5104 IF NO SWELLING IN FACE OR LEGS]

5103d. When during your pregnancy did your feet or legs swell?

First 3 months 1
Second 3 months 2
Last 3 months 3
Throughout pregnancy 4
Last month of preg only 5

5103e. Did the swelling go away if you elevated your feet?

Yes 1
No 2

5103f. Would the swelling go away after sleeping at night?

Yes 1
No 2

5103g. Did you ever have to stay in bed or curtail activities because of the swelling in your face or your legs?

Yes 1
No ..... 2 [GO TO Q5103i]

5103h. How many days did you stay in bed, or couldn't do normal activities, because of swelling?

_____ days

5103i. Did you take any steps to seek treatment for swelling of your face or legs?

Yes 1
No ..... 2 [GO TO Q5104]

5103j. Who treated you? _____

5103k. Where did you go? _____

5103l. What treatment did you receive? _____

D. Headaches

5104a. Did you have headaches during your pregnancy?

Yes 1
No ..... 2 [GO TO Q5105]

5104b. When during your pregnancy did the headaches occur?

First 3 months 1
Second 3 months 2
Last 3 months 3
Throughout pregnancy 4
Last month of preg only 5

5104c. How often did the headaches occur?

Almost never 1
A few times a week 2
Usually every day 3
Other _____ 4

5104d. Did you ever have to stay in bed or curtail activities because of headaches?

Yes 1
No ..... 2 [GO TO Q5104f]

5104e. How many days did you stay in bed, or couldn't do normal activities because of headaches?

_____ days

5104f. Did you take any steps to seek treatment for headaches?

Yes 1
No ..... 2 [GO TO Q5105a]

5104g. Who treated you?_____

5104h. Where did you go? _____

5104i. What treatment did you receive? _____

5104j. Did you ever have headaches before you became pregnant?

Yes, was the same during pregnancy 1
Yes was worse during pregnancy 2
No, do not normally have headaches 3

5104k. Do you still have headaches since delivery?

Yes, it is the same as during pregnancy 1
Yes, but it was worse during pregnancy 2
No 3

E. Dizzy Spells

5105a. Did you have dizzy spells during your pregnancy?

Yes 1
No ..... 2 [GO TO Q5106a]

5105b. When during your pregnancy did the dizzy spells occur?

First 3 months 1
Second 3 months 2
Last 3 months 3
Throughout pregnancy 4
Last month of preg only 5

5105c. Did you ever have to stay in bed or curtail activities because of dizzy spells?

Yes 1
No ..... 2 [GO TO Q5105e]

5105d. How many days did you stay in bed, or couldn't do normal activities because of dizzy spells?

_____ days

5105e. Did you take any steps to seek treatment for dizzy spells?

Yes 1
No ..... 2 [GO TO Q5106a]

5105f. Who treated you? _____

5105g. Where did you go? _____

5105h. What treatment did you receive? _____

F. Fever

5106a. Have you had a fever since your delivery?

Yes 1
No ..... 2 [GO TO Q5107]

5106b. Do you still have a fever?

Yes 1
No 2

5106c. How many days altogether have you had (did you have) a fever?

_____ days

5106d. Have you felt (did you feel) chills, or shaking with the fever?

Yes 1
No 2

5106e. Since the delivery, have you had to go to bed, or curtail your activities, because of sickness from the fever?

Yes 1
No ..... 2 [GO TO Q5106g]

5106f. How many days have you had to stay in bed or curtail your activities because of the fever?

_____ days

5106g. Did you seek treatment for the fever?

Yes 1
No ..... 2 [GO TO Q5107]

5106h. Who treated you? _____

5106i. Where did you go? _____

5106j. What treatment did you receive? _____

H. Vaginal Discharge

5107a. During pregnancy, many women will have some vaginal discharge. Did you have vaginal discharge during this pregnancy?

Yes 1
No ..... 2 [GO TO Q5108a]

5107b. Which of the following descriptions of this discharge best describes what you had during pregnancy?

Brownish or yellowish 1
Thick and white 2
Thick and jelly-like 3
Greenish 4
Other _____ 5

5107c. Did the discharge during your pregnancy smell bad or not?

Bad odor 1
No odor 2

5107d. Did you feel itchy during the time you had this discharge?

Yes 1
No 2

5107e. Did you ever have to stay in bed or curtail activities because of the discharge or related discomfort?

Yes 1
No ..... 2 [GO TO Q5107g]

5107f. How many days did you stay in bed, or couldn't do normal activities because of the discharge or related discomfort?

_____ days

5107g. Did you take any steps to seek treatment for the discharge?

Yes 1
No ..... 2 [GO TO Q5108a]

5107h. Who treated you? _____

5107i. Where did you go? _____

5107j. What treatment did you receive? _____

5107k. Did you have vaginal discharge prior to pregnancy?

Yes 1
No ..... 2 [GO TO Q5108a]

5107l. How did your vaginal discharge during pregnancy compare with that prior to pregnancy?

Was the same 1
Was different 2
(describe the difference _____)

I. Urinary Tract Infection

5108a. Did you have any problems with your urine or with urinating during your pregnancy?

Yes 1
No ..... 2 [GO TO Q5109a]

5108b. Which of the following best describes the problems you have had with your urine during the pregnancy?

Burning or pain when urinating 1
Difficulty holding or controlling urine 2
Frequent urination but no pain 3
Dark colored urine 4
Foul odor of urine 5
Other _____ 6

5108c. Was there fever?

Yes 1
No 2

5108d. Did you ever have to stay in bed or curtail activities because of the problems with your urine?

Yes 1
No ..... 2 [GO TO Q5108f]

5108e. How many days did you stay in bed, or couldn't do normal activities because of the urine problems or related discomfort?

_____ days

5108f. Did you take any steps to seek treatment for the problems?

Yes 1
No ..... 2 [GO TO Q5109a]

5108g. Who treated you? _____

5108h. Where did you go? _____

5108i. What treatment did you receive? _____

K. Injury

I'd like to ask you some questions about whether you have been injured at all during your pregnancy. I understand that these, like many questions we've been asking today, are very private events. I will not ask you to tell me the details of any event, or anything about a person who may have hurt you. My main concern is for your health, and the health of your baby.

5109a. During this pregnancy, have you had any kind of accident where you got hurt.

Yes 1
No ..... 2 [GO TO Q5201]

5109b. Please describe the accident and how you were hurt?

_____

5110a. Did anyone in this household ever hit you, shove you, or throw things at you?

Yes 1
No ..... 2 [GO TO Q5201]

[IF MORE THAN ONE INJURY, RECORD ANSWERS FOR EACH INJURY]

5110b. Can you describe to me what kind of injury you received?

_____

5110c. When did the injury occur?

_____ months ago

5111a. Did you have to stay in bed because of your injury?

Yes 1
No ..... 2 [GO TO Q5201]

5111b. How many days did you stay in bed because of your injury?

_____ days

SECTION II. ANTENATAL CARE UTILIZATION

I'd like to know about any health care or advice you received during your pregnancy from the people in your community, your family, friends, and from doctors or nurses.

5201a. During this pregnancy, did you ever go to a hospital or clinic for a pregnancy check-up?

Yes 1
No ..... 2 [GO TO Q5202]

5201b. Where did you go? _____

5201c. How many months pregnant were you when you first went?

_____ months

5201d. How many times altogether did you go?

_____ times

5201e. How soon before delivery did you last go?

_____ weeks

5201f. Did you go because you thought something was wrong with your own health or the baby's?

Yes 1
No ..... 2 [GO TO Q5202]

5201g. What were you worried about? _____

5202a. During this pregnancy, did anyone ever tell you about, or encourage you to go to a hospital or clinic for a pregnancy check-up?

Yes 1
No ..... 2 [GO TO Q5203]

5202b. Who told you about antenatal care? _____

[IF NO ANTENATAL CARE RECEIVE (Q5201A=NO), GO TO Q5205]

5203a. During any of your pregnancy health care check-up visits, did anyone talk with you about the following issues?

Warning/risk symptoms to watch for during pregnancy?

Yes 1
No 2

5203b. Signs of complications during labor to watch for ..... ?

Yes 1
No 2

5203c. The importance of using a safe delivery kit?

Yes 1
No 2

5203d. How to use a safe delivery kit?

Yes 1
No 2

5203e. Eating nutritious foods and weight gain during pregnancy .. ?

Yes 1
No 2

5203f. Importance of delivering the baby in a clinic?

Yes 1
No 2

5203g. Importance of delivering the baby with a trained attendant . ?

Yes 1
No 2

5203h. Importance of exclusive breastfeeding the baby during the first few days (i.e. colostrum)?

Yes 1
No 2

5203i. Your general health condition (i.e. vaginal bleeding, dizziness, swelling, abdominal pain, vomiting, headache) ..... ?

Yes 1
No 2

5203j. Use of birth control after pregnancy?

Yes 1
No 2

5204a. During any of your pregnancy check-up visits, did the doctor or nurse do any of the following?

Touched and felt around abdomen?

Yes 1
No 2

5204b. Touched and felt around the vagina?

Yes 1
No 2

5204c. Examined face, legs, and feet for swelling?

Yes 1
No 2

5204d. Took blood pressure?

Yes 1
No 2

5204e. Took blood sample?

Yes 1
No 2

5204f. Took urine sample?

Yes 1
No 2

5204g. Measured weight?

Yes 1
No 2

5204h. Measured height?

Yes 1
No 2

5204i. Measured arm size?

Yes 1
No 2

5204j. Gave tetanus injection?

Yes 1
No 2

5204k. Gave vitamins?

Yes 1
No 2

5204l. Gave iron tablets?

Yes 1
No 2

5204m. Gave safe delivery kit?

Yes 1
No 2

5205a. While you were pregnant, did a home visitor or health worker come to your house to give advice or treatment?

Yes 1
No ..... 2 [GO TO Q5406]

5205b. Where was this person from? _____

5205c. How many times did she come during your pregnancy?

_____ times

5205d. What advice or treatment did she give? _____

_____

5206a. Did anyone else come to your house to give advice or treatment? [PROBE FOR: TBA, dai, kobiraj, fakir, private doctor, pharmacist, homeopath, nurse].

Yes 1
No ..... 2 [GO TO Q5207]

5206b. Who was this? _____

5206c. How many times did any other people come to your house?

_____ times

5206d. What advice or treatment did they give? _____

_____

5207a. During this pregnancy, did you ever go outside of your home for advice or treatment from a TBA, dai, fakir, pharmacist, or kobiraj?

Yes 1
No ..... 2 [GO TO Q5208]

5207b. Where did you go? _____

5207c. Who did you see? _____

5207d. How many months pregnant were you when first went for a check-up like this?

_____ months

5207e. How many times altogether during this pregnancy did you go for a check-up like this?

_____ times

5207f. What kind of advice or treatment did you get? _____

_____

5208a. During this pregnancy, did you ever take any iron tablets?

Yes 1
No ..... 2 [GO TO Q5209]

5208b. How often did you take the iron tablets?

_____ times per day/week

5208c. How long did you take the iron tablets for?

_____ days/weeks/mos

5208d. Where did you get the iron tablets from? _____

5209a. During this pregnancy, did you receive an injection to prevent tetanus?

Yes, once 1
Yes, two times 2
No ..... 3 [GO TO Q5210]

5209b. Where/who did you receive the tetanus injection from?

_____

[IF PRIMIGRAVIDA, DO NOT ASK Q5210, GO TO Q5211]

5210. Have you received at least two injections for tetanus before this pregnancy?

Yes 1
No 2

5211a. Did you receive any other injections during this pregnancy?

Yes 1
No ..... 2 [END]

5211b. What kind of injection (for what purpose)? _____

_____

5211c. From where/whom did you receive the injection? _____

_____