Library . A-000012

ıchment 1.
CE SHEET) ETHICAL REVIEW COMMITTEE, ~~ICDDR~~, B. Date APRIL 6, 1993
MAY 18, 1993

ıcipal Investigator DR. SHAMS EL ARIFEEN Trainee Investigator (if any) _____

plication No. 93-017 Supporting Agency (if Non-ICDDR,B) _____

le of Study BIRTH WEIGHT AND T MORTALITY IN THE SLUMS OF DHAKA: A PROSPECTIVE STUDY

Project status:
(X) New Study
( ) Continuation with change
( ) No change (do not fill out rest of form)

cle the appropriate answer to each of the following (If Not Applicable write NA):

Source of Population:
(a) Ill subjects — Yes (No)
(b) Non-ill subjects — (Yes) No
(c) Minors or persons under guardianship — (Yes) No

Does the study involve:
(a) Physical risks to the subjects — Yes (No)
(b) Social Risks — Yes (No)
(c) Psychological risks to subjects — Yes (No)
(d) Discomfort to subjects — Yes (No)
(e) Invasion of privacy — (Yes) No
(f) Disclosure of information damaging to subject or others — Yes (No)

Does the study involve:
(a) Use of records, (hospital, medical, death, birth or other) — Yes (No)
(b) Use of fetal tissue or abortus — Yes (No)
(c) Use of organs or body fluids — Yes (No)

Are subjects clearly informed about:
(a) Nature and purposes of study — (Yes) No
(b) Procedures to be followed including alternatives used — (Yes) No
(c) Physical risks — Yes No 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)
(b) From parent or guardian (if subjects are minors) — Yes (No)
6. Will precautions be taken to protect anonymity of subjects — (Yes) No
7. Check documents being submitted herewith to Committee:
___ Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).
_X_ Protocol (Required)
_X_ Abstract Summary (Required)
_X_ 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
_X_ Informed consent form for parent or guardian
_X_ Procedure for maintaining confidentiality
_X_ 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 Ctte. for review.

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

Principal Investigator

Trainee

ENTERED 2 1 JUN 1998

1. Title:	Birth Weight and Infant Mortality in the Slums of Dhaka City: A Prospective Study
2. Principal Investigator:	Shams El Arifeen
Co-Investigators:	Gretchen Antelman Abdullah Hel Baqui Selina Amin
3. Starting Date:	June 1, 1993
4. Completion Date:	August 31, 1995
5. Total Direct Cost:	$125,577
Funding Source:	
6. Program Head:	Dr. R. Bradley Sack Associate Director, CHD

Protocol Approved by:

R. Bradley Sack 17 May 93

Signature, Program Head / Date

7. Abstract Summary

Birth weight is the single most important determinant of infant survival in developed countries. However, in developing countries, low birth weight (LBW) (<2500gm) may interact with other determinants of infant mortality such as breast feeding, exposure to smoke, growth, socio-economic status, etc., producing higher or lower risk of death than might be expected from each of the risk factors, including LBW, alone. These issues have been very inadequately studied, and never in Bangladesh. Also, we still know very little about the effect of LBW on cause-specific deaths in developing countries.

This study proposes to examine the effect of birth weight and gestational age on infant mortality, including mortality due to respiratory infections, and diarrhoea in the slums of Dhaka City. The attributable risk of LBW for infant mortality will be estimated.

A prospective observational design is proposed for the study. The study population consists of all infants born in the Urban Surveillance System (USS) area in a sample of the slum population of 5 thanas of Dhaka City. All pregnant women in the area will be identified through the USS and enrolled in the study. An arrangement for immediate notification of pregnancy outcomes will be set up so that all newborns may be visited ≤72 hours of birth for weighing the baby and assessing its gestational age. In addition to obtaining infant and maternal anthropometrics, information will also be obtained on infant feeding, exposure to smoke, morbidity and mortality through structured interviews. Each infant will be visited again at 1, 2 and 4 weeks; and at 3, 6, 9 and 12 months of age. All live births (1400) occurring in the USS area in one year will be recruited.

8. Reviews:

i. Ethical Review Committee: _____
(Approved/Not Approved)

ii. Research Review Committee: _____
(Approved/Not Approved)

iii. Director's Signature & remark, if any: _____

SECTION-II: RESEARCH PLAN

A. INTRODUCTION

1. Goals and Objectives

We propose to investigate the role of low birth weight (LBW) as a risk factor for infant death. Mortality differentials between infants born preterm and growth retarded infants will be examined. The study will also assess the effect of LBW on infant morbidity and mortality due to diarrhoea and respiratory infections and describe how LBW interrelates with other determinants of infant mortality.

The study has two broad goals. The first is to provide the information basis for interventions aimed at improving infant health and survival in the urban slums of Dhaka, Bangladesh. The second is to contribute to the literature on infant survival relative to birth weight, gestational age, and other risk factors prevalent in an urban developing country setting.

2. Background

a. Definitions:

According to the World Health Organization, low birth weight (LBW) is defined as a weight of less than 2500 gms at birth (WHO,1984; WHO,1980). LBW babies can be further classified into two broad subgroups: a) preterm, i.e., <37 weeks' gestation and b) small for gestational age (SGA), i.e., babies with intrauterine growth retardation (IUGR) (Ashworth,1992). There is no agreement on the definition of SGA, it being variously defined as birth weight ≤2SD below the mean weight for gestational age or less than the 10th centile according to a sex-specific fetal growth chart, the latter being the most commonly used (Pearse,1989; Ashworth,1992; Agair,1989; Kramer,1989). IUGR infants are not a homogeneous group as well. Investigators have subdivided IUGR into two categories: a) Type 1, i.e., symmetric or proportionate IUGR, caused by chronic intrauterine undernourishment resulting in infants with proportionate reduction in weight and length and thus a normal ponderal index and b) Type II, asymmetric or disproportionate IUGR, characterized by wasting with normal skeletal growth and a low ponderal index and reflects fetal malnutrition in the third trimester (Villar,1982a; Adair,1989). Ponderal Index, also known as Rohrer's Index is defined as 100 times weight (gms) by length (cms) cubed (Adair,1989; Pearse,1989). It needs to be emphasized that the above mentioned categories are not mutually exclusive, i.e., a premature infant can also have IUGR, a NBW can be both preterm and SGA. However, for the sake of simplicity, most of

the following review of the literature will ignore this overlapping of the various categories.

Abbreviations

LBW	:	Low Birth Weight (<2500 gms)
NBW	:	Normal Birth Weight (≥2500 gms)
PT	:	Pre-Term/Premature (<37 weeks gestation)
SGA	:	Small (weight) for Gestational Age
AGA	:	Appropriate (weight) for Gestational Age
IUGR	:	Intra-Uterine Growth Retardation
LMP	:	Last Menstrual Period

b. Prevalence:

According to World Health Organization estimates, about 21 million infants with low birth weight (LBW) were born in 1979, nearly 20% of all births worldwide (WHO,1980). However, more than 90% of the world's LBW infants are born in developing countries, of which, almost two-thirds occur in Middle South Asia (India, Pakistan, Bangladesh). Studies indicate that the incidence rates of LBW in parts of India and Bangladesh may be as high as 50% of all live births (WHO, 1980). One study from neighbouring India found a rate of LBW as high as 50% in the urban slums of Calcutta (Patel,1989). Another review of several studies from India concluded that the incidence of LBW ranged from 24-39% (Bhargava,1985).

It is assumed that in countries where the rate of LBW is relatively high (e.g. above 10%), the proportion of LBW infants who are growth retarded is almost twice that of LBW infants due to preterm delivery. In countries with low rates of LBW (5-10%), the reverse appears to be the case (Villar,1982).

Since birth weight alone is also very predictive of infant outcome, the distribution of weights within the LBW category assumes importance. In 1980, WHO published a review of LBW studies from around the world (WHO,1980). Among studies that provided birth weight distributions, not more than 10% of the births weighed 2000 gms or less. This however did not apply to South Asian populations where, in some areas, birth weights less than 2000 gms occurred at rates in excess of 20%.

The extent of LBW has not been well documented in Bangladesh, and less so in the urban slums. Data from rural Bangladesh, based on both clinic and home deliveries, suggest that the rates of LBW may be as high as 50% or even more (Khan,1979; Canosa,1989; WHO,1980). Another study found that the mean weight of all births occurring in a hospital in rural Bangladesh over a two year period was 2477 gms (Hort,1987). An unpublished study from

Matlab, another area in rural Bangladesh, reported 2587 gms as the mean birth weight of 77 clinic delivered babies (Fauveau,undated). There are several clinic/hospital based studies assessing the incidence of LBW in urban Bangladesh. In a clinic in Dhaka City, 44% of the sampled births in 1983 and 41% in 1989 weighed less than 2500 gms (Canosa,1989;Huque,1991). These births represent a low to middle socio-economic segment of the urban population. There is no birth weight data for the slum population of Dhaka City except for the information on 33 births weighed as part of a pilot project in the slums. The incidence of LBW was 27% in this birth sample (personal communication, A Uzma). This was a community based study where the babies were weighed in their homes within 72 hours of birth. This is a low estimate when compared with the results of other studies from Bangladesh. A probable reason for this may be the population used for the study. The pilot study was conducted in the 70 research clusters of the Urban Volunteer Programme of ICDDR,B. This was a mixed sample, consisting of about 60% slum and 40% non-slum population. As such, the study population may have been, socio-economically, somewhat better off than most of the other populations studied in Bangladesh as well as the slum population to be used for the proposed study. Furthermore, the small sample size and the likelihood that a large number of the births may have been missed by the notification system, raises suspicion regarding the accuracy of the estimates from the pilot project.

Only 4 studies of Bangladesh populations were located that provided information on prevalence of LBW by birth weight-gestational age categories. In rural Matlab, 10% of the births weighed less than 2000 gms (Khan,1979). Canosa (1989) conducted a perinatal survey in four different locations, an urban hospital and a clinic, a rural hospital and rural home deliveries. He found that 48 to 82% of LBWs were IUGR, the highest rates being in the poor rural population and the lowest in the urban middle class. About eleven percent of the births were ≤2000 gms (all 4 locations combined). In a 1989 study of births in an urban clinic in Dhaka utilized by low middle and lower classes, only 2.3% of the infants weighed ≤2000 gms at birth (Huque,1991). Of the births in a large rural hospital, north of Dhaka, 6.1% of births were premature (<35 wks) and 12.7% were growth retarded (≥35 wks & <2000 gms) (Hort,1987). In addition to these studies, data from the pilot project in Dhaka slums show that only 6.1% weighed less than 2000 gms and 21.2% weighed 2000-2499 gms. About fifty six percent (55.6%) of the LBW infants had IUGR, the rest being only preterm (personal communication, A Uzma).

c. Effect on mortality and morbidity:

It is now well established that birth weight is the single most important determinant of infant survival in developed countries (McCormick,1985; Kramer,1987). A study in Baltimore demonstrated LBW as the most important risk factor for both neonatal and post-

neonatal mortality (Shah,1971). Numerous hospital-based studies and a few community based studies in developing countries have provided evidence in support of the hypothesis that even in that setting, low birth weight is an important risk factor for infant mortality (WHO,1980; WHO,1984; Mata,1975; Victora,1987,1988; Ghosh,1979).

In two Bangladesh studies, about 30% of all neonatal deaths have been attributed to "complications of prematurity" or "small size at birth" (Bhatia,1989; Islam,1981). However, these studies did not have an objective measurement of birth weight or gestational age. As such, the attributable risk estimate may have been low as only the most severe cases would have been included. A study from India has estimated that LBW infants contributed over 70% of the perinatal deaths, 90% of the neonatal deaths, and 50% of the infant deaths (Singh,1988).

Several studies in developing countries have reported mortality risks by birth weight, gestational age and birth weight for gestational age. Consistently, premature infants are at higher risk than IUGR infants (Ashworth,1985; Victora,1987). The risk of mortality is highest among infants with birth weight less than 1500 gms, and lowest among infants weighing 3500-4500 gms at birth. The risks are greatest in the neonatal period but persist in the post-neonatal periods (Victora,1987,1988; Ghosh,1979; Rao,1978; Chase,1969).

The relationship between birth weight-gestational age and mortality appears to be quite complex. It has been shown that for a given birth weight, premature infants have higher mortality risk than their older colleagues. Conversely, at a given gestational age, higher birth weight is associated with lower mortality (Koops,1982). Studies have also shown that at comparable birth weights, SGA infants have lower infant mortality rates compared to AGA infants (van den Berg,1966; Starfield,1982). Moreover, at any gestational age, SGA infants had the highest mortality risk (Lubchenco,1972; Koops,1982). The heterogeneity within IUGR is also associated with differential morbidity and mortality consequences. Some studies have shown that disproportionate IUGR (wasted, low ponderal index) infants experience higher neonatal morbidity and mortality as compared to proportionate IUGR, i.e., stunted and normal ponderal index, infants (Haas,1987; Walther,1982; Caulfield,1991).

Although, extensive data exists on the association between low birth weight and infant mortality, not much is yet known about the effect of LBW on cause-specific deaths, especially in developing countries. In a 1985 review of studies from developing countries, Ashworth and Feachem concluded that though there is lack of satisfactory data, it is likely that there is an association between LBW and diarrhoea mortality in areas where diarrhoea is a major cause of death (Ashworth,1985). The

findings of a later review indicate that LBW is an important determinant of pneumonia mortality (Ashworth,1992). A study from India also suggested that low birth weight infants may be at higher risk of dying of respiratory infections (Datta,1987). Victora et al. (1987), studying a South American urban population, found that LBW was associated with higher risks for mortality due to pneumonia (RR[a]=6.7), diarrhoea (RR=2.5) and all infections (RR=3.9). In a subsequent case-control study from the same South American city, similar relative risks for cause-specific infant mortality was observed (Victora,1988). Data from the Inter-American Investigation of Mortality in Childhood implicate LBW as a contributory cause of death in 38% of neonatal respiratory deaths and 49% of neonatal diarrhoea deaths (Puffer,1973). Most studies have shown that the risk of neonatal mortality associated with LBW was higher for pneumonia than for diarrhoea (Ashworth,1992). This difference may be due to the different ages when these infections are acquired, since infants are usually at risk of pneumonia at much earlier ages than for diarrhoea. Evidence supporting this was provided by a Brazilian study where, the risk of pneumonia or diarrhoea deaths was similar once deaths in the first week of life were excluded (Victora,1988).

In a developing country such as Bangladesh, where infant mortality is very high, LBW may act as a direct cause of infant mortality, or as a risk factor resulting in increased incidence or severity of infectious disease during infancy. These relationships have never been studied in Bangladesh. It is known that neonatal mortality is highly related to ante-natal and perinatal factors, such as LBW. The extremely high rates of neonatal mortality in Bangladesh, between 70-90 per 1000 live births, (Islam,1981; Rahman,1989) suggests that LBW is probably associated with a large proportion of infant deaths.

Though the association between LBW and mortality due to pneumonia and diarrhoea appears to be very likely, the relationship between LBW and morbidity due to these two causes remain unclear. Very few studies have examined this issue. Data from India and Central America suggest that LBW infants, especially those with IUGR, may be more likely to suffer from diarrhoea (Mata,1978; Saha,1983; Mertens,1987). An association between LBW and pneumonia morbidity appears to be plausible, though available information have been conflicting. In an Indian study, no difference in pneumonia incidence was detected between LBW and NBW infants (Datta,1987). However, other studies have observed higher rates of respiratory infections (Drillien,1959) and lower respiratory infections (Douglas,1953) among LBW infants. Hospital admission studies indicate higher risk of admissions for acute respiratory infections among LBW infants (Ashworth,1992).

---

[a] RR : Relative Risk

Studies have also suggested that LBW infants may be at higher risk of illness in general (McCormick,1985).

Respiratory diseases are responsible for a high proportion of morbidity and mortality among LBW infants during the neonatal period, when the risk of illness and death associated with LBW is also the highest. In addition to respiratory infections, LBW neonates are at greater risk of suffering and dying from asphyxia and respiratory distress syndrome (Rosso,1989; van den Berg,1966; McCormick,1985; Mayfield,1990; Warshaw,1990; Kliegman,1987). Apart from respiratory diseases, premature neonates are more likely to suffer from respiratory distress syndrome and less likely to have asphyxia than newborns with IUGR (Kliegman,1987). Among the babies with IUGR, the disproportionate are much more likely to suffer from asphyxia (Caulfield,1991; Walther,1982).

LBW newborns are also more likely to have congenital anomalies. The likelihood of having congenital malformations, which are often fatal, is greater among infants with IUGR, especially in the proportionate category (McCormick,1985; van den Berg,1966; Kliegman,1987).

It is thus apparent that premature and disproportionate SGA infants are at highest risk of mortality, especially in the first month of life. However, the survivors in these two categories usually catch up with their term-AGA colleagues in terms of growth. This phenomena can be explained by what has been termed the timing hypothesis for the aetiology of IUGR (Caulfield,1991; Villar,1982a; Villar,1989; Urrusti,1972). Proportionate SGA infants are considered to have been subjected to chronic intrauterine stress, i.e., since early in pregnancy. This has, on the one hand, made them more adaptable to the extrauterine environment, but has also, on the other hand, resulted in a reduction of their growth potential (Rosso,1989; Villar,1989). Disproportionate SGA infants, born with adequate length and brain size, are considered to have suffered intrauterine stress late in pregnancy and thus have preserved most of their growth potential (Villar,1989). The higher mortality in these infants probably reflects functional consequences of late intrauterine deprivation, including reduced metabolic reserves, as will be apparent from the following discussions on the mechanisms leading to morbidity and mortality among LBW infants. In contrast, the higher mortality among premature infants is primarily the result of immature body functions and low birth weight (Mayfield,1991). These infants, not having been subjected to any intrauterine stress, usually tend to preserve their growth potential.

d. Mechanisms by which LBW may lead to morbidity and mortality:

Impaired immunity appears to be an important pathway between LBW and morbidity and mortality. Studies have shown that LBW infants are born with impaired immune systems, however, in infants with IUGR, this impairment lasts much longer than in premature infants

(Ferguson, 1978; Chandra,1981; Saha,1983). Nutritional deficits including micronutrient deficiencies have been known to be responsible, at least in part, for the immune impairment (Gross,1980; Chandra,1983; Chandra,1991). Preterm babies are born with low body stores of iron, zinc and copper since more than 60% of the mother-fetus transfer occurs in the 3rd trimester (Widdowson,1974). Babies with IUGR have smaller livers and thus smaller micronutrient stores (Usher,1974). Premature and SGA infants also tend to have lower vitamin A levels (Wallingford,1986; Shah,1984). Premature infants have lower levels because a major part of the maternal-foetal transfer occurs in the later part of pregnancy (Takahashi,1975, Wallingford,1986; Montreewasuwat,1979). The lower levels observed in IUGR is probably associated with the liver size, which tends to be smaller in infants with IUGR (Usher,1974). The low levels of vitamin A have obvious negative implications for the infant in terms of immune function (Smith,1987) and morbidity and mortality (Humphrey, 1992; Sommer,1983,1986).

Impaired pulmonary functions may partially explain the higher risk of pulmonary diseases among LBW infants. In two studies of pulmonary function of LBW infants, lung function was found to be impaired until at least 7 years of age (Mansell,1987; Chan,1989). LBW infants who suffer from respiratory distress syndrome have a higher likelihood of contracting lower respiratory infections later (Outerbridge,1972). Immaturity of surfactant production and lung structure, more likely in the premature baby, is the basic problem leading to the development of respiratory distress syndrome. Asphyxia, which inhibits surfactant production may also trigger or exacerbate respiratory distress syndrome (Gross,1990). Infants with IUGR are at high risk of asphyxia since, a chronic reduction in placental blood flow may result in persistently low oxygen and glucose availability to the foetus, the later leading to a reduction in foetal glycogen stores (Caulfield,1991; Rosso,1989).

Hypothermia and hypoglycemia are two additional mechanisms whereby LBW may lead to neonatal morbidity (Kliegman,1987). Premature and SGA neonates are at high risk of suffering from hypothermia and hypoglycemia (Rosso,1989; Kliegman,1987; Lubchenco,1971). Both of these are potentially lethal conditions. Disproportionate SGA infants are at higher risk of hypothermia and hypoglycemia compared to the proportionate (Caulfield,1991; Walther,1982).

Newborns respond to environmental cold through several mechanisms including generation of heat through exothermic metabolism in the subcutaneous brown adipose tissue (Mayfield,1990; Rosso,1989; Aherne, 1966). Since most of the adipose tissue deposition occurs in the third trimester, premature infants have low or absent brown adipose tissue, thereby explaining their higher risk for hypothermia (Mayfield,1990; Aherne, 1966). SGA infants,

especially the disproportionate, also have low brown adipose tissue for similar reasons (Villar,1989; Warshaw,1990). The presence of hypoglycemia may reduce the efficacy of the thermogenetic mechanism (Bhakoo,1974; Hey,1969).

Hypoglycemia in the LBW infant is thought to be the result of low glycogen stores at birth, higher metabolic rates due to low fat stores and hypothermia, higher glucose needs due to relatively larger brain size (especially in the disproportionate baby), and defects in glucose metabolism (Caulfield,1991; Rosso,1989). Asphyxia and hypothermia, by reducing glycogen stores, may also precipitate hypoglycemia (Mayfield,1990).

It is thus obvious, that asphyxia, respiratory distress, hypothermia and hypoglycemia are closely associated conditions, and the occurrence of one predisposes the neonate to the others.

LBW infants show considerable catch-up growth, growing faster than their normal birth weight (NBW) colleagues, though, never quite achieving the growth of the NBW infants. However, IUGR infants remain persistently stunted even 3 years after birth as compared to preterm infants who, starting at a smaller weight, grow rapidly to surpass the IUGR infants by 1 year of age and almost attain the weight of the infants born at term with normal weights (Mata,1975; Villar,1984, Cruise,1973; Saha,1983). Infants with proportionate IUGR achieve significantly lower post natal growth compared to infants with disproportionate IUGR who show considerable catch-up growth (Holmes,1977; Villar,1984; Adair,1989).

It has been suggested that the continued growth retardation in the IUGR infants, especially among the stunted, may reduce the ability of the respiratory system to respond effectively to infective agents with a consequent increase in morbidity and mortality (Ashworth,1992). This may in part be due to chronic pulmonary conditions in SGA infants predisposing to respiratory infections (McCormick,1985) and in part due to impairment of immune functions as a consequence of growth faltering (Beisel,1979). In addition to impaired immunocompetence, immature lung function and impaired post-natal growth, reduced breast feeding may also be responsible for the higher risk of pneumonia deaths associated with LBW since studies have shown that LBW infants may be less likely to be breastfed (Barros,1986). Reduced breast feeding, continued post-natal growth faltering and impaired immune functions may also be important factors in the causal pathway between LBW and diarrhoea morbidity and mortality.

e. Interactions with other Factors:

In a study of a New York population, it was found that socioeconomic circumstances had little effect once birth weight was controlled for (Paneth,1982). This suggests that in

developed countries, the effect of low socioeconomic status on mortality risk operates primarily through infant birth weight. There is no data to suggest that a similar phenomenon exists in developing countries. However, in environments where low socioeconomic status is related to poor sanitation, low literacy, lack of access to health services, and other important risk factors that persist throughout infancy, then it seems unlikely that LBW would be the most important factor in the causal pathway between socioeconomic status and infant survival. We would thus expect that the relative risk for infant death associated with low birth weight to be lower than the levels observed in developed countries with other proximate determinants of death playing more important roles.

In developing countries, low birth weight may interact with other determinants of infant mortality such as low socio-economic status, not breast feeding, poor growth, exposure to smoke, etc. Such interactions may produce higher or lower risk of death than might be expected from each of the risk factors including LBW, alone. These issues have been very inadequately studied, mainly because most births in developing countries occur at home resulting in lack of birth weight data.

The effect modification may occur in two ways. The risk associated with the "effect modifiers" may be dependent on the birth weight-gestational age characteristics of the infant, e.g., not breast feeding or poor growth may increase the risk of LBW infants to a greater extent than NBW infants. Alternatively, the "effect modifiers" may have direct independent effects on infant mortality risk, e.g., poor socio-economic status may produce an additive increase in the mortality risk in both LBW and NBW infants, thus reducing the mortality differentials between the two groups.

A review of the literature suggests that both mechanisms may be operative for most of the effect modifiers. In a Brazilian study, Victora et al (1987) provide supporting evidence for this supposition. They report that the relative risk of death associated with LBW was about 3.5 times higher in the high income families. Review of the absolute infant mortality rates indicate that being in the low income group increases the mortality risk of both LBW and NBW infants, though the increase in risk of NBW infants is much higher (5.3 times) than the risk of LBW infants (1.5 times). This may be explained by postulating that LBW infants may already be at the extremes of mortality risks and other factors may have limited capacity in further increasing he risk. Alternatively, improvement in the economic conditions may be more likely to produce greater mortality reduction in the NBW infants than in the LBW infants. Furthermore, the greater contribution of the lower risk IUGR in the LBW category in developing countries may also have a role in limiting any increase in mortality risks among the LBW infants. It is obvious

that low SES increases mortality risks across the board, however, the increase is relatively greater in the NBW infants. Therefore, part of higher risk associated with low SES is independent of infant characteristics, another component is conditioned on such characteristics.

Complex interactions are likely between birth weight, breast feeding, growth and mortality. A review of the literature indicate the presence of associations between birth weight and breast feeding, breast feeding and growth, birth weight and growth, breast feeding and mortality, and growth and mortality.

Birth weight and breast feeding:
Several studies have shown that low birth weight infants may be less likely to be breast fed and if breast fed, more likely to be weaned at earlier ages than their heavier colleagues (Lopez,1984; WHO,1981; Barros,1986). However, others studies have failed to observe an association between breast-feeding and birth weight (WHO,1981).

Breast feeding and growth:
Breast-feeding is now considered an important determinant of infant growth. One study reported growth in excess of the NCHS average in a cohort of exclusively breastfed infants during the first 3-4 months of life (Butte,1984). In another study, infants weaned earlier had slower subsequent growth than infants weaned at a later age (Rowland,1986). Studies have also noted that the nutrient composition of breast milk of mothers of preterm infants is adequate for the needs of the infant (Gross,1983; Anderson,1981).

Birth weight and growth:
We have already noted that LBW infants usually achieve poorer growth than NBW infants (Saha,1983). The growth faltering is marked in the proportionate SGA infants, as compared to preterm and disproportionate SGA babies (Adair,1989). This may be explained partly by reduced growth potential at birth, especially in infants with proportionate IUGR. Many studies from developed countries have demonstrated this phenomena (Falkner 1981; Cruise 1973; Van den Berg,1966). Some data from developing countries have also shown a similar relationship (Saha,1983). Perceived inadequate growth leading to earlier, often inadequate, weaning with resultant higher risk of infections may also be responsible for the retarded growth among the LBW infants (Barros,1986). Poor milk volume production in mothers of LBW infants may be yet another reason for the slower growth in these infants (Whitehead,1978; WHO,1981).

Breast feeding and mortality:
There is no doubt that breast-feeding is an important determinant of infant survival. Several studies have shown a

negative association between exclusive breast feeding and infant mortality (Grulee,1934; Robinson,1951; Plank,1973; Victora,1987a). Even in preterm infants, breast feeding has resulted in reduced mortality (Joaquim,1985).

Growth and mortality:
Growth faltering during infancy is associated with higher risk of death (Kielman,1978; Chen,1980; Heywood,1982; Alam,1989). Undernourished children are more likely to die of infectious diseases such as pneumonia and diarrhoea (Tupasi,1988; Martorell,1984). Impaired immune functions is believed to be mainly responsible for predisposing malnourished children to infections (Beisel,1979). The combination of growth faltering, the higher likelihood of impaired immune functions, and chronic functional consequences of the perinatal experience place LBW infants, especially those with proportionate IUGR, at increased risk.

The close interlinkage between birth weight, breast feeding and growth is very likely to modify the effect of each on infant mortality, often in ways that may be difficult to understand and explain. Further information will be required to improve our ability to understand the complex interplay of these factors and be in a better position to plan appropriate interventions. We may even conceive of a scenario where some LBW infants who receive appropriate nutrition and achieve catch-up growth, are able to overcome the disadvantage acquired at birth in terms of higher long term mortality.

The situation is further complicated by the continued presence in the infant's environment, of the factors that are potentially related to infant survival, independent of birth weight and gestational age. Among these factors, exposure to environmental smoke have been receiving considerable attention. In developing countries, a child's exposure to smoke is usually from two sources, cigarette smoking, usually by parents, and biomass smoke, usually from cooking (Smith,1992). Several studies have shown an association between exposure to smoke, either tobacco or biomass, and ARI morbidity (Chen,1988; Pandey,1989; Smith,1992). It is likely that exposure to smoke is also a risk factor for mortality, especially from ARI, though there is lack of data to support this hypothesis (Smith,1992). However, indirect evidence of a mortality effect of smoking is available from a study evaluating the association between maternal smoking (during pregnancy) and infant mortality (Malloy,1988). The authors report that maternal smoking has virtually no effect on overall neonatal mortality once adjusted for birthweight, but is still a significant risk factor for infant mortality due to respiratory diseases. Malloy et al (1988) explain this by suggesting that most of the effect of maternal smoking on neonatal mortality plays through birth weight. This is supported by the now well established fact that maternal smoking is an important

determinant of LBW (Sexton,1984). Reviewing their data, Malloy et al (1988) also suggest that the excess risk for respiratory disease deaths may be the result of continued exposure to smoke after birth. This is plausible since mothers who smoke during pregnancy are likely to do so after birth as well.

In evaluating the effect of smoke exposure on infant mortality, it is often difficult to disentangle the effect of pre and post natal exposure (Chen,1988). It is also hard to disaggregate the effects of tobacco and biomass smoke especially when a child may be exposed to both. Nevertheless, Campbell et al (1989) report that carriage on mother's back (proxy for exposure to cooking smoke) and father's smoking habits are independently associated with higher mortality risks. Researcher's have also provided evidence of possible interactions between birth weight and post-natal exposure to smoke. Chen et al (1988) reported higher smoke associated ARI morbidity in the lower birth weight infants. In the study by Malloy et al (1988), higher risk for respiratory disease deaths was reported in the LBW babies, and as we have already discussed, this is more likely the effect of post-natal exposure rather than that of pre-natal exposure acting through birth weight.

It would be of considerable interest to examine the interplay between birth weight and smoke exposure in a population as underprivileged as the slums of Dhaka. Since the reported prevalence of cigarette smoking among females in this population is as high as 20% (Rogers,1992), and about ??% of the households use smoke producing cooking fuel (Unpublished data, UHEP,1993), this issue is likely to be important and would need to be described before effective interventions can be planned and implemented in this population.

3. Rationale

The prospective design will enable us to observe the effect of birth weight, gestational age, birth weight for gestational age, and heterogeneity among the growth retarded, on infant morbidity and mortality by major causes. We will not be classifying the birth into the various birth weight categories at the time of data collection, but will do so at the time of analysis. This will enable us to examine the appropriateness of the criteria used for the categorization.

We will also be able to examine the role of other factors, especially breast feeding, growth, exposure to smoke and socioeconomic status, as determinants of infant mortality or as confounders in the relationship between LBW and infant mortality. The proposed study design will allow us to examine the possibly complex interactions that may exist in between these factors. As we have already mentioned, LBW influences subsequent breast feeding

and nutritional status after birth. Studies have also observed that both breast feeding and malnutrition are important determinants of infant mortality (Wray,1977; Alam,1989). We also note that the mortality risk estimates for LBW in most of the studies referred to "Background" section were not adjusted for breast feeding and post-natal nutritional status. Therefore, it is difficult to assess the extent to which low birth weight is itself responsible for infant mortality over and above that due to these factors. The confounding or interaction effect of socio-economic and environmental factors need further investigation.

The study will have adequate statistical power to detect neonatal and infant mortality differences between preterm, SGA and AGA infants and between different birth weight categories. We will also be able to investigate, with statistical certainty, the effect of birth weight on infant mortality due to respiratory infections and diarrhoea. However, the study will be limited in its ability to investigate the mortality effect during the post-neonatal period, mortality due to other causes, heterogeneity within the IUGR category, and interactions with other factors. Despite the limited power on these issues, the study will provide essential slum-specific descriptive statistics and information on important trends, that will be useful for both programme planning and future studies.

The urban slum population of Dhaka is a particularly depressed segment of the community. Infant mortality may be as high as 142 per 1000 live births. Infectious diseases are responsible for a major portion of infant deaths (Unpublished data, UHEP, 1992). The prevalence of LBW in this population is also expected to be high. It is likely that infants, irrespective of birth weight may be at high risk of death. The role of birth weight and gestational age in determining infant survival in such a unique environment needs to be assessed.

B. SPECIFIC AIMS

The main objective of the proposed research is to examine the effect of low birth weight on infant mortality due to diarrhoea and respiratory infections. The study will also evaluate the effect of LBW on morbidity due to diarrhoea and respiratory infections during infancy. In addition, the possible effects of breast feeding, infant growth, exposure to smoke, socioeconomic status and other risk factors will be explored for their relationship to LBW and infant mortality. The specific objectives and associated hypotheses are:

i. Descriptive Objectives

1. To determine the incidence of low birth weight and estimate neonatal and post neonatal mortality rates.

2. To examine the effect of birth weight and gestational age on post-neonatal mortality.

3. To describe the effect of heterogeneity among infants with intrauterine growth retardation on infant mortality.

4. To assess how birth weight is associated with cause-specific infant mortality.

5. To describe the morbidity and mortality experience of the neonate as it relates to birth weight and gestational age.

6. To examine how (a) socioeconomic status, (b) breast feeding, (c) catch-up growth, and (d) household smoke may influence the effect of birth weight on infant mortality.

7. To estimate the attributable risk due to LBW for infant mortality.

ii. Hypothesis Testing Objectives

Objectives

1. To estimate the effect of low birth weight on infant mortality.

2. To examine the effect of intrauterine growth retardation, prematurity and birth weight less than 2000 gm on neonatal and infant mortality.

3. To assess how birth weight is associated with infant mortality due to respiratory infections, and due to diarrhoea.

Specific Hypotheses

1. *Higher neonatal, post-neonatal and infant mortality rates will be observed among infants with LBW compared to NBW infants.*

2. *Higher infant and neonatal mortality rates will be observed among infants born preterm compared to NBW infants.*

3. *Higher infant and neonatal mortality rates will be observed among infants born with intra-uterine growth retardation compared to NBW infants.*

4. *Higher infant and neonatal mortality rates will be observed among infants born preterm compared to infants born with intra-uterine growth retardation.*

5. *Higher infant mortality rates will be observed among infants weighing <2000 gms at birth compared to infants weighing 2000-2499 gms at birth.*

6. *Infant mortality due to respiratory infections and diarrhoea will be negatively associated with an infant's birth weight.*

Special Notes:

1. Newborns weighing less than 1500 gms at birth are conventionally identified as very low birth weight (VLBW) babies given the extremely high risk associated with this category (McCormick,1985). However, in the proposed study, the cut-off of 2000 gms will be used to differentiate within the LBW category. The proposed study design has a higher likelihood of producing a biased sample of <1500 gm birth weight newborns due to under-reporting and early death, hence the choice of a higher cut-off. However, to avoid confusion the term very low birth weight will not be used for newborns weighing less than 2000 gms.

2. Attributable risk is probably the single most important statistic for identifying program priorities and evaluating program effectiveness. Though several definitions have been used, attributable risk conventionally indicates the proportion of the "disease" in the population that can be attributed to the "risk factor" of interest (Lilienfeld,1980). It is affected by both the relative risk of the "disease" associated with the "risk factor" and with the prevalence of the "risk factor" in the population (Kahn,1989), and is thus very population-specific. Public health workers use attributable risk to estimate expected reduction in the "disease" in the population following reduction in the prevalence of the "risk factor", i.e., the possible impact of an intervention aimed at reducing the "risk factor".

   A high attributable risk for infant mortality has been associated with LBW. However, these estimates have usually been based on data from studies in developed countries where the relative risk of mortality among LBW infants is very high. It has been suggested that in developing countries, the impact of improving birth weight on death rates may not be high, given the low relative risk in these countries (Victora,1987). However, it is likely that very high prevalence of LBW, as has been seen in South Asia, may result in a high attributable risk estimate even in the presence of low relative risks. This is a likely scenario in the slums of Dhaka, thus justifying the need for estimating the attributable risk of being LBW for infant mortality, taking into account the effect of interacting factors and confounders.

C. METHODS OF PROCEDURE

1. Study Population

This study has been designed as a follow-on to another study examining the determinants of low birth weight and perinatal mortality in the same pregnancy cohort.

The study population consists of all live born infants living in the Urban Surveillance System (USS) area in Dhaka. The Urban Surveillance System is operated by the Urban Health Extension Project (UHEP) of the International Center for Diarrhoeal Disease Research, Bangladesh (ICDDR,B). The target population of the UHEP consists of the slum population of 5 thanas (Mohammadpur, Lalbagh, Kotwali, Sutrapur and Demra) of Dhaka City. The total slum population in these 5 thanas is about 400,000. There are approximately 800 slums with sizes varying from 10 households each to many thousands (Paljor,1991).

The Urban Surveillance System tracks vital and demographic events in a multistage probabilistic sample of UHEP's target population. Cluster sampling techniques were used for this purpose with sampling units being clusters of 20-55 households. A total of 235 clusters were selected. The total population of the USS area is about 42,700 in about 8200 households. An estimated 1400 births are expected to occur annually in the area.

The longitudinal registration of this population assists researchers by providing baseline information, a sampling frame, and a mechanism to follow subjects over time. Using a quarterly cycle, information is collected on births, deaths, migration, pregnancies, marital status, breast feeding, education, occupation and several socio-economic status (SES) indicators.

In this population most deliveries occur at home. Thus, birth weight or gestational age cannot be assessed unless the pregnancy is identified prospectively, and arrangements for immediate notification of pregnancy outcomes have been made in advance. Therefore, the prospective design is the only option, despite being expensive and time consuming.

2. Inclusion Criteria

All live births in the USS area, after 28 completed weeks of gestation, during the study period will be eligible for the study.

3. Exclusion Criteria

There are no exclusion criteria. Infants not weighed within 72 hours or those who die before being weighed within 72 hours will **NOT** be excluded but analyzed separately. These infants will be included to provide a complete description of the mortality experience of infants in this population and provide information on possible selection bias. Infants who have congenital anomalies such as cerebral palsy, cleft lip or palate will also **NOT** be excluded, since congenital anomalies is often associated with LBW.

4. Study Design

This is a prospective "open-cohort" observational study. All pregnant women in the area will be identified through the USS by the fourth month of pregnancy and enrolled in the study. An arrangement (described later) for immediate notification of pregnancy outcomes will be worked out with the mother so that all newborns may be weighed within 72 hours of birth. The infants will be prospectively followed until they are 12 months old.

This study will collaborate, with two other studies on the same cohort of mothers and infants. On study examines "**maternal morbidity and choice of delivery services**", and the other seeks to identify "**the determinants of LBW and perinatal mortality**". The collaboration will primarily be in the form of coordination and sharing of information, manpower and visits.

5. Variables and Data Collection

a. Variable Definition and Measurement

Appendix A provides operational definitions of all variables to be used in this study. The construction of secondary variables have also been presented.

Several kinds of variables will be collected; some as continuous variables (e.g. educational level, age, income, etc.); some will be collected on ordinal scales (e.g. severity of illness, etc.); and some according to nominal categories (e.g. presence/absence of a characteristic or condition, etc.). The continuous variables may later be categorized based on the literature, and/or the distribution of our data.

The dependent variables in this study are:

1) a) Overall infant mortality (yes/no)
   b) Infant mortality due to pneumonia (yes/no)
   c) Infant mortality due to diarrhoea (yes/no)

2) Infant morbidity (pneumonia or diarrhoea)
(# of days, # of episodes; during the total recall period preceding the seven visits)

The independent variables (excluding secondary variables) are:

1) Infant status at birth:
Birth weight; length; gestational age; and head, chest and arm circumferences.

2) Infant growth:
Weight; length; and head, chest and arm circumferences.

3) Infant care:
Breast feeding (initiation, duration, etc.); and health care.

4) Maternal factors:
Gravidity; age; preceding and succeeding interpregnancy interval; and maternal nutritional status (anthropometrics).

5) Socioeconomic and household factors:
Education; employment; income; dwelling structure, assets; religion; number of household members; indoor cooking smoke, and passive tobacco smoke.

b. Data Collection Procedures

In the proposed study, infant anthropometrics and retrospective interviews to assess infant feeding, morbidity and mortality will be conducted on the study cohort. In addition, observations of the household environment will be made including type of cooking area and stove and structure of house.

Table I
Summary of Activities at Follow-up Visits

INFORMATION TYPE	VISITS							
	1st (≤72hrs)	2nd (1wk)	3rd (2wks)	4th (1mo)	5th (3mos)	6th (6mos)	7th (9mos)	8th (12mos)
Infant Anthropometrics	✓			✓	✓	✓	✓	✓
Maternal Anthropometric		✓		✓	✓	✓	✓	✓
Gestational Age	✓							
Morbidity-Mortality	✓	✓	✓	✓	✓	✓	✓	✓
Infant Feeding	✓	✓	✓	✓	✓	✓	✓	✓
Pregnancy Status					✓	✓	✓	✓
Passive Smoking		✓		✓	✓	✓	✓	✓
Household Smoke		✓		✓	✓	✓	✓	✓

Trained field workers will visit each mother-child unit eight times over a period of 12 months, i.e., within 72 hours of delivery; at 1, 2 and 4 weeks of age; and at 3, 6, 9 and 12 months of age. The first three visits will be shared with the other two collaborating studies (**maternal morbidity..** and **determinants of LBW..**). The details of the data collected at all visits have been presented in Appendix B. Table I presents a summary of the data collected at each visit.

Information on morbidity and mortality will be used to assign cause of illness and death based on the case definitions and criteria presented in Appendix C. In case of death, verbal autopsies will be performed to elicit information on events preceding death. For liveborn infants who die before being weighed, verbal autopsies will still be performed to obtain cause of death. These infants will be included in the analysis of cause-specific mortality. Live infants, reached after 72 hours will still be weighed. Data on household cooking and risk of exposure to smoke will be updated whenever there is change/shift in household structure.

Some information, on parental characteristics and the mother's pregnancy history, including immunizations with tetanus toxoid, that will be collected as part of the collaborating studies (**maternal morbidity...** and **determinants of LBW...**), will also be used for this study (Table II). Additional information available from the Urban Surveillance System database are also listed in Table II.

Table II
Supplementary Information

FROM THE COLLABORATING STUDIES

<u>Mother</u>

* Age
* Marital Status
* Interpregnancy interval preceding current birth
* TT Immunization
* Prior pregnancy outcomes
  - # of miscarriages
  - # of still births
  - # of live births
* Number of children still alive

<u>Father</u>

* Age

<u>Infant</u>

* Sex
* Birth Order
* Immunization

FROM THE URBAN SURVEILLANCE SYSTEM DATABASE

Education (mother & father)
Income
Dwelling structure
Number living in house
LMP prior to birth of participating infant
Employment (mother & father)
Religion
Assets
Water & sanitation

All attempts will be made to undertake the visits on time, as required by the protocol. The first visit must be made immediately after receiving notification of the birth. The next three visits will be made within ±2 days of the scheduled day, though the second visit cannot be before 7 days post partum. Remaining visits may be made within ±1 week of the schedule. For infants who move out of the USS clusters, but are still in Dhaka City, whenever possible, their addresses will be obtained from family members/neighbours in an attempt to continue follow-up of these infants outside the USS area.

The gestational age assessment within 72 hours will be conducted by interviewers with some medical training. These interviewers will primarily collect information for the collaborating study on **"maternal morbidity ..."**. All other interviews and assessments will be conducted by trained study interviewers (without medical qualifications).

Interviewers will be trained at a maternity clinic and a children's hospital on anthropometric measurements and gestational age determination. They will undergo field training on the use of questionnaires, morbidity follow-up and verbal autopsy. With respect to anthropometric measures and gestational age assessments, the interviewers will undergo reliability training before starting data collection. The reliability of these measurements will be periodically verified throughout data collection.

6. Logistics

A pregnant woman should be identified by the USS system within the first 16 weeks of pregnancy. As part of the collaborating study on **"determinants of LBW..."**, the Study Interviewers will visit the pregnant woman at about 6 months of pregnancy to explain the study and enroll her. The method of immediately notifying her pregnancy outcome will be explained to the pregnant woman. She will be given a "referral card" which will include her name, an identification number, household address (or location), and expected date of delivery. A household member will be identified who will notify the woman's delivery by bringing the card into the nearest UHEP field office as soon as possible after labour starts. If no household member is able to notify, then the woman will be asked to identify a close friend or neighbor living nearby who can be enlisted to notify the birth. The family notifier will be invited to accompany the Interviewer to the office to make location at the time of notification easier. At the subsequent prenatal visit, the procedure will be explained again to both the woman and the notifier and they will be encouraged to report the delivery promptly. The family notifier will receive travel reimbursement and will be compensated for lost income due to the time spent to notify.

Anthropometric measurements require large and often heavy equipment. Since we are proposing to obtain maternal and infant anthropometrics in the home, this poses some logistic problems. Therefore, a Female Helper (FH) will be recruited on a daily wage basis. The FH will accompany the Study Interviewer (SI) on all the visits, except the third visit at 2 weeks post-partum. The FH will not only assist in the transport of the equipment but also during actual measurements. The team of two (FH & SI) will use auto-rickshaws/rickshaws for transporting the equipment to the slums.

Notification during the 2 day weekend is likely to be a problem. This will be handled by having the interviewer and helper teams take weekends off on different days. This will slightly increase manpower needs.

Since hypothermia is of concern in newborns, especially in the LBW, all examinations, such as gestational age assessments, observations for chest retractions, etc., will be conducted without completely uncovering the child. The newborn will be weighed wrapped in a "gumchaa" (a local towel made of thin cloth) of standard weight. After weighing, the "gumchaa" will be given to the child as a gift.

Some of the births in this population may take place in hospitals and clinics in Dhaka City. The most likely institutions will be identified and arrangements will be made with them for collecting information on birth weight, and allowing our interviewers to visit the mother and infant for collecting information on morbidity and mortality during the stay in those institutions.

All infants requiring treatment will be referred to the nearest health care facility with whom we will already have made collaborative arrangements for such referral. If the office is notified of an emergency (before, during or after delivery and during infancy), or the interviewer encounters one during her visit, then the woman and/or the infant will be immediately referred to the collaborating hospitals. All infants will also be referred for immunizations at each visit prior to the recommended time for vaccination. Such referral will provide information on timing and availability of vaccination. Reminders will be given at subsequent visits, if necessary.

7. Sample Size

The hypotheses 1-6 (page 15) will be the basis for the sample size calculations. Due to logistic constraints, i.e., the need for a large sample size, the remaining objectives will only involve descriptive statistics.

Expected incidence of LBW, IUGR and prematurity in the study population and the associated relative risks for death based on currently available information. Appendix D summarizes available

information on prevalence of LBW and its sub-categories in Bangladesh and presents some information on relative risks for infant mortality by birth weight categories.

Preliminary analysis of the 1st year data of the USS reveal that the infant mortality rate (IMR) is about 142 per 1000 live births. Of these infant deaths, about 22.5% have been estimated to be due to respiratory infections and 20.7% due to diarrhoea (Unpublished data, UHEP,1993). Based on the USS data, and on the review presented in Appendix D, we made some assumptions for the study population regarding the expected incidence of LBW (<2500 gms) and relative risks for infant mortality (overall & cause specific) by birth weight-gestational age categories. These assumptions are presented in Appendix E. The expected relative risk of mortality for LBW vs. NBW, i.e., 3.0, is the weighted average of the relative risks associated with the different birth weight categories, the weights being the population distributions of these categories. We have also assumed that the same relative risk (3.0) will apply when comparing LBW to NBW in terms of infant mortality due to respiratory infections and diarrhoea.

We propose to recruit all live births (about 1400) occurring in the USS area in one year. We expect that about 15% of the births would not be notified or not notified soon enough to be weighed within 72 hours. We also expect a 5% refusal to participate and a 20% lost to follow up during the study. Adjusting the sample size for these factors, the starting size of the cohort becomes (1400*0.85*0.95* 0.80)=904. We also expect that some pregnant mothers will deliver at their parental homes, usually located outside Dhaka. This would, obviously, reduce the number of births available for this study. However, we do not account for this in our sample size as it is already accounted for in the birth rate where only births occurring in the USS areas are included. Since the last recruited infant will have to be followed for 12 months the total length of the data collection period will be 24 months.

Table III presents power of the study to detect a given difference (shown in Appendix E) for the various comparisons, when the total sample is 904.

Table III
Power Calculations at the 5% Significance Level

Group 1 (high risk)			Group 2 (low risk)			Power
Category	Number	MR	Category	Number	MR	
Overall Infant Mortality as the Outcome						
LBW	271	26.6%	NBW	633	8.9%	>99.9%
IUGR	163	17.7%	NBW	633	8.9%	86.2%
Preterm	108	39.9%	NBW	633	8.9%	>99.9%
Preterm	108	39.9%	IUGR	163	17.7%	98.0%
2000-2499gm	181	17.7%	NBW	633	8.9%	88.5%
<2000gm	90	44.3%	NBW	633	8.9%	>99.9%
<2000gm	90	44.3%	2000-2499gm	181	17.7%	99.5%
Infant Mortality due to Pneumonia as the Outcome						
LBW	271	6.0%	NBW	633	2.0%	83.3%
Infant Mortality due to Diarrhoea as the Outcome						
LBW	271	5.5%	NBW	633	1.8%	80.4%
Neonatal Mortality as the Outcome						
LBW	305	14.6%	NBW	712	3.6%	>99.9%
IUGR	183	8.9%	NBW	712	3.6%	80.0%
Preterm	122	23.2%	NBW	712	3.6%	>99.9%
Preterm	122	23.2%	IUGR	183	8.9%	92.3%
Post-Neonatal Mortality as the Outcome						
LBW	271	11.9%	NBW	633	5.3%	91.1%
IUGR	163	8.8%	NBW	633	5.3%	40.3%
Preterm	108	16.7%	NBW	633	5.3%	95.3%
Preterm	108	16.7%	IUGR	163	8.8%	50.0%

Note: The larger sample size in the neonatal period reflects 10% losses to follow up rather than the 20% for the whole study.

A method modified from Fleiss (1981) has been used for the power estimation. The following formula have been used. The probability of Type I error used in the estimations is 0.05.

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

Where, n = Sample Size in the Experimental (higher risk) Group
r = (# in Group 2)/(# in Group 1) Ratio
$z_{\alpha/2}$ = Normal Deviate for Type I error
z_{β} = Normal Deviate for Type II error (1-Power)
P_1 = Event Probability in Group 1
Q_1 = Non-Event Probability in Group 1
P_2 = Event Probability in Group 2
Q_2 = Non-Event Probability in Group 2
$\overline{P}$ = Weighted Mean Event Probability = $\frac{P_1+rP_2}{r+1}$
$\overline{Q}$ = Weighted Mean Non-Event Probability = $1-\overline{P}$

As we can see, the power of the study ranges from as high as 99.9% to as low as 40.3% at the 5% significance level, depending on the specific comparison and outcome of interest.

8. Data Management and Analysis Plan

Each afternoon, the returned questionnaires and data forms will be reviewed and edited by a field research officer for completeness and accuracy. If necessary, an interviewer will revisit the household for clarification or missing information. Data will then be entered into the computer. A program incorporating range and consistency checks will be used for data entry. Data will be periodically checked using frequency distributions and cross-tabulations to identify outliers and illogical data.

Descriptive statistics (mean, median, variance, frequency tables) will be used to assess the distribution characteristics of the dependent and independent variables. As appropriate, recoding and/or categorization will be done for bivariate analysis. Rates and proportions will be estimated and 95% confidence intervals calculated.

The dependent variables in this study are categorical with two levels. For categorically expressed independent variables, bivariate associations with dependent variables will be examined using the χ^2 test and other appropriate tests. The means of continuous independent variables will be compared across the two levels of the dependent variables using t-tests. Stratifications will be performed to look for potential confounding or interactions and adjusted point and period estimates of risk ratios and relative risks will be calculated.

Logistic regression will be used to assess the simultaneous effect of multiple independent factors on the dependent variables. Such regression procedures will allow simultaneous control of several confounding factors and identification of interactions. Several different regression models will be built for each dependent

variable. Each model will include one of the primary dependent variables of concern, i.e. birth weight and gestational age or IUGR (yes/no) and preterm delivery (yes/no), and different combinations of independent variables of interest. Several models will then be created by including potentially confounding and interacting variables, e.g. age, sex, socio-economic status variables, breastfeeding, nutritional status variables, exposure to smoke, etc. These models will determine whether each of the primary variables are related to the dependent variables after controlling for confounding variables.

Using the adjusted odds ratios obtained from the regression models and the prevalence of the risk factors in the community, the attributable risks can be calculated. This will provide an estimate of the expected reduction in the incidence of the outcome of interest if a given risk factor is reduced or eliminated.

9. Reliability of Measures, Validity and Limitations

a. Reliability Testing

Reliability testing will be done on the data collection instruments for gestational age assessment, anthropometrics, and questionnaires. Overall, repeat measurements will be taken of a 5% sample of all data collection for each of these three categories, and equally spread over visits of interviewers. The investigators will conduct the repeat measurements for gestational age assessment and anthropometrics. In case of questionnaires, repeat measures will only be taken for certain components, identified on the basis of importance and likelihood of bias. These will be done by other interviewers. Half of the total number of repeat measurements will be conducted in the first 3 months of the study to identify any problems early.

b. Validity of Birth Weight and Gestational Age Measures:

In the proposed study, our ability to observe an effect or a lack thereof is quite dependent on the validity of our measurements. Birth weight and gestational age measures are of special concern in the proposed study and requires some discussion.

It is known that the weight of the newborn starts declining soon after birth and, presumably, weights taken later than 24 hours after birth may not accurately reflect weight at birth. The total weight loss, in a cohort of newborns in the US, in the immediate post natal period is 8-15%, maximal weight loss occurring 4-6 days after birth (Shaffer,1987). In a Bangladesh study, serial weights were taken at 12 hourly intervals in a group of newborns at a Matlab delivery clinic. The mean birth weight declined until 60 hours after birth. An increasing trend was noted at 72 and 84 hours post-partum. The maximal decline

was only 3.4% though birth weight declined by 2.9% in the first 24 hours (personal communication, A de Francisco). Given these data, the 72 hours limit for birth weight measurement in this study is not unreasonable. Further, repeat weights will be taken at 72 hours in a 20% sample of the births where weights were obtained within 24 hours. This will allow us to measure the bias due to delayed birth weight measurement.

A related issue is receiving notification of births within 72 hours. It is expected that, in not more 15% of the births will there be complete failure or delayed notification (>72 hours). This is an improvement from what is likely to have happened in the pilot study in 1989. Birth notification in that study used Volunteers of the Urban Volunteer Programme (UHEP's predecessor) for surveillance. Investigators of that study identify poor planning and organization, weak efforts on the part of the investigators, and failure to adequately raise the interest of the volunteers as reasons for the low on-time notification rate in that study. The notification system for the proposed study is designed to overcome these shortfalls in the previous study. Moreover, the proposed system will be pilot tested prior to the main study.

The gestational age of the infants will be measured using the method described by Capurro (1978). This is a simplified version of the Dubowitz (1970) method, using only five somatic signs of maturity and is thus easier to use in the community. The interviewers will receive extensive training on the use of the Capurro method followed by periodic reliability checks during the study, which will consist of simultaneous assessment of gestational age by one of the investigators in a 5% sample, using both Capurro and Dubowitz methods. Assessment with the Dubowitz method will allow comparison of the two methods. Though the Capurro method has been successfully used in developing countries, in both clinical and field situations (Ferraz,1990), problems remain with such postnatal gestational age assessments. Such methods usually measure gestational age to within ±2 weeks of the actual, but the error is usually greater in preterm or LBW infants (Kliegman,1987; Finnstrom,1977; Yogman,1989). It has been observed that gestational age assessments overestimates gestational age in the preterm and underestimates in the postterm baby (Alexander,1990; Shukla,1987). For a given gestational age, gestational age assessments may underestimate the gestational age of SGA infants compared to the AGA (Ounsted,1978). Gestational age assessed postnatally and that estimated from LMP (last menstrual period) dates are similar but slightly different indicators. The LMP date based gestational age indicates (calendar) time spent in utero whereas postnatal gestational age assessment reflects fetal maturity over time which shows some individual variation.

Separate analyses will be conducted using the postnatally assessed gestational age and gestational age derived from LMP dates obtained from the surveillance system operating in the study population. No case mixing will be done, e.g., in cases where the LMP date is unavailable postnatally assessed gestational age will not be used. Having access to gestational age estimates from two sources will also enable us to assess the usefulness of using postnatal assessments in estimating gestational age in this population.

c. Sources of Bias

We anticipate several major sources of bias in the proposed study.

First, notification is expected to be less likely in the event of early neonatal deaths. Even if notified, some newborns may die before being reached by the interviewer. Since, a large proportion of these early deaths are likely to be LBW, there is likely to be some unavoidable bias in the study. Since, most of these pregnancy outcomes will be eventually picked up by the USS, we will be able to assess whether these mothers and families differed in any way from the study participants.

Second, a large proportion of pregnant women return to their parent's home for delivering their babies. This tradition is more common among primigravidae who are also at the highest risk of infant mortality. This is likely to bias the results of the study towards the null. However we do not anticipate any difference between migrating primigravidae and non-migrating primigravidae, thus allowing us to measure the magnitude of the bias. The USS database will allow us to check for any socio-demographic differences.

Third, since, within the 72 hours limit, we are more likely to reach newborns later than sooner after birth, and since weight of the baby declines after birth, our birth weight measurements will be lower than the actual weight at birth. However, this will only cause us to classify a higher weight baby as a lower weight baby, and thus bias our risk estimates towards the null, which is acceptable. The plan to obtain weights at 72 hours in a sample of babies actually weighed within 24 hours will allow us to measure the extent of the bias and even adjust all birth weight estimates, if necessary.

Fourth, referral of infants requiring treatment, which we must do on ethical grounds, will effect our results by reducing mortality and thus making the risk estimates more conservative.

Finally, gestational age determination may be a further, though yet unknown, source of bias. Though, the Dubowitz method was recommended for use in the first five days of life, we could not locate any such recommendations for the Capurro method. We are

not sure whether this method is equally good at 72 hours as at birth. However, the availability of LMP dates from the USS database, collected with a maximal recall of 1-4 months, will allow us to compare with the findings from the Cappuro method. We will also be able to perform separate analysis using either the Capurro method or the LMP date. Dubowitz assessments, available in a small sub-sample, will be used to validate the Capurro method.

d. Other Limitations:

If 80% is the minimum acceptable power then the proposed study does not have the power to detect a mortality difference between IUGR and NBW and between Preterm and IUGR in the post-neonatal period, a limitation of the study. As already mentioned, the study will probably be limited in its ability to estimate the extent of interactions with statistical certainty. However, lack of adequate data prevent us from estimating the power of the study on this question. The question of interaction can be examined in two ways, through contingency tables and through regression analysis. Based on some conservative assumptions on the expected level of interactions in this population (not shown), the study does not have adequate power to detect interactions in contingency tables. However, assuming that to have adequate power in regression analysis, the ratio of total sample size and number of variables (including dummy variables and interaction terms) needs to be at least 20 (Personal communication, AH Baqui). Since the total sample size is about 900, there should be adequate power for a maximum of 45 variables. None of the regression models we intend to use for our analyses is likely to have so many variables. Therefore, the study probably has adequate power for hypothesis testing, in regression analysis, on interactions as well as on mortality differentials during the post-neonatal period.

However, we propose to conduct preliminary analysis 10 months into the study. This will provide us with information on interactions as well as the post-neonatal period. If it appears that marginal increases in the sample size, with minimal and acceptable increase in costs, will provide the study with adequate power on these questions then the sample size will be increased. Moreover, even in case of the comparisons where we do have adequate power, the sample size is often marginal, plus the calculations are based on a series of assumptions which may have been erroneous. The preliminary analysis will also enable us to check the adequacy of our sample size for these comparisons also.

10. Ethical Implications, Informed Consent and Confidentiality

Verbal informed consent will be obtained from the mother of each participating infant, after thorough explanation of the purpose of the study, requirements of participation, risks and benefits to the

participant. The vast majority of this population is illiterate, so a verbal consent is the only option.

The study interviewers will be trained to identify and respond to symptoms of serious infant morbidity that they will encounter and refer these infants to a collaborating hospital, if certain referral criteria are met. Specific arrangements will be agreed on with these hospitals so that appropriate medical care of the referred infants is ensured.

Even though the study does not include any interventions, some of the information collected will be of a sensitive nature raising potential ethical problems. The interviewers will be instructed to conduct all interviews in private, exceptions only being made if the respondent insists on the presence of others. Each questionnaire and data collection form will be given an identification code. The linkage between the code and study participant's name will be kept in a locked register at the UHEP office. Interviewers will be instructed to maintain strict confidentiality of the information they collect.

D. SIGNIFICANCE

Though extensive data exists on LBW, very little is known about the incidence of LBW, its determinants and consequences in an urban slum setting. Such information would be essential before planning and implementing any specific intervention in this population aimed at reducing the incidence of LBW and thus improve child survival.

We would need to know:

a. Whether an intervention was necessary and feasible, i.e., whether LBW was indeed a problem in this population in terms of attributable mortality and whether the most important contributory factors were amenable to interventions;

b. The specific nature of the intervention, i.e., which of the pre and post-natal factors should be targeted for reducing the mortality impact of LBW;

c. The size of the impact expected from such interventions; and

d. Whether there would be need to address other pre and post-natal risk factors so that the impact of the intervention is maximized.

The proposed study, in conjunction with the sister study on "**the determinants of LBW and perinatal mortality**" has been designed to address these information needs.

The proposed study will also provide estimates of cause specific neonatal and infant mortality rates and incidence of LBW for an urban slum population. Such data would be very useful in setting priorities for health programming and serving as the baseline for evaluating the impact of child survival interventions in this population.

The prospective design used in the study will allow (a) the measurement of bias due to losses to follow-up; (b) measurement of birth weight, gestational age and infant anthropometrics; and (c) different analytical questions to be defined and answered simultaneously since data will not be limited to predefined "cases" and "controls" at the time of data collection.

Finally, the proposed study will contribute to the literature on the association of birth weight, gestational age and birth-weight-for-gestation with infant survival and interactions with other determinants of infant mortality.

E. FACILITIES REQUIRED

It is proposed that existing facilities within the Urban Health Extension Project will be utilized for this study. Office space and administrative support already available in the project will be adequate for the study. We do not anticipate excessive demands on project resources. It is however proposed that additional computer hardware be procured exclusively for this study. Finally, additional personnel would need to be recruited.

F. COLLABORATIVE ARRANGEMENTS

Collaborative agreements will be worked out with the paediatrics and obstetrics & gynaecology departments of Mitford and Dhaka Medical Hospital and with Dhaka Shishu (children's) Hospital for referral and treatment of study participants and their mothers. An agreement will also be reached with the investigators of the USS and the "**maternal morbidity...**" and "**determinants of LBW ...**" studies on collaborative data collection and sharing, coordination and exchange of information and on data ownership.

REFERENCES

Adair LS. (1989) Low Birth Weight and Intrauterine growth Retardation in Filipino Infants. Pediatrics, 84:613-22.

Aherne W, Hull D. (1966) Brown adipose tissue and heat production in the newborrn infant. J Path Bact. 91:223-34.

Alam N, Wojtyniak B, Rahaman MM. (1989) Anthropometric indicators and risk of death in children. Lancet. 1:1247-50.

Alexander CR, Hulsey TC et al. (1990) Factors influencing the relationship between a newborn assessment of gestational maturity and gestational age interval. Paed Perinat Epidemiol. 4:133-46.

Anderson GH, Atkinson et al. (1981) Energy and micronutrient content of human milk dusring early laction from mothers giving birth prematurely and at term. Am J Clin Nutr. 34:258-

Ashworth A, Feachem RG. (1985) Interventions for control of diarrhoeal diseases among young children: prevention of low birth weight. Bull WHO. 63:165-84.

Ashworth A, Rogers S. (1992) Interventions to reduce morbidity and mortality from pneumonia in children: reducing the incidence of low birth weight (unpublished) WHO ARI Programme.

Barros FC, Victora CG et al (1986) Birth weight and duration of breast-feeding: Are the beneficial effects of human milk being overestimated? Pediatrics. 78:656-661.

Beisel WR, (1979) Malnutrition and immune response. In: Neuberger A & Jukes TH eds., International Review of Biochemistry, Biochemistry of Nutrition I, Vol. 27. Unversity Park Press, Baltimore.

Bhakoo ON, Scopes JW. (1974) Minimal rates of oxygen consumption in small date babies during the first week of life. Arch Dis Child. 49:583-5.

Bhargava SK, Sachdev HPS et al (1985) Current status of infant growth measurements in the perinatal period in India. Acta Paed Scand. 319:103-110.

Bhatia S. (1989) Patterns and causes of neonatal and postneonatal mortality in rural Bangladesh. Stud Fam Plan. 20:136-146.

Butte NF, Garza C et al. (1984) Human milk intake and growth in exclusive breast-fed infants. J Ped. 104:187-95.

Canosa CA. (1989) Intrauterine growth retardation in India and Bangladesh. In: Senterre J. ed., Intrauterine Growth Retardation. Nestle Nutrition Workshop Series, Vol.18, New York, Raven Press; 183-204.

Capurro H, Konichezky S et al. (1978) A simplified method for diagnosis of gestational age in the newborn infant. J Ped. 93:120-122.

Caulfield LE, Haas JD et al. (1991) Differences in early postnatal morbidity risk by patterrn of fetal growth in Argentina. Paed Perinat Epidemiol. 5:263-75.

Chan KN et al. (1989) Lung function in children of low birth weight. Arch Dis Child. 64:1284-93.

Chandra RK. (1991) Trace elements and immune responses. In:Chandra RK ed., Trace elements in nutrition of children - II. Nestle Nutrition Workshop Series, Vol.23. New York, Raven Press. pp201-14.

Chandra RK. (1983) Nutrition, immunity and infection: present knowledge and future directions. Lancet. i:688-91.

Chandra RK. (1981) Serum thymic hormone activity and cell-mediated immunity in healthy neonates, preterm infants and small-for-gestational age infants. Pediatr. 67:407-11.

Chase HC. (1969) Infant mortality and weight at birth: 1960 United States birth cohort. Am J Pub Health. 59:1618-28.

Chen LC, Chowdhury AKMA et al. (1980) Anthrpometric assessment of energy-protein malnutrion and subsequent risk of mortality among preschool aged children. Am J Clin Nutr. 33:1836-45.

Chen Y, Li W et al. (1988) Chang Ling epidemiological tudy of children's health: I: Passive smoking and children's respiratory diseases. Int J Epidemiol. 17:348-55.

Cruise MO. (1973) A longitudinal study of the growth of low birthweight infants. I. Velocity and distance growth, birth to 3 years. Pediatrics. 51:620-28.

Datta N, Kumar V et al. (1987) Application of care managemnet to the control of acute respiratory infections in low birth weight infants: A feasibility study. Bull WHO. 65:77-82.

Douglas JWB, Mosford C. (1953). Health of premature children from birth to four years. Br Med J. :748-54.

Drillien CM. (1959) A longitudinal study of the growth and development of prematurely and maturely born children. Part IV. Morbidity. Arch Dis Child. 34:210-7.

Dubowitz JMS, Dubowitz V, Goldberg C. (1970) Clinical assessment of gestational age in the newborn infant. J Pediatr. 77:1-10.

Falkner F. (1981) Maternal nutrition and fetal growth. Am J Clin Nut. 34:769-74.

Fauveau V, Briend A et al. (undated) Chest circumferance at birth: An alternative to birthweight to detect neonates at risk of early mortality. International Centre for Diarrhoeal Disease Research, Bangladesh. Unpublished Report.

Ferguson AC. (1978) Prolonged impairment of cellular immunity in children with intrauterine growth retardation. J Pediatr. 93:52-6.

Ferraz EM, Gray RH. (1990) Determinants of Preterm Delivery and Intrauterine Growh Retardation in North East Brazil. Int J Epidemiol. 19:101-8.

Finnstrom O. (1977) Studies on maturity in newborn infants: IX. Further observations on the use of external characteristcs in estimating gestational age. Acta Paed Scand. 66:601-4.

Fleiss JI. (1981) Determinining Sample Sizes Needed to Detect a Difference Between Two Proportions. In: Statistical Methods for Rates and Proportions. John Wiley & Sons, New York. p.33-49.

Ghosh S, Ramanujacharyulu TKTS et al. (1979) Mortality pattern in an urban birth cohort. Ind J Med Res. 69:616-23.

Gross I. (1990) Respiratory Distress Syndrome. In: Oski FA ed., Principles and Practice of Pediatrics. JB Lippincott Co. Philadelphia; 333-7.

Gross RL & Newberne PM. (1980) Role of nutrition in immunologic function. Physio Rev. 60:180-302.

Gross SJ. (1983) Growth and biochemical responses of preterm infants fed human milk or modified infant formula. N Engl J Med. 308:237-41.

Grulee CG, Sanford HN et al. (1934) Breast and artificial feeding: Influence on morbidity and mortality of twenty thousand children. JAMA. 103:735-9.

Haas JD, Balcazar H, Caulfield L. (1987) variation in early neonatal mortality for different types of fetal growth retardation. Am J Phys Anthrop. 73:467-73.

Hey En, Katz G. (1969) Temporary loss of metabolic response to cold stress in infants of low birth weight. Arch Dis Child. 44:323-30.

Heywood P. The functional significance of malnutrition-growth and prospective risk of death in the highlands of Papua New Guinea. J Food Nutr. 39:13-19.

Hort KP. (1987) Seasonal variation of birthweight in Bangladesh. Ann Trop Paed. 7:66-71.

Holmes GE, Millar HC et al. (19) Postnatal somatic growth in infants with a typical fetal growth pattern. Am J Dis Child. 131:1078-83.

Humphrey JH, West KP et al. (1992) Vitamin A deficiency and attributable mortality among under-5-year-olds. Bull WHO. 70:225-32.

Huque F, Hussain AMZ. (1991) Detection of Low-Birth-Weight New Born Babies by Anthropometric Measurement in Bangladesh. Ind J Ped. 58:223-31.

Islam MS, Rahaman MM et al (1981) Infant mortality in rural Bangladesh: An analysis of causes during neonatal and postneonatal period. ICDDR,B Scientific Report, no. 44.

Joaquim MCM, de Mendonca LA et al. (1985) The advantages of human milk in the feeding of the premature infant. J Trop Ped. 31:43-8.

Kahn HA, Sempos CT. (1989) Attributable Risk. In: Statistical Methods in Epidemiology. Oxford University Press, New York; 72-84.

Khan M, Curlin GT et al. (1979) Growth and development studies: Rural Meheran. Comilla. Bang Med J. 7:74-90.

Kielmann AA, McCord C. (1978) Weight-for-age as an index of risk of death in children. Lancet. 1:1247-50.

Kliegman Rm, Behrman RE. (1987). The High Risk Infant. In: Behrman RE & Vaughan VC eds., Nelson Textbook of Pediatrics. 13th edition. WB Saunders Co. Philadelphia; 373-85.

Koops BL, Morgan LJ et al. (1982) Neonatal mortality risk in relation to birth weight and gestational age: update. J Ped. 101:969-77

Kramer MS. (1987) Determinants of low birth weight: Methodological assessment and meta-analysis. Bull WHO. 65:663-737.

Lilienfeld AM, Lilienfeld D. (1980) Observational Studies: I. Retrospective and Cross-Sectional Studies. In: Foundations of Epidemiology. 2nd edition. Oxford University Press, New York; 191-225.

Lopez Bravo I et al. (1984) Breastfeeding, weight gains, diarrhoea and malnutrition in the first year of life. Bull PAHO. 18:151-63.

Lubchenco LO, Searls DT et al. (1972) Neonatal mortality rate: relationship to birthweight and gestational age. J Ped. 81:814-22.

Lubchenco LO, Bard H. (1971) Incidence of hypoglycemia in newborn infants classified by birth weight and gestational age. Pediatrics. 47:437-40.

Malloy MH, Kleinman JC et al. (1988) The association of maternal smoking with age and cause of infant death. Am J Epid. 128:46-55.

Mansell AL et al. (1987) pulmonary follow-up of moderately low birth weight infants with or without respiratory distress syndrome. J Pediatr. 110:111-5.

Martorell R, Ho TJ. (1984) Malnutrition, morbidity and mortality. In: Mosely WH & Chen LC eds., Child Survival: Strategies for Research. Pop Dev Rev. 10 (suppl):49-68.

Mavalankar DV, Gray RH, Trivedi CR. (1992) Risk factors for preterm and term low birth weight in Ahmedabad, India. Unpublished manuscript.

Mata LJ, Urrutia Jj et al. (1975) Survival and Physical Growth in Infancy and Early Childhood: Study of Birth Weight and Gestational Age in a Guatemalan Indian Village. Am J Dis Child. 129:561-6.

Mata LJ. (1978) The children of Santa Maria Cauque: a prospective field study of health and growth. MIT Press, Cambridge.

Mayfield SR, Unuy R et al. (1990) The Premature Infant. In: Oski FA ed., Principles and Practice of Pediatrics. JB Lippincott Co. Philadelphia; 297-304.

McCormick MC (1985) The contribution of low birth weight to infant mortality and childhood morbidity. N Eng J Med. 312:82-90.

Mertens TE, Cousns SN, Feachem RG. (1987) Evidence of a prolonged association between low birthweight and paediatric diarrhoea in Sri Lanka. Trans Roy Soc Trop Med Hyg. 81:196-

Montreewasuwat N, Olson JA. (1979) Serum and liver concentrations of vitamin A in Thai fetuses as a function of gestationanl age. Am J Clin Nutr. 32:601-6.

Ounsted K, Chalmers CA et al. (1978) Clinical assessment of gestational age at birth: the effects of sex, birthweight, and weight for lenght of gestation. Early Hum Dev. 1978:73-80.

Outerbridge EW, Nogrady M et al. (1972) Idiopathic respiratory distress syndrome: recurrent respiratory illness in survivors. Am J Dis Child. 123:99-104.

Paljor N, Sack RB. Project Proposal: Urban Surveillance System. July 1991 (*unpublished*)

Pandey MR, Boleij JSM et al. (1989). Indoor air pollution in developing countries and acute respiratory infection in childre. Lancet. 1:427-8.

Paneth N, Wallenstein S et al. (1982) Social Class indicators and mortality in low birthweight infants. Am J Epidem. 116:364-75.

Patel RB. (1989) Care of low birth weight babies in slums. Ind J Ped. 56:231-237.

Pearse RG. (1989) Definitions: Problems and Limitations of Intrauterine Growth Curves. In: Senterre J. ed., Intrauterine Growth Retardation. Nestle Nutrition Workshop Series, Vol.18, New York, Raven Press; 65-77.

Plank SJ, Milanesi MI. (19__) Infant feeding and infant mortality in rural Chile. Bull WHO. 48:203-10.

Puffer RR, Serrano CV. (1973) Patterns of mortality in childhood. Pan American Health Organization, Scientific Publication No. 262, Washington D.C. pp41-54 .

Rahman S. (1989) Neonatal mortality patterns in rural Bangladesh. J Trop Ped. 35:199-202.

Rao PS, Inbaraj SG. (1978) A prospective study of infant mortality and congenital malformations in relation to intra-uterine growth rates in south India. Ind J Med Res. 67:245-54.

Robinson M. (1951) Infant morbidity and mortality: A study of 3266 infants. Lancet. 1:788-94.

Rogers S, Kirkwood BR. (1992) Potential impact of interventions to prevent pneumonia in children. Report prepared for meeting to discuss Reviews of Interventions to Reduce Morbidity and Mortality from Pneumnonia in Children, WHO, Geneva, 2-4 March, 1992.

Rosso P. (1989) Morbidity and Mortality in Intrauterine Growth Retardation. In: Senterre J. ed., Intrauterine Growth Retardation. Nestle Nutrition Workshop Series, Vol.18, New York, Raven Press; 123-140.

Rowland MGM. (1986) The weanling's dilemma: are we making progress? Acta Paed Scand. 323:33-42.

Saha K et al. (1983) A six-months' follow-up study of growth, morbidity and functional immunity in low birthweight neonates with special reference to intrauterine growth retardation in small-for-gestational-age infants. J Trop Ped. 29:278-82.

Sexton M, Hebel JR et al. (1984) A clinical trial of change of maternal smoking and its effect on birthweight. JAMA. 251:911-5.

Shaffer SG, Quimiro CL et al. (1987) Postnatal Weight Changes in Low Birth Weight Infants. Pediatr. 79:702-5.

Shah FK, Abbey H. (1971) Effects of some factors on neonatal and postneonatal mortality. Mil Mem Fun Qtr. 49:33-57.

Shah RS, Rajalakshmi R. (1984) Vitamin A status of the newborn in relation to gestational age, body weight, and maternal nutritional status. Am J Clin Nutr. 40:794-800.

Shukla H, Atakent YS et al. (1987) Postnatal overestimation of gestational age in preterm infants. Am J Dis Child. 141:1106-7.

Singh M, Paul VK. (1988) Strategies to reduce perinatal and neonatal mortality. Ind Ped. 25:499-509.

Smith KR, Rogers S. (1992) Interventions to reduce morbidity and mortality from pneumonia in children: reducing exposure to household biomass smoke (Unpublished). WHO ARI Programme.

Sommer A. Tarwotjo I et al. (1983) Increased mortality in mild vitamin A deficiency. Lancet. ii:585-8.

Sommer A, Tarwotjo I et al. (1986) Impact of vitamin A supplementation on childhood mortality: A randomized controlled community trial. Lancet. i:1169-73.

Starfield B, Shapiro S et al. (1982) Mortality and morbidity in infants with intrauterine growth retardation. J Ped. 101: 978-83.

Takahashi YI, Smith JE et al. (1975) Vitamin A deficiency and fetal growth and development in the rat. J Nutr. 105. 105:1299-1300.

Tupasi TE, Velmonte MA et al. (1988) Determinants of morbidity and mortality due to acute respiratory infections: implications for intervention. J Inf Dis. 157:615-23.

Urrusti J, Yoshida P et al. (1972) Human fetal growth retardation: I. Clinical features of sample with intrauterine growth retardation. Pediatrics. 50:547-58.

Usher RH & Maclean FH. (1974) Normal fetal growth and significance of fetal growth retardation. In: Davis JA & Dobbing J ed., Scientific foundations of pediatrics. London, Heinemann; 69-80.

Van Den Berg BJ, Yerushalmy J. (1966) The relationship of the rate of intrauterine growth of infants of low birthweight to mortality, morbidity, and congenital anomalies. J Ped. 69:531-45.

Victora CG, Barros FC et al. (1987) Birthweight and infant mortality: A longitudinal study of 5914 Brazilian children. Int J Epidem. 16:239-245.

Victora CG, Smith PG et al. (1987a) Evidence for a strong protective effect of breast-feeding against infant deaths due to infetious diseases in Brazil. Lancet. 2:319-22.

Victora CG, Smith PG et al. (1988) Influence of birth weight on mortality from infectious diseases: A case-control study. Pediatrics. 81:807-811.

Villar J et al. (1984) Heterogeneous growth and mental development of intrauterine growth retarded infants during the first three years of life. Pediatr. 74:783-91.

Villar J, Belizan JM. (1982) The relative contribution of prematurity and fetal growth retardation to low birth weight in developing and developed societies. Am J Obs Gyn. 143:793-798.

Villar J, Belizan JM (1982a) The timing factor in the pathophysiology of intruterine growth retardation syndrome. Obs Gyne. 37:499-506.

Villar J, Belizan et al. (1989) Postnatal Experiences of Intruterine Growth-Retarded Infants. In: Senterre J. ed., Intrauterine Growth Retardation. Nestle Nutrition Workshop Series, Vol.18, New York, Raven Press; 261-77.

Wallingford JC, Underwood BA. (1986) Vitamin A Deficiency in Pregnancy, Lactation and the Nursing Child. in: Bauernfeind JC eds., Vitamin A Deficiency and its Control. Academic Press Inc. Orlando, FL; 101-52.

Walther FJ, Ramaekers LHJ. (1982) Neonatal morbidity of SGA infants in relation to their nutritional status at birth. Acta Paed Scand. 71:437-40.

Warshaw JB. (1990) Intrauterine Growth Retardation. In: Oski FA ed., Principles and Practice of Pediatrics. JB Lippincott Co. Philadelphia; 304-6.

Widdowson EM et al. (1974) Trace elements in foetal and early postnatal development. Proc Nutr Soc. 33:275-83.

Whitehead RG, Rowland MGM et al. (1978) Factors influemcing lactation performance in rural Gambian mothers. Lancet. 2:178-81.

World Health Organization Working Group. (1986) Use and interpretation of anthropometric indicators of nutritional status. Bull WHO, 64:929-41.

World Health Organization. (1984) The incidence of low birth weight: An update. Wkly Epid Rec. 59:205-12.

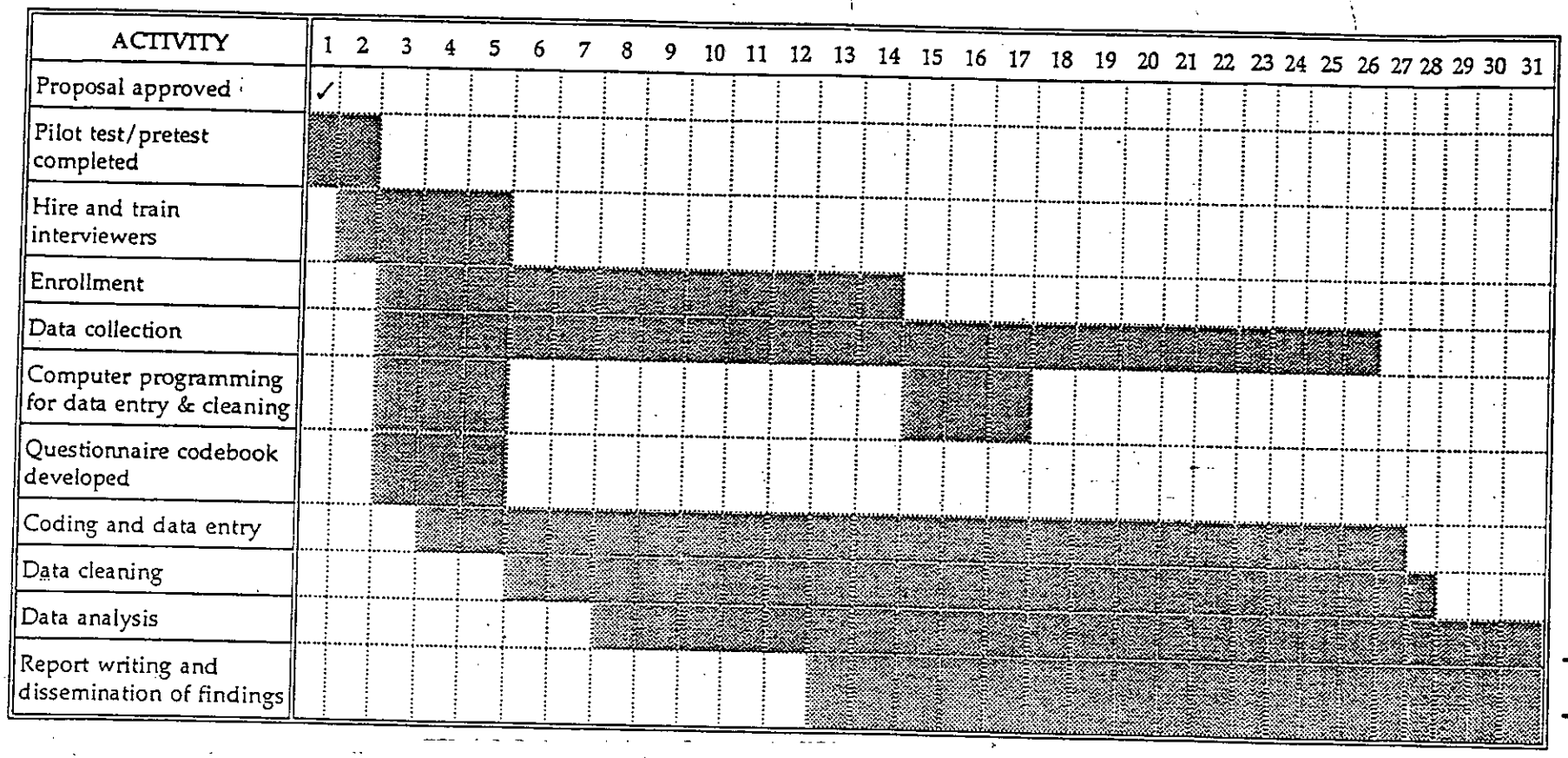
World Health Organization. (1981) Contemporary Patterns of Breast-Feeding. Report on the WHO Collaborative Study on Breast-Feeding. Geneva.

World Health Organization, Division of Family Health. (1980) The incidence of low birth weight: A critical review of available information. Wrld Hlth Stat Qrtrly. 33:197-224.

Wray JD. (1977) Maternal nutrition, breast-feeding and infant survival. In: Mosley WH., eds. Nutrition and Human Reproduction. Plenum Press. New York.

Yogman MW, Kraemer HC et al. (1989) Identification of intrauterine growth retardation among low birth weight preterm infants. J Ped. 115:799-807.

FLOW CHART FOR RESEARCH ACTIVITIES



FLOW CHART FOR RESEARCH ACTIVITIES (Contd..)

Specific Tasks for Staff:

Dr. Shams El Arifeen Principle Investigator	- Develop and finalize protocol - Select interviewers - Provide training to interviewers - Participate in pilot and pretests - Finalize questionnaires - Assist in planning and maintenance of all logistics for the study - Participate in quality control supervision of the interviewers - Assist with clinical assessment of infant morbidity and mortality - Code responses, data analysis, writing of findings, interpretations, recommendations
(to be identified/hired) Co-investigator	- Assist in coordinating and monitoring of all day-to-day activities of the study - Assist in planning and maintenance of all logistics for the study - Assist in selecting interviewers - Provide training to interviewers - Participate in pilot and pretests - Assist in finalizing questionnaires - Conduct quality control supervision of the interviewers - Primary person for clinical assessment of infant morbidity and mortality - Assist with coding responses, data analysis, and writing of findings, interpretations and recommendations
(to be identified/hired) Field Research Officer	- Coordinate and monitor all day-to-day activities of the study - Plan and maintain all logistics for the study - Carry out all administrative work necessary for the study - Assist in training of interviewers - Participate in pilot and pretests - Assist in finalizing questionnaires - Conduct quality control supervision of the interviewers
to be identified/hired) rogrammer	- Design, write, test and implement programme for data entry, validation and analysis

(to be identified/hired) Data Entry Assistant	- Routinely enter data. - Conduct random checks of entered data for errors - Prepare and disseminate weekly status report of all active participating infants
(to be identified/hired) Interviewer	- Conduct interviews and re-interviews of mothers using questionnaires - Obtain anthropometric measurements of mothers and infants - Conduct simple physical examination of infants
(to be hired) Female Helper	- Assist in transportation of anthropometric equipment in the field - Assist interviewer in obtaining anthropometric measurements of mothers and infants

BUDGET

		YEAR 1				YEAR 2				YEAR 3			SUB-TOTAL
SALARY:													
POSITION	GRADE	#	RATE	MAN-MTH	TOTAL	#	RATE	MAN-MTH	TOTAL	#	RATE	MAN-MTH	TOTAL	
Shams El Arifeen-RI (25%)	NOA	1	641	12	1923	1	705	12	2115	1	776	2	388	4,426
Research Investigator (25%)	NOA	1	641	12	1923	1	705	12	2115	1	776	2	388	4,426
Programmer	GS5	1	379	4	1516	1	417	2	834					2,350
Field Research Officer(50%)	GS5	3	379	12	6822	3	417	12	7504	3	459	2	1376	15,702
Data Entry Assistant (25%)	GS3	1	237	12	711	1	261	12	782	1	287	2	143	1,636
Interviewer	GS3	-	237	108	25596	-	261	63	16424	-	287	6	1721	43,741
Female Helper (Daily Wage)	-	-	50	108	5400	-	55	63	3465	-	61	6	363	9,228
TOTAL					43891				33240				4378	81,509
LOCAL TRAVEL														
			RATE	VISITS	TOTAL		RATE	VISITS	TOTAL		RATE	VISITS	TOTAL	
For Interviewers			1.00	6419	6419		1.10	4194	4613		1.21	105	127	11,159
For Missed/Hospital Visits (30%)			1.00	1926	1926		1.10	1258	1384		1.21	32	38	3,348
For Birth Notifier			1.88	2567	4813		1.88	233	438					5,250
For 50% Duplicate Birth Notification			1.88	642	1203		1.88	58	109					1,313
For Investigators/Supervisors (15%)			1.00	963	963		1.10	629	692		1.21	16	19	1,674
TOTAL					15323				7236				184	22,744
EQUIPMENT/SUPPLIES														
			RATE	#	TOTAL		RATE	#	TOTAL		RATE	#	TOTAL	
Gumcha to wrap baby for weighing			0.53	1400	735		0.00	0	0		0.00	0	0	735
Birth Weight Scale			250.00	10	2500		0.00	0	0		0.00	0	0	2,500
Maternal Weight Scales			400.00	6	2400		0.00	0	0		0.00	0	0	2,400
Other Equip.			100.00	10	1000		0.00	0	0		0.00	0	0	1,000
Computer + Acessories			5000.00	1	5000		-	-	500		-	-	167	5,667
Office Supplies			-	-	1000		-	-	1000		-	-	333	2,333
TOTAL					12635				1500				500	14,635
PHOTOCOPY EXPENSES			0.03	128380	3851		0.03	83880	2768		0.03	2100	69	6,689
SUB-TOTAL DIRECT					75701				44744				5132	125,577
MISCELLANEOUS/UNANTICIPATED (10%)					7570				4474				513	12,558
10% of Personnel, Travel, & Photocopy Costs for Possible Sample Size Increases					6307				4324				463	11,094
OVERHEAD (32%)					24224				14318				1642	40,185
GRAND TOTAL					113801				67861				7750	189,413

BUDGET (Contd...)

JUSTIFICATION FOR INTERVIEWERS

72 Hour Postpartum Visit

Activity	Number	Time in Hours: Interview	Travel	Total
Completed Interviews	1400	0.50	0.75	1750
5% Corrections (a)	70	0.25	0.75	70
Total				1820
Interviewers needed for this visit for each of 12 months				1.26(b)

7 Day Postpartum Visit

Activity	Number	Time in Hours: Interview	Travel	Total
Completed Interviews	1400	0.50	0.75	1750
5% Corrections	70	0.25	0.75	70
Total				1820
Interviewers needed for each of 12 months for this visit				1.26

14 Day Postpartum Visit

Activity	Number	Time in Hours: Interview	Travel	Total
Completed Interviews	1400	0.50	0.75	1750
5% Corrections	70	0.25	0.75	70
Total				1820
Interviewers needed for this visit for each of 12 months				1.26

1 Month Postpartum Visit

Activity	Number	Time in Hours: Interview	Travel	Total
Completed Interviews	1358 (c)	0.50	0.75	1698
5% Corrections	68	0.25	0.75	68
Total				1765
Interviewers needed for each of 12 months for this visit				1.23

(a) Travel, interview and editing time for visits made for making corrections.
(b) The number of interviewers needed for each of 12 months for a particular visit is based on 30 hour week and 48 week year. This accounts for editing and other daily activities, holidays, sick-days, etc.
(c) Minus 42 (30 per 1000 live births) reported dead (expected) at 14 day visit.

3 Month Postpartum Visit

Activity	Number	Time in Hours: Interview	Travel	Total
Completed Interviews	1317 (d)	0.50	0.75	1647
5% Corrections	66	0.25	0.75	66
Total				1712
Interviewers needed for each of 12 months for this visit				1.19

6 Month Postpartum Visit

Activity	Number	Time in Hours: Interview	Travel	Total
Completed Interviews	1304 (e)	0.50	0.75	1630
5% Corrections	65	0.25	0.75	65
Total				1695
Interviewers needed for each of 12 months for this visit				1.18

9 Month Postpartum Visit

Activity	Number	Time in Hours: Interview	Travel	Total
Completed Interviews	1281 (f)	0.50	0.75	1601
5% Corrections	64	0.25	0.75	64
Total				1665
Interviewers needed for each of 12 months for this visit				1.16

12 Month Postpartum Visit

Activity	Number	Time in Hours: Interview	Travel	Total
Completed Interviews	1258 (g)	0.50	0.75	1573
5% Corrections	63	0.25	0.75	63
Total				1635
Interviewers needed for each of 12 months for this visit				1.14

(d) Minus 41 (30 per 1000 live births) reported dead (expected) at 1 month visit.
(e) Minus 13 (9 per 1000 live births) reported dead (expected) at 3 month visit.
(f) Minus 23 (16 per 1000 live births) reported dead (expected) at 6 month visit.
(g) Minus 23 (16 per 1000 live births) reported dead (expected) at 9 month visit.

BUDGET (Contd...)

INTERVIEWER REQUIREMENT (PERSON-MONTHS) BY VISIT TYPE AND DATA COLLECTION MONTH

Visit Type	Data Collection Months 1	2	3	4	5	6	7	8	9	10	11	12	13
72 hrs	0.63	0.63	1.26	1.26	1.26	1.26	1.26	1.26	1.26	1.26	1.26	1.26	0.63
7 day	0.63	0.63	1.26	1.26	1.26	1.26	1.26	1.26	1.26	1.26	1.26	1.26	1.26
14 day	0.63	0.63	1.26	1.26	1.26	1.26	1.26	1.26	1.26	1.26	1.26	1.26	1.26
1 mon	0.00	0.61	0.61	1.23	1.23	1.23	1.23	1.23	1.23	1.23	1.23	1.23	1.23
3 mon	0.00	0.00	0.00	0.59	0.59	1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19
6 mon	0.00	0.00	0.00	0.00	0.00	0.00	0.59	0.59	1.18	1.18	1.18	1.18	1.18
9 mon	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.58	0.58	1.16	1.16
12 mon	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.57
Total	**1.90**	**2.50**	**4.40**	**5.61**	**5.61**	**6.20**	**6.79**	**6.79**	**7.38**	**7.96**	**7.96**	**8.54**	**8.47**
Staff Needs by Field Office:													
MDPUR	1	1	2	3	3	3	3	3	3	4	4	4	4
LALBGH	1	1	2	2	2	2	2	2	3	3	3	3	3
SUTRPR	1	1	2	2	2	3	3	3	3	3	3	3	3
Total	**3**	**3**	**6**	**7**	**7**	**8**	**8**	**8**	**9**	**10**	**10**	**10**	**10**

Visit Type	Data Collection Months 14	15	16	17	18	19	20	21	22	23	24	25	26
72 hrs	0.63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
7 day	0.63	0.63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
14 day	0.63	0.63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1 mon	0.61	0.61	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
3 mon	1.19	1.19	0.59	0.59	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
6 mon	1.18	1.18	1.18	1.18	1.18	0.59	0.59	0.00	0.00	0.00	0.00	0.00	0.00
9 mon	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	0.58	0.58	0.00	0.00	0.00
12 mon	0.57	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	0.57	0.57
Total	**6.59**	**6.53**	**4.06**	**4.06**	**3.46**	**2.88**	**2.88**	**2.29**	**1.71**	**1.71**	**1.13**	**0.56**	**0.56**
Staff Needs by Field Office:													
MDPUR	3	3	2	2	2	2	2	1	1	1	1	1	1
LALBGH	2	2	2	2	1	1	1	1	1	1	1	1	1
SUTRPR	3	3	2	2	2	1	1	1	1	1	1	1	1
Total	**8**	**8**	**6**	**6**	**5**	**4**	**4**	**3**	**3**	**3**	**3**	**3**	**3**

Note:

However, for ease of hiring and training we propose to have 6 interviewers in the first 3 months, 8 in the next 5 months and 10 in the following 5 months. After that, we would start relieving staff according to estimated needs.

BUDGET (Contd...)

NUMBER OF VISITS BY VISIT TYPE AND DATA COLLECTION MONTH

Visit Type	Data Collection Months 1	2	3	4	5	6	7	8	9	10	11	12	13	Total
72 hrs	58	58	117	117	117	117	117	117	117	117	117	117	58	1342
7 day	54	54	108	108	108	108	108	108	108	108	108	108	108	1292
14 day	54	54	108	108	108	108	108	108	108	108	108	108	108	1292
1 mon	0	57	57	113	113	113	113	113	113	113	113	113	113	1245
3 mon	0	0	0	55	55	110	110	110	110	110	110	110	110	988
6 mon	0	0	0	0	0	0	54	54	109	109	109	109	109	652
9 mon	0	0	0	0	0	0	0	0	0	53	53	107	107	320
12 mon	0	0	0	0	0	0	0	0	0	0	0	0	52	52
Total	166	223	389	500	500	555	609	609	664	717	717	770	765	7184

Visit Type	Data Collection Months 14	15	16	17	18	19	20	21	22	23	24	25	26	Total
72 hrs	58	0	0	0	0	0	0	0	0	0	0	0	0	58
7 day	54	54	0	0	0	0	0	0	0	0	0	0	0	108
14 day	54	54	0	0	0	0	0	0	0	0	0	0	0	108
1 mon	57	57	0	0	0	0	0	0	0	0	0	0	0	113
3 mon	110	110	55	55	0	0	0	0	0	0	0	0	0	329
6 mon	109	109	109	109	109	54	54	0	0	0	0	0	0	652
9 mon	107	107	107	107	107	107	107	107	53	53	0	0	0	961
12 mon	52	105	105	105	105	105	105	105	105	105	105	52	52	1206
Total	600	594	375	375	320	266	266	212	158	158	105	52	52	3535

CONSENT FORM

PROTOCOL

Birth Weight and Infant Mortality in the Slums Of Dhaka City: A Prospective Study

VERBAL CONSENT FORM:

Urban Health Extension Project at the ICDDR,B (Cholera Hospital) is conducting a special study on infants born in the slums of Dhaka.

The purpose of this research is to know more about the growth and health of the baby at birth and during infancy and thus help us make recommendations for improving child health services in Dhaka. We want to do this by asking a few questions today and on several occasions until your baby is one year old. The questions will be about the health and feeding of your baby and about your home. We will also examine your baby to see that he/she is all right, and we will measure the baby's weight, length, arm, chest and head and your weight, height and arm.

If you agree to participate in this research, we would like to examine your baby today and ask you a few questions about your baby. This will take 30 minutes. I will come again when the baby is 7 days old and when the baby's age is 2 weeks, and 1, 3, 6, 9 and 12 months. None of these visits will take more than 30 minutes. These visits will help us understand how well the baby had been growing, and about any health problems he/she may have suffered from.

The examination of your baby will not harm him/her in any way, rather, it will help us better assess his/health. If your baby is ill we will help you seek treatment at a nearest hospital. Except for the time spent in answering, there is no possibility of any harm to you or your baby from answering our questions.

We know that some of the questions we will ask you about your baby and home will be personal, therefore, we keep your answers secret. That is why this questionnaire does not have your name.

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 services at the Cholera Hospital as usual. If have any questions about the study, you can contact the principle investigator, Shams El Arifeen, or the Urban Health Extension Project at the telephone number 600003.

Do you agree to participate in this research?

Signature of Person obtaining consent

Date of Consent

Signature of Principle Investigator

গবেষণা প্রকল্পের নাম:

ঢাকা নগরীর বস্তি এলাকায় জন্মকালীন ওজন ও শিশু মৃত্যু: একটি অনুসরণমূলক গবেষণা।

মৌখিক সম্মতি পত্র

আরবান হেল্থ একসটেনশন প্রজেক্ট, আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র (কলেরা হাসপাতাল) ঢাকার বস্তি এলাকায় নবজাত শিশুদের উপর একটি বিশেষ গবেষণা করছে।

জন্ম এবং এক বছর বয়স পর্যন্ত শিশুর শারীরিক বৃদ্ধি ও স্বাস্থ্য সম্পর্কে আরও বেশী জানা এই গবেষণার উদ্দেশ্য এবং এর সাহায্যে আমরা ঢাকায় শিশু স্বাস্থ্য সেবার উন্নয়ন সম্পর্কে সুপারিশ করতে পারব। আজকে এবং শিশুর এক বছর বয়স পর্যন্ত আরও কয়েকবার আপনাকে কিছু প্রশ্ন করে আমরা এই কাজ করতে চাই। আপনার শিশুর স্বাস্থ্য ও আহার, এবং আপনার ঘর সম্পর্কে আমরা প্রশ্ন করব। এছাড়া আমরা আপনার শিশুকে পরীক্ষা করে দেখব সে ঠিক আছে কিনা এবং তার ওজন, উচ্চতা, বাহু, বুক, ও মাথার মাপ নেব। আমরা আপনার ওজন, উচ্চতা, ও বাহুর মাপও নেব।

আপনি এই গবেষণায় অংশ গ্রহণ করতে সম্মত হলে, আজকে আমরা আপনার শিশুকে পরীক্ষা করতে চাই এবং তার সম্পর্কে কিছু প্রশ্ন করতে চাই। এতে প্রায় ৩০ মিনিটের মত সময় লাগবে। শিশুর বয়স যখন ৭ দিন হবে তখন আমরা আবার আসব এবং এরপর আবার শিশুর ১৪ দিন ও ১, ৩, ৬, ৯, ও ১২ মাস বয়সে আসব। কখনই ৩০ মিনিটের বেশী সময় লাগবে না। এ সব কিছু আমাদের বুঝতে সাহায্য করবে আপনার শিশু কেমন বাড়ছে এবং সে কোন স্বাস্থ্য সমস্যায় পরেছে কিনা।

আপনার শিশুকে পরীক্ষার ফলে তার কোন প্রকার ক্ষতি হবে না, বরং তা আমাদেরকে তার স্বাস্থ্যের মূল্যায়ণ করতে সাহায্য করবে। আপনার শিশু যদি অসুস্থ হয় তবে আমরা নিকটবর্তী একটি হাসপাতালে তার চিকিৎসা পেতে সাহায্য করব। আমাদের প্রশ্নের উত্তর দেয়ার ফলেও আপনার ও আপনার শিশুর কোন ক্ষতি হবে না। শুধু উত্তর দেয়ার জন্য কিছু সময় যাবে।

আমরা জানি যে আপনার শিশু ও ঘর সম্পর্কে প্রশ্ন করলে, তার কিছু কিছু প্রশ্ন হবে আপনার একান্ত ব্যক্তিগত। সেজন্য আমরা আপনার উত্তরগুলো গোপন রাখব। এই জন্যই এই প্রশ্নমালায় আপনার নাম নাই।

এমন কিছু প্রশ্ন যদি থাকে যা আপনি উত্তর দিতে না চান তাতে কোন অসুবিধা নাই। আপনি এই গবেষণার প্রশ্নগুলোর উত্তর না দেয়ার 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 ডা: সামস এল আরেফিন অথবা আরবান হেল্থ একসটেনশন প্রজেক্ট এর সাথে ৬০০০০৩ নম্বরে যোগাযোগ করতে পারেন।

আপনি কি এই গবেষণায় অংশগ্রহণ করতে রাজি আছেন?

সম্মতি গ্রহণকারীর স্বাক্ষর

সম্মতির তারিখ

মূল গবেষকের স্বাক্ষর

Appendix A

OPERATIONAL DEFINITIONS OF VARIABLES

VARIABLES		DEFINITION
Name	Type	
OUTCOME VARIABLES		
Mortality	Binary (Yes/No)	(# of Deaths)/(# of live births) Deaths may be neonatal, post-neonatal or infant, as appropriate
Cause-specific mortality	Binary (Yes/No)	(# of Cause-Specific Deaths)/(# of live births) As appropriate, causes may be pneumonia, diarrhoea, others, and deaths may be neonatal, post-neonatal or infant.
Morbidity	Continuous - Total # of Days	Total days with specific morbidity summed across the recall periods of each of the 8 visits.
	- # of Episodes	Total # of episodes of specific morbidity summed across the recall periods of each of the 8 visits.
INDEPENDENT VARIABLES		
Infant Status at Birth	Continuous	Actual measures of Birth weight, length, gestational age, weight for gestational age, ponderal index, head, chest and arm circumferences
	Ordinal	Categorization of the above indices based on distribution of data
	Binary	NBW/LBW, Stunted/Wasted IUGR
	Nominal	Preterm, IUGR, NBW
Infant Growth	Continuous	Actual measures of weight, length, weight for age, length for age, weight for length, head, chest and arm circumferences, growth velocity
	Ordinal	Categorization of the above indices based on distribution of data
	Binary	Well Nourished/Malnourished
	Nominal	Stunted Wasted Wasted & Stunted

VARIABLES		DEFINITION
Name	Type	
INDEPENDENT VARIABLES (contd..)		
Breast feeding	Ordinal	Categorization of breast feeding pattern based on distribution of data
	Binary	Exclusive BF/Other Predominant BF/Other
Maternal Nutritional Status	Continuous	Actual measures of weight, height, body mass index and arm circumferences, post partum weight gain.
	Ordinal	Categorization of the above indices based on distribution of data
	Binary	Well Nourished/Malnourished
Maternal Gravidity	Ordinal	Categorization based on distribution of number of prior live/still births
	Binary	Primigravida/multigravida
Maternal Age	Continuous	Actual measures of age
	Ordinal	Categorization of age based on distribution of data
Interpregnancy Interval	Continuous	Actual measures of duration (preceding/ succeeding)
	Ordinal	Categorization based on distribution of data
Maternal/Paternal Education	Continuous	Actual measures of years of schooling
	Ordinal	Categorization based on distribution of data
	Binary	Some education/No education
Maternal/Paternal Employment	Ordinal	Categorization based on distribution of data
	Binary	Employed/Unemployed
Household Income	Continuous	Actual measures of income
	Ordinal	Categorization based on distribution of data
	Binary	High/Low income
Dwelling Structure	Binary	Good/Poor
	Ordinal	Categorization based on distribution of data

VARIABLES		DEFINITION
Name	Type	
INDEPENDENT VARIABLES (contd..)		
Family Assets	Binary	High/Low (based on ownership of key assets)
	Ordinal	Categorization based on distribution of data
Family Religion	Nominal	Actual religion (Muslim, Hindu, Christian, etc.)
Household Size	Continuous	Actual number of household members
	Ordinal	Categorization based on distribution of data
Exposure to smoke - cigarette	Binary	Smoke/Not smoke
	Ordinal	Categorization based on distribution of data
Exposure to smoke - cooking	Binary	Exposed to cooking smoke/not exposed

Appendix B

Details of Data Collected at Each Visit

Each mother-child unit will be visited within 72 hours of delivery; at 1, 2 and 4 weeks of age; and at 3, 6, 9 and 12 months of age. Information collected at these visits are as follows.

* **1st visit within 72 hours of birth**

- The newborns will be physically examined to detect congenital anomalies. A non-invasive procedure described by Capurro (1978) will be used to assess the baby' gestational age[1]. A simple clinical examination will be performed including respiration rate counts, signs of respiratory distress and dehydration, and rectal temperature.

- Head, arm and chest circumferences; and weight and length of the newborn will be measured. Standardized equipment will be used for this purpose. The approximate age of the child in hours will also be noted.

- Information will be collected on perinatal outcome, i.e., whether live birth or still birth; whether still alive or dead; if dead, the cause of death; and the baby's gender. Information will also be collected on any morbidity since birth.

- Information on the dietary intake of the child since birth, including breast feeding, will be obtained through a food frequency questionnaire. A categorization modified from Labbok et al will be used to classify breast feeding patterns (Labbok,1990)[2]. These categories are:
  a. Exclusive
  b. Predominant (addition of water & non-nutritious drinks)
  c. Partial (breast milk + other food)
  d. Lack (complete lack or token breast feeding)

- Information on the delivery, e.g., location, difficult or not, cord prolapse or twisting, expulsion of placenta, meconium staining, bleeding, etc., and on symptoms of toxaemia and/or eclampsia during the pregnancy will be obtained.

- We will ascertain whether the newborn was exposed to smoke from any sources at or after birth, especially sources associated with birth rituals.

* **2nd, 3rd and 4th visits at 1, 2 and 4 weeks post-partum respectively**

At all three visits

- Neonatal morbidity and death since the last visit and cause of death will be assessed using a structured questionnaire. In addition to interviewing the mother about morbidity, the infant will be subjected to a simple clinical examination including respiration rate counts, signs of respiratory distress and dehydration, and rectal temperature. Information on cause of death is now routinely collected by the USS using verbal autopsy methods. During the period of this study, verbal autopsies will continue to be performed by USS interviewers. However, we will still collect information on morbidity preceding death using the structured questionnaire.

- Information on the dietary intake of the child since the last visit, including breast feeding, will be obtained through a food frequency questionnaire. Any changes in breast feeding and intake of other food since the last visit will also be noted along with time of changes.

---

1 Capurro H, Konichezky S et al. (1978) A simplified method for diagnosis of gestational age in the newborn infant. J Ped. 93:120-122.

2 Labbok M, Krasovec K. Toward Consistency in Breastfeeding Definitions. Stu F Plan. 1990; 21(4):226-9.

2nd visit at 1 week post-partum only

- Mother's weight, and mid-upper arm circumference will be measured.

- We will ascertain whether the newborn was exposed to smoke from any sources at or after birth, especially sources associated with birth rituals.

4th visit at 4 weeks post-partum only

- Head, arm and chest circumferences; weight; and length of the infant will be measured using standardized equipment.

- Mother's weight, and mid-upper arm circumference will be measured.

- Information on the usual cigarette smoking behavior of the family members, specifically of the care givers of the infant, will be obtained.

- Information on household cooking and risk of exposure to smoke will be obtained using questionnaires.

<u>5th, 6th, 7th and 8th visits at 3, 6, 9 and 12 months of age respectively</u>

- Head, arm and chest circumferences; and weight and length of the infant will be measured using standardized equipment.

- Mother's weight and mid-upper arm circumference will be measured at the time of the 4th visit. This will allow measurement of post-partum change in maternal weight.

- The mother (or guardian if mother absent) will be asked to report all morbidity episodes of the child in the last two weeks. The infants will also be examined for signs present at the time of the visit. Predetermined case definitions will be used to identify cases of pneumonia and diarrhoea. The decision to obtain only 2 week recall of morbidity was based on two considerations, (a) recall over a period exceeding 2 weeks is likely to be inaccurate and increasing the frequency of visits would be logistically extremely difficult, and (b) Though we will not be able to collect complete incidence information, we would still be able to make valid comparisons between LBW and NBW in terms of morbidity, and thus be able to examine the causal linkage between LBW and cause-specific death.

- In case of death since the last visit, the cause of death will be determined. As already stated, the USS routinely collects cause of death information. We propose to use the USS for cause of death data. However, we will still collect information on morbidity preceding death using our structured questionnaire if the time period falls within the previous 2 weeks.

- A 7 day recall of dietary intake of the child will be obtained. At these visits information on breast feeding in the last 7 days and any changes in breast feeding and intake of other food since the last visit will also be obtained and specific time of changes will be noted

- The mother will be asked about her current pregnancy status and if pregnant again, her LMP date would be recorded.

- Information on the usual cigarette smoking behavior of the family members, specifically of the care givers of the infant, will be obtained.

- Information on household cooking and risk of exposure to smoke will be obtained using questionnaires.

6th, 7th and 8th visit at 6, 9 and 12 months of age only

- Information will be obtained about occurence of measles since the last visit. Predefined case definitions will be used to identify cases of measles.

Appendix C

Cause of Morbidity and Death

In line with current USS procedures, information collected by the interviewers will be independently reviewed by three physicians. Predefined case definitions will be used to assign cause of morbidity or death. The final cause will be based on the majority decision among three physicians. Multiple causes of death will be allowed.

The proposed case definitions for pneumonia, asphyxia, respiratory distress syndrome, measles and diarrhoea are as follows:

Pneumonia

The case definition for pneumonia has been modified from the one recommended by the World Health Organization.[1]

Symptoms and signs used in the diagnosis of pneumonia can be classified into three categories:

I. Cough and difficult breathing.
II. Chest indrawing and rapid breathing (if <2 months old then ≥60/minute, if >2 months old then ≥50/minute).
III. Convulsions, noise during breathing (stridor, wheezing), nasal flaring, fever (≥38°C), central cyanosis (blue lips/skin), whether feeding well, able to drink, and abnormally sleepy or difficult to wake.

Infants will be considered to have pneumonia if the following minimum number of symptoms/signs are present, i.e., if there is history or presence of either:

- any one symptom/sign from each of the three categories, or
- any one symptom/sign from category I and both symptom/signs from category II.
- both symptom/signs from category I and any one symptom/sign from category II.

An episode of pneumonia shall be considered a new incident case if at least seven days free of any symptom or signs separate it from the previous episode.

Perinatal Asphyxia

A history of the following will be used to reach a diagnosis of perinatal asphyxia (modified from Cochran,1990 and Ment,1990)[2].

- Baby showed some signs of life after birth
- Baby did not cry or cried weakly after birth.
- Baby's breathing was weak and irregular (not distressed).
- The baby did not suckle normally.
- Baby was lethargic, floppy.
- Baby's skin was bluish.

---

[1] World Health Organization. (1991) Acute respiratory infections in children: Case management in small hospitals in developing countries, A manual for doctors and other senior health workers. Program for the Control of Acute Respiratory Infections. World Health Organization.

[2] Cochran WD. (1990) Management of the normal newborn. In: Oski FA ed., Principles and Practice of Pediatrics. JB Lippincott Co. Philadelphia; 276-81.

Ment LR. (1990) Perinatal Asphyxia. In: Oski FA ed., Principles and Practice of Pediatrics. JB Lippincott Co. Philadelphia; 318-21.

Respiratory Distress Syndrome (RDS)

The following history will be used to reach a diagnosis of RDS (modified from Bhakoo et al,1975 and Gross,1990)[3].

- Respiratory distress within 4 hours of death, and gets steadily worse. Respiratory distress is characterized by difficult breathing, rapid breathing (≥60 per minute) or chest retractions.
- Improvement of respiratory distress after 48-72 hours.

Differentiating neonatal pneumonia from perinatal asphyxia or respiratory distress syndrome may be difficult. If differentiation is not possible, either all cases will be lumped together as pneumonia or deaths in the first 7 days will be excluded in the analysis of impact of birth weight and gestational age on pneumonia-specific mortality.

Measles

An infant will be diagnosed as having measles if there is history or presence of fever, generalized rash lasting 3 or more days and either cough, coryza or conjunctivitis.[4]

Diarrhoea

Diarrhoea is conventionally defined as occurrence of loose or liquid stool 3 or more times per day or bloody stools.[5] However, this definition is unlikely to be appropriate for the very young, breastfed infant. Therefore, the mother's perception of the episode will be used to define diarrhoea. If, according to the mother, the child's stool was unusually frequent and unusually loose then this would be defined as diarrhoea. Presence of blood will be classified as diarrhoea if there was at least one loose stool. At least 3 days free of symptoms and signs shall separate episodes.

Other Conditions

Current medical guidelines would be used to define morbidity episodes due to other causes.

Criteria for Cause of Death

An infant will have died of pneumonia, measles, diarrhoea or other conditions if there had been an episode of these conditions immediately preceding death. Measles, if occurring within 6 weeks of death, will be considered as the cause of death. Standardization will be achieved with USS guidelines for conducting verbal autopsies. These guidelines are currently under review.

---

[3] Bhakoo ON, Narang et al. (1975) Neonatal morbidity and mortality in hospital born babies. Ind Ped. 12:443-50.

[4] Centers for Disease Control. (1990) Measles. in; Case Definitions for Public Health Surveillance. MMWR. 39(RR-13):23.

Cutts F. (1990) Measles Control in the 1990s: Principles for the next decade. Expanded Programme on Immunization. World Health Organization. WHO/EPI/GEN/90.2.

[5] Baqui AH, Black RE et al. (1991) Methodological Issues in Diarrhoeal Diseases Epidemiology: Definition of Diarrhoeal Episodes. Int J Epidemiol. 20(4):1057-63.

Appendix D

Summary of Available Information

Table D.1
Summary of Available Information on LBW Prevalence in Bangladesh.

STUDIES	LBW	IUGR	Preterm	2000-2499gms	<2000gms
Khan, 1970	50%	-	-	40%	10%
Canosa, 1989	45%	30%	14%*	33%	11%
Huque, 1991	41%	-	-	39%	2%
Urban Slum Pilot Study, 1989	27%	15%	12%	21%	6%

*Estimated from data presented .

Table D.2
Relative risks for Infant Mortality by Cause and Birth Weight and Gestational Age in Selected Populations

	Ghosh, 1979* (N.Delhi)	Victora, 1987 (Brazil)			Chase, 1969 (USA)
IMR>	47	38			25
	Overall	Overall	Diarr	ARI	Overall
NBW	1.0	1.0	1.0	1.0	1.0
LBW	4.4	10.6	2.5	6.7	17.0
NBW	1.0	1.0	-	-	-
IUGR	3.4	4.4	-	-	-
Preterm	7.3	10.8	-	-	-
NBW	1.0	1.0*	-	-	1.0*
2000-2499	3.0	6.1	-	-	5.2
<2000	15.0	19.6	-	-	39.5

*Estimated from data presented

Note:
The exact definition of LBW and the sub-categories used in the three studies differ slightly. However, this is unlikely to have had a major effect on the risk estimates.

Appendix E

Assumptions Regarding Expected Birth Weight Distribution and Relative Risks for Infant Mortality by Cause in Dhaka Slums

	NBW ≥2500 gm	LBW				
		TOTAL	IUGR	PRE TERM	2000-2499gm	<2000 gm
DISTRIBUTION	70.0%	30.0%	18.0%	12.0%	20.0%	10.0%
Infant Mortality by Cause						
OVERALL:						
Relative risk	1.0	3.0	2.0	4.5	2.0	5.0
Mortality	8.9%	26.6%	17.7%	39.9%	17.7%	44.3%
PNEUMONIA:						
Relative risk	1.0	3.0				
Mortality	2.0%	6.0%				
DIARRHOEA:						
Relative risk	1.0	3.0				
Mortality	1.8%	5.5%				
Neonatal Mortality						
Relative risk	1.0	4.1	2.5	6.5		
Mortality	3.6%	14.6%	8.9%	23.2%		
Post-Neonatal Mortality						
Relative risk	1.0	2.3	1.7	3.2		
Mortality	5.3%	11.9%	8.8%	16.7%		

ABSTRACT SUMMARY FOR ETHICAL REVIEW COMMITTEE

Protocol: Birth Weight and Infant Mortality in the Slums of Dhaka City: A Prospective Study

The purpose of this study is threefold. First, to determine the incidence of low birth weight (LBW), intrauterine growth retardation (IUGR) and prematurity, and estimate neonatal and post neonatal mortality rates in an urban slum population of Bangladesh. Second, to test several hypotheses regarding the effect of birth weight and gestational age on infant morbidity and cause-specific mortality in this population. And third, to estimate the contribution of low birth weight to infant mortality observed in this population (the attributable risk).

The methods and procedures used by this study are summarized below:

1) The required subject population of this study is newborn infants living in the Urban Surveillance System (USS) area in Dhaka. The USS is operated by the Urban Health Extension Project (UHEP) of ICDDR,B. The USS tracks vital and demographic events in a sample of the slum population of 5 thanas (Mohammadpur, Lalbagh, Kotwali, Sutrapur and Demra) of Dhaka City. The rationale is to ascertain infants' weight and gestational age at birth and to observe the infants until their first birthday in order to examine the effect of birth weight and gestational age in infant morbidity and mortality. This information would be essential before designing specific interventions aimed at reducing infant mortality in this population. The participants (infants) will be not be able to give voluntary informed consent so parental consent will be obtained.

2) This study poses no physical, psychological or social risks to the infant. Anthropometric and gestational age assessments, and the minimal physical examination pose no physical risk to the infants. Since the interviews deal with personal information, there are potential social and psychological risks to the family if the data are not kept confidential. There are no alternative research methods for obtaining the necessary information. There is no possibility of any legal risks to the study participants, as no data collected relate to the legal status (e.g. illegal behaviors) of family members.

3) To minimize psychological and social risks to the mother, all interviews will be conducted in private, exceptions only being made if the respondent insists on the presence of others. Only questions that are considered acceptable and necessary will be asked and they will be asked in manner that is sensitive to the believes of the respondent. Interviewing a mother soon after birth or infant death may pose potential psychological risk to the mother; interviewers will be instructed to reschedule the interview if the mother prefers to wait.

   Anthropometric and gestational age assessments, and physical examination will be done with minimal uncovering of the newborn to prevent any cooling. Excessive cooling of the newborn, especially if small or premature is often of concern, but which is not a possibility in this study. During weighing, infants will be kept wrapped in a cloth of known weight.

4) Each questionnaire and data collection form will be given an identification code. Interviewers will maintain strict confidentiality of the information they collect. 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 (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. When a respondent has completed an interview, the cover sheet with her name and address will be separated from the interview and retained by the investigator in a locked cabinet. Only the investigator will have access to this material.

Data entered onto the computer will not include the names or addresses of the respondents, but will include the unique identifier.

5) A pregnant woman would be identified by the USS system. As part of the collaborating study on **"determinants of LBW..."**, the Study Interviewers will visit the pregnant woman to explain the method of immediately notifying her pregnancy outcome. As soon as the pregnancy outcome is notified to the nearest UHEP Field Office, an interviewer will visit the woman in her home to introduce herself and describe the study. The interviewer will discuss the purpose, requirements, risks and benefits of the study with the woman and obtain her consent.

   (a) Signed consent will not be obtained. Since most women in this population are illiterate and not accustomed, or comfortable with signing forms, so a verbal consent is the only option. 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, signed by the Principle Investigator and Interviewer will be given to the woman.

   (b) Information will not be withheld from a subject.

   (c) The attached consent form states that the subject's confidentiality will be protected. Compensation is not provided by this study. The consent form states that referral and assistance for treatment at a nearby hospital will be provided.

6) All interviews will take place in the woman's own home. Eight interviews will be conducted over a period of 12 months, i.e., within 72 hours of delivery; at 1, 2 and 4 weeks of age; and at 3, 6, 9 and 12 months of age. No interview is expected to last more than 30 minutes.

7) The only direct benefit to participation in the study is medical referral and ensured treatment at a nearby collaborating hospital when necessary. All infants who are referred will be given an identifying card, signed by a collaborating physician at the hospital (and accompanied by an interviewer if necessary) so that they are received and cared for in a timely manner.

   For the society in general, we will be able to provide population-specific information on the effect of birth weight and gestational age on infant health and propose more effective public health interventions in Dhaka city for improving infant survival. We would be in a position to determine whether an intervention was necessary and feasible, i.e., whether LBW was indeed a problem in this population in terms of attributable mortality and whether the most important contributory factors were amenable to interventions.

   The proposed study will also provide estimates of cause specific neonatal and infant mortality rates and incidence of LBW for an urban slum population. Such data would be very useful in setting priorities for health programming and serving as the baseline for evaluating the impact of child survival interventions in this population.

8) No records, organs, tissue, body fluids, the fetus or the abortus will be required for the study.

Appendix F

Questionnaires

Study # __/__/__/__/

Version Date: January 1, 1985

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

URBAN HEALTH EXTENSION PROJECT

24 HOUR POSTPARTUM INTERVIEW

d of Household's Name _____

her's Name _____ Mother's Name _____

ld's Name _____ Respondent's Name _____

ress: _____

_____

DATA MANAGEMENT:

TEAR OFF THIS SHEET AND FILE SEPARATELY]

sha

_____/_____
Interviewer's Initials & Code

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

URBAN HEALTH EXTENSION PROJECT

24 HOUR POSTPARTUM INTERVIEW

ratum No.:___ Cluster No.:___ Struc. No.:___ HH No.:___

Head ID:___ Father's ID:___ Mother's ID:___ Respondent's ID:___

ild's ID:___ Child's P No.:_____

P Date: _____/_____/_____ EDD: _____/_____/_____

te of Reporting: _____/_____/_____/ Time of Reporting: _____ a.m./p.m.

entity of Reporter:

Husband	1
Other male family member _____	2
Other female family member _____	3
Neighbour/Friend	4
UHEP Volunteer	5
Slum caretaker/manager	6
Other _____	7

te of Visit: ____/____/____ Time of Visit: _____ a.m./p.m.

st persons present
ring interview: _____

ll be asking you questions today about your baby's health.

CTION I: INFANT OUTCOME, WELL-BEING AND FEEDING

01a. What day was your baby delivered? [PROBE AND CALCULATE DATE OF BIRTH]

____/____/____
dd mm yy

01b. What time of the day did you deliver? [PROBE AND CALCULATE]

____:____ a.m./p.m.

02. Was it a boy or a girl?

Boy 1
Girl 2

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

Alive . . . . . 1 [GO TO Q1105]
Dead 2

04. Did the baby show any signs of life, like crying or taking a breath?

Yes . . . . . 1 [GO TO Q1122]
No . . . . . 2 [GO TO Q1140]

05a. Have you put the baby to your breast yet?

Yes 1
Not yet . . . . . 2 [GO TO Q1106]
Will not breastfeed . . 3 [GO TO Q1106]

05b. When did you first put him/her to your breast?

_____ hrs after birth

05c. On which days did you breastfeed him/her?
[RECORD INFORMATION IN THE NEONATAL FEEDING CARD]

05d. How frequently are you breastfeeding the baby?

≥3 times/day 1
1-2 times/day 2
Less than once/day . . 3
Don't Know 9

06a. Have you fed anything to the baby besides breastmilk, for example, water, sugar water, honey, milk, etc.?

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

06b. What have you given the baby since birth?

Plain water 02
Sugar water 03
Honey 04
Animal milk 05
Powdered milk 06
Other liquid 07
Other _____ 11

06c. Did you feed these to the baby before or after first giving breastmilk?

	Before	After	Not Breastfed
Plain water	1	2	3
Sugar water	1	2	3
Honey	1	2	3
Animal milk	1	2	3
Powdered milk	1	2	3
Other liquid	1	2	3
Other _____	1	2	3

06d. On which days did you feed him/her these items?
[RECORD INFORMATION IN THE NEONATAL FEEDING CARD]

06e. On the days that you gave these items to the baby, how many times in a day did you feed him/her?

	≥3 times/day Yes	No
Plain Water	1	2
Sugar Water	1	2
Honey	1	2
Animal Milk	1	2
Powdered Milk	1	2
Other Liquid	1	2
Other_____	1	2

06f. Did you give anything to the baby to drink from a bottle?

Yes 1
No 2
Don't Know 9

If yes, what? _____

107a. Was the baby born normal, or was there something physically wrong with the baby's head, body or limbs?

Looked normal . . . . . 1 [GO TO Q1108]
Malformation/Injury . . 2
Don't Know . . . . . 9 [GO TO Q1108]

107b. What was wrong with the baby? _____

108a. Were there bruises or marks of injury on the baby's body after birth?

Yes 1
No . . . . . 2 [GO TO Q1109]
Don't Know . . . . . 9 [GO TO Q1109]

108b. Can you describe where the bruises or marks were, and what they looked like?

_____

109a. Is your baby suffering from any illness today?

Yes 1
No . . . . . 2 [GO TO Q1110]
Don't Know . . . . . 9 [GO TO Q1110]

109b. Please describe what is wrong? **[WHAT, WHEN, HOW LONG]**

_____

_____

110a. Did the baby fail to breathe, cry or suckle normally during the first day (hours) after birth?

Yes 1
No 2
Don't Know 9

110b. Was the baby limp or unconscious during the first three days after birth?

Yes 1
No 2
Don't Know 9

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

Yes 1
No 2
Don't Know 9

1112a. Did the baby have fever at all since birth?

Yes	1	
No	2	[GO TO Q1113]
Don't Know	9	[GO TO Q1113]

1112b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

1113a. Did the baby have cough at all since birth?

Yes	1	
No	2	[GO TO Q1114]
Don't Know	9	[GO TO Q1114]

1113b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

1114a. Did the baby have difficulty in breathing at any time since birth?

Yes	1	
No	2	[GO TO Q1115]
Don't Know	9	[GO TO Q1115]

1114b. How soon after birth did the difficulty in breathing start?

_____ hours after birth

1114c. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

1115a. Did the baby have chest indrawing at any time since birth?
[CHEST INDRAWING = INWARD MOVEMENT OF THE LOWER CHEST WHEN BREATHING IN]

Yes	1	
No	2	[GO TO Q1116]
Don't Know	9	[GO TO Q1116]

1115b. How soon after birth did the chest indrawing start?

_____ hours after birth

1115c. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

1116a. Did the baby have short rapid breaths at any time since birth?

Yes	1	
No	2	[SKIP Q1116b & c]
Don't Know	9	[SKIP Q1116b & c]

1116b. How soon after birth did the rapid breathing start?

_____ hours after birth

16c. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

F THERE WAS NO COUGH OR DIFFICULT BREATHING OR CHEST INDRAWING OR RAPID EATHING GO TO Q1118]

17a. Did the baby stopped feeding well because of breathing difficulty?

Yes 1
No 2
Don't Know 9

17b. Was the baby abnormally sleepy, difficult to wake, limp or unconscious during this illness?

Yes 1
No 2
Don't Know 9

17c. Did the baby's skin/lips become dark or bluish during this illness?

Yes 1
No 2
Don't Know 9

17d. Did the baby make noise from the chest when breathing during this illness?

Yes 1
No 2
Don't Know 9

17e. Did the baby's nostrils move and spread out while breathing during this illness?

Yes 1
No 2
Don't Know 9

18a. Did the baby have diarroea and/or bloody stool at any time since birth? [DIARRHOEA: FREQUENT UNUSUALLY LOOSE STOOL]

Yes, loose 1
Yes, liquid 2
No . . . . . 3 [GO TO Q1119]
Don't Know . . . . . 9 [GO TO Q1119]

18b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

18c. What was the maximum number of stools on any one day?

18d. Was there any blood in the stools?
[THE ANSWER IS YES EVEN IF BLOOD WAS SEEN JUST ONCE]

Yes 1
No 2
Don't Know 9

18e. Was there any mucus in the stools?
[THE ANSWER IS YES EVEN IF MUCUS WAS SEEN JUST ONCE]

Yes 1
No 2
Don't Know 9

18f. At the time of the diarrhoea, was the baby at any time weak, limp or drowsy?

Yes 1
No 2
Don't Know 9

.8g. At the time of the diarrhoea, did the baby also have intense thirst?

Yes 1
No 2
Don't Know 9

8h. At the time of the diarrhoea, did the baby also have dry mouth and tongue?

Yes 1
No 2
Don't Know 9

8i. At the time of the diarrhoea, did the baby also have loose skin?

Yes 1
No 2
Don't Know 9

8j. At the time of the diarrhoea, did the baby also have a depression in the front of the head?

Yes 1
No 2
Don't Know 9

8k. At the time of the diarrhoea, did the baby also have sunken eyes?

Yes 1
No 2
Don't Know 9

181. At the time of the diarrhoea, how was the baby's urine?

Normal 1
Less frequent than normal . . . 2
No urine in last 8 hours . . . 3
Don't Know 9

18m. Did you give ORT to the baby?

No 1
Packet 2
Home made 3
Don't Know 9

19a. Did the baby have spasms or convulsions at any time since birth?

Yes 1
No . . . . . 2 [GO TO Q1120]
Don't Know . . . . . 9 [GO TO Q1120]

19b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

20a. Has the baby had any other illness or symptoms since birth?

Yes 1
No . . . . . 2 [GO TO Q1121]
Don't Know . . . . . 9 [GO TO Q1121]

20b. Please describe the illness/symptoms? [WHAT, WHEN, HOW LONG]

_____

_____

_____

21a. Have you received any treatment or medicine for your baby?

Yes 1
No . . . . . 2 [GO TO Q1201]
Don't Know . . . . . 9 [GO TO Q1201]

21b. For what condition was the baby treated? _____

_____

21c. Who gave you treatment or medicine? _____

21d. What kind or treatment or medicine did you receive?

_____

TO SECTION 11, 1201]

END: MODULE ON EARLY NEONATAL DEATH

22a. Was the baby born normal, or was there something physically wrong with the baby's head, body or limbs?

Looked normal . . . . . 1 [GO TO Q1123]
Malformation/Injury . . 2
Don't Know . . . . . 9 [GO TO Q1123]

22b. What was wrong with the baby? _____

23a. Were there bruises or marks of injury on the baby's body after birth?

Yes 1
No . . . . . 2 [GO TO Q1124]
Don't Know . . . . . 9 [GO TO Q1124]

23b. Can you describe where the bruises or marks were, and what they looked like?

_____

24. Was the baby born smaller than usual?

Yes 1
No 2
Don't Know 9

25a. Did the baby fail to breathe, cry or suckle normally during the first day (hours) after birth?

Yes 1
No 2
Don't Know 9

26b. Was the baby limp or unconscious during the first three days after birth before dying?

Yes 1
No 2
Don't Know 9

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

Yes 1
No 2
Don't Know 9

28a. Did the baby have fever at all before death?

Yes 1
No . . . . . 2 [GO TO Q1129]
Don't Know . . . . . 9 [GO TO Q1129]

28b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

29a. Did the baby have cough at all before death?

Yes	1	
No	2	[GO TO Q1130]
Don't Know	9	[GO TO Q1130]

29b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

30a. Did the baby have difficulty in breathing at any time before death?

Yes	1	
No	2	[GO TO Q1131]
Don't Know	9	[GO TO Q1131]

30b. How soon after birth did the difficulty in breathing start?

_____ hours after birth

30c. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

31a. Did the baby have chest indrawing at any time before death?
[CHEST INDRAWING = INWARD MOVEMENT OF THE LOWER CHEST WHEN BREATHING IN]

Yes	1	
No	2	[GO TO Q1132]
Don't Know	9	[GO TO Q1132]

31b. How soon after birth did the chest indrawing start?

_____ hours after birth

31c. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

32a. Did the baby have short rapid breaths at any time before death?

Yes	1	
No	2	[SKIP Q1132b & c]
Don't Know	9	[SKIP Q1132b & c]

32b. How soon after birth did the rapid breathing start?

_____ hours after birth

32c. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

THERE WAS NO COUGH OR DIFFICULT BREATHING OR CHEST INDRAWING OR RAPID ATHING GO TO Q1134]

33a. Did the baby stopped feeding well because of breathing difficulty?

Yes 1
No 2
Don't Know 9

33b. Was the baby abnormally sleepy, difficult to wake, limp or unconscious during this illness?

Yes 1
No 2
Don't Know 9

33c. Did the baby's skin/lips become dark or bluish during this illness?

Yes 1
No 2
Don't Know 9

33d. Did the baby make noise from the chest when breathing during this illness?

Yes 1
No 2
Don't Know 9

33e. Did the baby's nostrils move and spread out while breathing during this illness?

Yes 1
No 2
Don't Know 9

34a. Did the baby have diarroea and/or bloody stool at any time before death? **[DIARRHOEA: FREQUENT UNUSUALLY LOOSE STOOL]**

Yes, loose 1
Yes, liquid 2
No . . . . . 3 [GO TO Q1135]
Don't Know . . . . . 9 [GO TO Q1135]

34b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

34c. What was the maximum number of stools on any one day?

_____

34d. Was there any blood in the stools?
[THE ANSWER IS YES EVEN IF BLOOD WAS SEEN JUST ONCE]

Yes 1
No 2
Don't Know 9

34e. Was there any mucus in the stools?
[THE ANSWER IS YES EVEN IF MUCUS WAS SEEN JUST ONCE]

Yes 1
No 2
Don't Know 9

34f. At the time of the diarrhoea, was the baby at any time weak, limp or drowsy?

Yes 1
No 2
Don't Know 9

34g. At the time of the diarrhoea, did the baby also have intense thirst?

Yes 1
No 2
Don't Know 9

34h. At the time of the diarrhoea, did the baby also have dry mouth and tongue?

Yes 1
No 2
Don't Know 9

34i. At the time of the diarrhoea, did the baby also have loose skin?

Yes 1
No 2
Don't Know 9

34j. At the time of the diarrhoea, did the baby also have a depression in the front of the head?

Yes 1
No 2
Don't Know 9

34k. At the time of the diarrhoea, did the baby also have sunken eyes?

Yes 1
No 2
Don't Know 9

1341. At the time of the diarrhoea, how was the baby's urine?

Normal 1
Less frequent than normal . . . 2
No urine in last 8 hours . . . 3
Don't Know 9

134m. Did you give ORT to the baby?

No 1
Packet 2
Home made 3
Don't Know 9

135a. Did the baby have spasms or convulsions at any time before death?

Yes 1
No . . . . . 2 [GO TO Q1136]
Don't Know . . . . . 9 [GO TO Q1136]

135b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

136a. Has the baby had any other illness or symptoms before death?

Yes 1
No . . . . . 2 [GO TO Q1137]
Don't Know . . . . . 9 [GO TO Q1137]

136b. Please describe the illness/symptoms? **[WHAT, WHEN, HOW LONG]**

_____

_____

_____

137a. Have your received any treatment or medicine for your baby?

Yes 1
No . . . . . 2 [GO TO Q1138]
Don't Know . . . . . 9 [GO TO Q1138]

137b. For what condition was the baby treated? _____

_____

137c. Who gave you treatment or medicine? _____

137d. What kind or treatment or medicine did you receive?

_____

38a. Had you put the baby to your breast before he/she died?

Yes 1
No . . . . . 2 [GO TO Q1139]

138b. When did you first put him/her to your breast?

_____ hrs after birth

138c. On which days did you breastfeed him/her?
[RECORD INFORMATION IN THE NEONATAL FEEDING CARD]

138d. How frequently were you breastfeeding the baby?

≥3 times/day 1
1-2 times/day 2
Less than once/day . . 3
Don't Know 9

139a. Had you fed anything to the baby besides breastmilk, for example, water, sugar water, honey, milk, etc.?

Yes 1
No . . . . . 2 [GO TO SECTION III]

139b. What else had you given the baby?

Plain water 02
Sugar water 03
Honey 04
Animal milk 05
Powdered milk 06
Other liquid 07
Other _____ 11

139c. Did you feed these to the baby before or after first giving breastmilk?

	Before	After	Not Breastfed
Plain water	1	2	3
Sugar water	1	2	3
Honey	1	2	3
Animal milk	1	2	3
Powdered milk	1	2	3
Other liquid	1	2	3
Other _____	1	2	3

139d. On which days did you feed him/her these items?
[RECORD INFORMATION IN THE NEONATAL FEEDING CARD]

139e. On the days that you gave these items to the baby, how many times in a day did you feed him/her?

	≥3 times/day Yes	No
Plain Water	1	2
Sugar Water	1	2
Honey	1	2
Animal Milk	1	2
Powdered Milk	1	2
Other Liquid	1	2
Other_____	1	2

139f. Did you give anything to the baby to drink from a bottle?

Yes 1
No 2
Don't Know 9

GO TO SECTION III]

SB: MODULE ON STILLBIRTH

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

_____

141. Was the baby smaller than usual?

Yes 1
No 2
Don't Know 9

142. Did the baby have an an unusual color?

Yes 1
No 2
Don't Know 9

143. Did the baby have an unusual smell?

Yes 1
No 2
Don't Know 9

O TO SECTION III]

TION II: INFANT ANTHROPOMETRY, PHYSICAL EXAMINATION & GESTATIONAL AGE

I would like to examine your baby. This examination is very simple and ick. Nothing I do will hurt the baby, or make him/her uncomfortable.

01. **Anthropometrics:**

ight _____gms

ngth _____cms

Mid-upper Arm Circumference _____mms

Chest Circumference _____mms

Head Circumference _____mms

02. **Physical Examination of the Baby:**

FINDINGS	CODING CATEGORIES
emperature	_____°F
espiration Rate	_____/minute
hest Indrawing	Normal . . . . . 1 Indrawing present 2
ydration Status	Normal . . . . . 1 Moderate Dehydration . . . . 2 Severe Dehydration 3

3. **Gestational Age Assessment (Capurro's Method):**

in ture	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
r rm	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	
east e	No breast tissue / 0	Diameter < 0.5 cm / 5	Diameter 0.5 - 1.0 cm / 10	Diameter > 1.0 cm / 15	
antar eases	No creases / 0	Faint red marks over anterior ½ / 5	Definite red marks over anterior ½, indentations over anterior third / 10	Indentations over anterior ½ / 15	Deep indentations over more than anterior ½ / 20
arf gn	/ 0	/ 6	/ 12	/ 18	
ad	/ 0	/ 4	/ 8	/ 12	

Total Score = _____

CTION III: DELIVERY & PREGNANCY HISTORY

I would like to ask you a few questions about your delivery and egnancy

01. Where was your baby delivered?

Marital home 1
Hospital/clinic (name_____) 2
Parent's home (Dhaka___ Village___) 3
Other relative's home (Dhaka___Village___) . . . 4
(Relation_____)
Other_____ 5

2. 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

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

Less than ½ Hour . . . 1
½ to 1 hour 2
More than 1 hour . . . 3

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

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

Less than 6 hours . . . 1
6 to 12 hours 2
12 to 24 hours 3
More than 24 hours . . 4

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

05. Did this seem like the normal amount of time, or was it too long, or unusually short?

Normal time 1
Longer than usual . . . 2
Shorter than usual . . 3

06. Do you think that your labor and delivery was normal, or were there any problems?
[PROBE, MULTIPLE ANSWERS POSSIBLE]

Yes, no problem 1
Too long 2
Water broke too early 3
Too much pain 4
Too much bleeding 5
Baby in wrong position 6
(What position: _____)
Afterbirth did not come quickly . . . 7
{<½, ½-2, >2 (___) hours after birth}
Tearing of perineum 8
Cord came out or was twisted around baby's neck 9
The baby was covered with a greenish/light brown material . . . 10
Convulsions 11
Other _____ 10

'a. Did you ever have convulsions during pregnancy?

Yes 1
No . . . . . 2 [GO TO Q1308]

'7b. When during your pregnancy did the convulsions occur?

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

'8a. Did you have headaches during your pregnancy?

Yes 1
No . . . . . 2 [GO TO Q1309]

'8b. 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

'9a. Did you have dizzy spells during your pregnancy?

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

'9b. 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

nk you for spending so much time telling us about yourself and your baby. will come back in a week to see how you and the baby are doing.

[redacted]

NEONATAL MORBIDITY FORM

Stratum No.: ____ Cluster No.: ____ Structure No.: ____ Household No.: ____

Mother's SL#: ___ Mother's Name: _____ Infants SL#: ___ Infant's Name: _____

[Put "11" if present on a given day, "00" if not present]

SYMPTOM		DAYS POST PARTUM															
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	Visit Due>>																
	DOV* >>																
Fever																	
Cough																	
Difficult breathing																	
Chest indrawing																	
Rapid breathing																	
Diarrhoea																	
Spasms/Convulsions																	

SYMPTOM		DAYS POST PARTUM														
		17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Visit Due>>															
	DOV* >>															
Fever																
Cough																
Difficult breathing																
Chest indrawing																
Rapid breathing																
Diarrhoea																
Spasms/Convulsions																

*DOV = Date of actual visit

Interviewer Initial & Code: _____/____

Low Birth Weight and Infant Mortality

Study # __/__/__/__/

NEONATAL FEEDING CARD

Stratum No.: ____ Cluster No.: ____ Structure No.: ____ Household No.: ____

Mother's SL#: ___ Mother's Name:_____ Infants SL#: ___ Infant's Name:_____

[Put "11" if item is given, "00" if not given]

Food Item		DAYS POST-PARTUM															
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	Visit Due>>																
	DOV*																
Breast Milk																	
Plain Water																	
Sugar Water																	
Honey																	
Animal Milk																	
Powdered Milk																	
Other Liquid																	
Other_____																	

*DOV = Date of actual visit

Interviewer Initial & Code:_____/_____

Low Birth Weight and Infant Mortality

Study # __/__/__/__/

[Put "11" if item is given, "00" if not given]

Food Item		DAYS POST-PARTUM														
		17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Visit Due>>															
	DOV*															
Breast Milk																
Plain Water																
Sugar Water																
Honey																
Animal Milk																
Powdered Milk																
Other Liquid																
Other_____		--														

*DOV = Date of actual visit

Interviewer Initial & Code:_____/_____

Study # __/__/__/__/

Draft Date: January 1, 1985

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

URBAN HEALTH EXTENSION PROJECT

7 DAY / 2 WEEK / 1 MONTH POSTPARTUM INTERVIEWS

ad of Household's Name _____

ther's Name _____ Mother's Name _____

ild's Name _____ Respondent's Name _____

dress: _____

_____

D DATA MANAGEMENT:

TEAR OFF THIS SHEET AND FILE SEPARATELY]

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

URBAN HEALTH EXTENSION PROJECT

7 DAY / 2 WEEK / 1 MONTH POSTPARTUM INTERVIEWS

:ratum No.:___ Cluster No.:___ Struc. No.:___ HH No. ___

l Head ID:___ Father's ID:___ Mother's ID:___ Respondent's ID:___

ild's ID:___ Child's P No.:_____

lanned Date of Visit: ____/____/____

:tual Date of Visit: ____/____/____

.st persons present
ıring interview: _____

[redacted]

ll be asking you questions today about your delivery, your health during egnancy and postpartum, and about your baby's health.

CTION I: INFANT WELL-BEING AND BREASTFEEDING

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

Alive 1
Dead . . . . . 2 [GO TO Q2113]

02a. Are you currently breastfeeding the baby?
[THE ANSWER IS YES EVEN IF BREASTMILK WAS GIVEN ON A SINGLE DAY ONLY SINCE THE LAST VISIT]

Yes 1
Not any more 4
Don't Know . . . . . 9 [GO TO Q2103]

02b. On which days did you breastfeed him/her?
[RECORD INFORMATION IN THE NEONATAL FEEDING CARD]

02c. How frequently are you breastfeeding the baby?

≥3 times/day 1
1-2 times/day 2
Less than once/day . . 3
Don't Know 9

03a. Have you fed anything to the baby besides breastmilk, for example, water, sugar water, honey, milk, etc.?
[THE ANSWER IS YES EVEN IF FOOD ITEM WAS GIVEN ON A SINGLE DAY ONLY SINCE THE LAST VISIT]

Yes 1
No . . . . . 2 [GO TO Q2104]

03b. What have you given the baby since my last visit?

Plain water 02
Sugar water 03
Honey 04
Animal milk 05
Powdered milk 06
Other liquid 07
Other _____ 11

03c. On which days did you feed him/her these items
[RECORD INFORMATION IN THE NEONATAL FEEDING CARD]

103d. On the days that you gave these items to the baby, how many times in a day did you feed him/her?

	≥3 times/day Yes	No
Plain Water	1	2
Sugar Water	1	2
Honey	1	2
Animal Milk	1	2
Powdered Milk	1	2
Other Liquid	1	2
Other_____	1	2

03e. Did you give anything to the baby to drink from a bottle?

Yes 1
No 2
Don't Know 9

If Yes, What? _____

104a. Is your baby suffering from any illness today?

Yes 1
No . . . . . 2 [GO TO Q2105]
Don't Know . . . . . 9 [GO TO Q2105]

104b. Please describe what is wrong? [WHAT, WHEN, HOW LONG]

_____

_____

_____

105a. Did the baby have fever at all since my last visit?

Yes 1
No . . . . . 2 [GO TO Q2106]
Don't Know . . . . . 9 [GO TO Q2106]

105b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

106a. Did the baby have cough at all since my last visit?

Yes 1
No . . . . . 2 [GO TO Q2107]
Don't Know . . . . . 9 [GO TO Q2107]

106b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

107a. Did the baby have difficulty in breathing since my last visit?

Yes 1
No 2
Don't Know 9

[IF YES, ASK] On which days did the baby have this symptom? **[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]**

107b. Did the baby have chest indrawing since my last visit? **[CHEST INDRAWING = INWARD MOVEMENT OF THE LOWER CHEST WHEN BREATHING IN]**

Yes 1
No 2
Don't Know 9

[IF YES, ASK] On which days did the baby have this symptom? **[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]**

107c. Did the baby have short rapid breaths since my last visit?

Yes 1
No 2
Don't Know 9

[IF YES, ASK] On which days did the baby have this symptom? **[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]**

IF THERE WAS NO COUGH OR DIFFICULT BREATHING OR CHEST INDRAWING OR RAPID REATHING GO TO Q2109]

108a. Did the baby stopped feeding well because of breathing difficulty?

Yes 1
No 2
Don't Know 9

108b. Was the baby abnormally sleepy, difficult to wake, limp or unconscious during this illness?

Yes 1
No 2
Don't Know 9

108c. Did the baby's lips become dark or bluish at any time during this illness?

Yes 1
No 2
Don't Know 9

08d. Did the baby make noise from the chest when breathing during this illness?

Yes 1
No 2
Don't Know 9

08e. Did the baby's nostrils move and spread out while breathing during this illness?

Yes 1
No 2
Don't Know 9

09a. Did the baby have diarrhoea and/or bloody stool at any time since my last visit? [DIARRHOEA: FREQUENT UNUSUALLY LOOSE STOOL]

Yes, loose 1
Yes, liquid 2
No . . . . . 3 [GO TO Q2110]
Don't Know . . . . . 9 [GO TO Q2110]

09b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

09c. What was the maximum number of stools on the day the diarrhoea was worst?

_____

09d. Was there any blood in the stools?
[THE ANSWER IS YES EVEN IF BLOOD WAS SEEN JUST ONCE].

Yes 1
No 2
Don't Know 9

09e. Was there any mucus in the stools?
[THE ANSWER IS YES EVEN IF MUCUS WAS SEEN JUST ONCE]

Yes 1
No 2
Don't Know 9

9f. At the time of the diarrhoea, was the baby at any time weak, limp or drowsy?

Yes 1
No 2
Don't Know 9

09g. At the time of the diarrhoea, did the baby also have intense thirst?

Yes 1
No 2
Don't Know 9

9h. At the time of the diarrhoea, did the baby also have dry mouth and tongue?

Yes 1
No 2
Don't Know 9

9i. At the time of the diarrhoea, did the baby also have loose skin?

Yes 1
No 2
Don't Know 9

9j. At the time of the diarrhoea, did the baby also have a depression in the front of the head?

Yes 1
No 2
Don't Know 9

9k. At the time of the diarrhoea, did the baby also have sunken eyes?

Yes 1
No 2
Don't Know 9

9l. At the time of the diarrhoea, how was the baby's urine?

Normal 1
Less frequent than normal . . . 2
No urine in last 8 hours . . . 3
Don't Know 9

9m. Did you give ORT to the baby?

No 1
Packet 2
Home made 3
Don't Know 9

10a. Did the baby have spasms or convulsions at any time since my last visit?

Yes 1
No . . . . . 2 [GO TO Q2111]
Don't Know . . . . . 9 [GO TO Q2111]

10b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

sha

111a. Did the baby have any other illness or symptoms since my last visit?

Yes 1
No . . . . . 2 [GO TO Q2112]
Don't Know . . . . . 9 [GO TO Q2112]

111b. Please describe the illness/symptoms? **[WHAT, WHEN, HOW LONG]**

_____

_____

_____

12a. Have you received any treatment or medicine for your baby?

Yes 1
No . . . . . 2 [GO TO SECTION II]
Don't Know . . . . . 9 [GO TO SECTION II]

112b. For what condition was the baby treated? _____

_____

112c. Who gave you treatment or medicine? _____

112d. What kind or treatment or medicine did you receive?

_____

GO TO SECTION II]

END: MODULE ON NEONATAL DEATH

13. When did the baby die?

Date of Death _________

14a. Did the baby have fever before death since my last visit?

Yes 1
No . . . . . 2 [GO TO Q2115]
Don't Know . . . . . 9 [GO TO Q2115]

14b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

15a. Did the baby have cough before death since my last visit?

Yes 1
No . . . . . 2 [GO TO Q2116]
Don't Know . . . . . 9 [GO TO Q2116]

15b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

16a. Did the baby have difficulty in breathing before death since my last visit?

Yes 1
No 2
Don't Know 9

[IF YES, ASK] On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

16b. Did the baby have chest indrawing before death since my last visit? **[CHEST INDRAWING = INWARD MOVEMENT OF THE LOWER CHEST WHEN BREATHING IN]**

Yes 1
No 2
Don't Know 9

[IF YES, ASK] On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

16c. Did the baby have short rapid breaths before death since my last visit?

Yes 1
No 2
Don't Know 9

[IF YES, ASK] On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

THERE WAS NO COUGH OR DIFFICULT BREATHING OR CHEST INDRAWING OR RAPID ATHING GO TO Q2118]

7a. Did the baby stopped feeding well because of breathing difficulty?

Yes 1
No 2
Don't Know 9

7b. Was the baby abnormally sleepy, difficult to wake, limp or unconscious during this illness?

Yes 1
No 2
Don't Know 9

7c. Did the baby's skin/lips become dark or bluish at any time during this illness?

Yes 1
No 2
Don't Know 9

7d. Did the baby make noise from the chest when breathing during this illness?

Yes 1
No 2
Don't Know 9

7e. Did the baby's nostrils move and spread out while breathing during this illness?

Yes 1
No 2
Don't Know 9

8a. Did the baby have diarrhoea and/or bloody stool before death since my last visit? [DIARRHOEA: FREQUENT UNUSUALLY LOOSE STOOL]

Yes, loose 1
Yes, liquid 2
No . . . . . 3 [GO TO Q2119]
Don't Know . . . . . 9 [GO TO Q2119]

8b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

8c. If yes, what was the maximum number of stools on the day the diarrhoea was worst?

_____

18d. Was there any blood in the stools?
[THE ANSWER IS YES EVEN IF BLOOD WAS SEEN JUST ONCE]

Yes 1
No 2
Don't Know 9

18e. Was there any mucus in the stools?
[THE ANSWER IS YES EVEN IF MUCUS WAS SEEN JUST ONCE]

Yes 1
No 2
Don't Know 9

18f. At the time of the diarrhoea, was the baby at any time weak, limp or drowsy?

Yes 1
No 2
Don't Know 9

18g. At the time of the diarrhoea, did the baby also have intense thirst?

Yes 1
No 2
Don't Know 9

18h. At the time of the diarrhoea, did the baby also have dry mouth and tongue?

Yes 1
No 2
Don't Know 9

18i. At the time of the diarrhoea, did the baby also have loose skin?

Yes 1
No 2
Don't Know 9

18j. At the time of the diarrhoea, did the baby also have a depression in the front of the head?

Yes 1
No 2
Don't Know 9

18k. At the time of the diarrhoea, did the baby also have sunken eyes?

Yes 1
No 2
Don't Know 9

81. At the time of the diarrhoea, how was the baby's urine?

Normal 1
Less frequent than normal . . . 2
No urine in last 8/12 hours . . 3
Don't Know 9

8m. Did you give ORT to the baby?

No 1
Packet 2
Home made 3
Don't Know 9

9a. Did the baby have spasms or convulsions before death since my last visit?

Yes 1
No . . . . . 2 [GO TO Q2120]
Don't Know . . . . . 9 [GO TO Q2120]

9b. On which days did the baby have this symptom?
[RECORD INFORMATION IN THE NEONATAL MORBIDITY CARD]

0a. Did the baby have any other illness or symptoms before death since my last visit?

Yes 1
No . . . . . 2 [GO TO Q2121]
Don't Know . . . . . 9 [GO TO Q2121]

0b. Please describe the illness/symptoms? **[WHAT, WHEN, HOW LONG]**

_____

_____

_____

1a. Since my last visit but before death, did you receive any treatment or medicine for your baby?

Yes 1
No . . . . . 2 [GO TO Q2122]
Don't Know . . . . . 9 [GO TO Q2122]

1b. For what condition was the baby treated? _____

_____

1c. Who gave you treatment or medicine? _____

1d. What kind or treatment or medicine did you receive?

_____

22a. Were you breastfeeding the baby?
[THE ANSWER IS YES EVEN IF BREASTMILK WAS GIVEN ON A SINGLE DAY ONLY SINCE THE LAST VISIT]

Yes 1
No . . . . . 4 [GO TO Q2123]

22b. On which days did you breastfeed him/her?
[RECORD INFORMATION IN THE NEONATAL FEEDING CARD]

22c. How frequently were you breastfeeding the baby?

≥3 times/day 1
1-2 times/day 2
Less than once/day . . 3
Don't Know 9

23a. Did you feed anything to the baby besides breastmilk, for example, water, sugar water, honey, milk, etc.?
[THE ANSWER IS YES EVEN IF FOOD ITEM WAS GIVEN ON A SINGLE DAY ONLY SINCE THE LAST VISIT]

Yes 1
No . . . . . 2 [GO TO Q2201]

23b. What else had you given the baby since my last visit?

Plain water 02
Sugar water 03
Honey 04
Animal milk 05
Powdered milk 06
Other liquid 07
Other _____ 11

23c. On which days did you feed him/her these items?
[RECORD INFORMATION IN THE NEONATAL FEEDING CARD]

23d. On the days that you gave these items to the baby, how many times in a day did you feed him/her?

	≥3 times/day Yes	No
Plain Water	1	2
Sugar Water	1	2
Honey	1	2
Animal Milk	1	2
Powdered Milk	1	2
Other Liquid	1	2
Other_____	1	2

3e. Did you give anything to the baby to drink from a bottle?

Yes 1
No 2
Don't Know 9

If yes, what? _____

TO SECTION II]

CTION II. INFANT & MATERNAL ANTHROPOMETRY, & INFANT PHYSICAL EXAMINATION

ECK] Infant Alive and this is the 1 Month Visit. [GO TO Q2201]
Infant Alive and this is the 7 or 14 Day Visit. [GO TO Q2202]
Infant Dead and this is the 7 Day or 1 Month visit. [GO TO Q2203]
Infant Dead and this is the 14 Day Visit. [END INTERVIEW]

I would like to examine your baby. This examination is very simple and ck. Nothing I do will hurt the baby, or make him/her uncomfortable.

1. **Infant Anthropometrics:**

ght _____gms

gth _____cms

Mid-upper Arm Circumference _____mms

Chest Circumference _____mms

Head Circumference _____mms

2. **Physical Examination of the Baby:**

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

FINDINGS	CODING CATEGORIES
mperature	_____°F
spiration Rate	_____/minute
est Indrawing	Normal . . . . . 1 Indrawing present 2
dration Status	Normal . . . . . 1 Moderate Dehydration . . . . 2 Severe Dehydration 3

THIS IS 2 WEEK VISIT, THEN END INTERVIEW]

203. **Maternal Anthropometrics:**

eight _____gms Mid-upper Arm Circumference _____mms

eight _____cms **[ONLY 7 DAY VISIT]**

[redacted]

CTION III: EXPOSURE TO SMOKE

301. Who takes care of the baby most of the time?

Mother 1
Father 2
Grand mother 3
Grand father 4
Sister 5
Brother 6
Uncle 7
Aunt 8
Relative/Neighbour . . 9
Other_____ . . 10

302a. Does that person smoke?

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

302b. How many cigarettes per day does that person smoke?

_____

303a. Does anybody else, who stay at home most of the time, smoke?

Yes 1
(relation_____)
No 2

303b. How many cigarettes per day does that person smoke?

_____

IF THIS IS 1 MONTH VISIT, THEN GO TO Q2305]

304a. Was the baby subjected to a ritual after birth that exposed it to smoke?

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

304b. Please describe?

_____

_____

_____

305a. What type of oven do you use?

Gas	1
Kerosene	2
Firewood/leaves/twigs	3
Cow-dung	4
Garbage/scraps	5
Rags/clothes	6
Other_____	7

305b. Where is the oven located?

Inside main structure	1
Adjoining main structure	2
Separate structure	3
Open	4
Other_____	5

305c. Does the cooking area fill up with smoke when used?

Always	1
Sometimes (≥once/day)	2
On occasions	3
Never	4

305d. How many hours is spent cooking meals for the family?

_____ hours

305c. Does the child's caretaker do most of the household cooking?

Yes	1
No	2

305d. Where does the child usually stay while cooking is in progress?

Cooking area	1
Close to cooking area	2
Main Structure (cooking area not in main structure)	3
Outside, in the open (not exposed to smoke)	4

Thank you for spending so much time telling us about your baby. We will come back soon to see how you and the baby are doing.

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

URBAN HEALTH EXTENSION PROJECT

3 / 6 / 9 / 12 MONTH POSTPARTUM INTERVIEW

ead of Household's Name _____

ather's Name _____ Mother's Name _____

hild's Name _____ Respondent's Name _____

ddress: _____

_____

TO DATA MANAGEMENT:

TEAR OFF THIS SHEET AND FILE SEPARATELY].

TO INTERVIEWER:

BEFORE GOING TO THE FIELD, CHECK LATEST WEEKLY STATUS REPORT AND RESPOND TO Q3102a AND Q3103a].

Study # __/__/__/__/

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

URBAN HEALTH EXTENSION PROJECT

6/9/12 MONTH POSTPARTUM INTERVIEW

atum No.:___ Cluster No.:___ Struc. No.:___ HH No. ___

Head ID:___ Father's ID:___ Mother's ID:___ Respondent's ID:___

ld's ID:___ Child's P No.:_____

nned Date of Visit: ____/____/____

ual Date of Visit: ____/____/____

persons present
ing interview: _____

sha

Interviewer's Initials & Code

CTION I: INFANT WELL-BEING AND FEEDING

ll be asking a few questions today about you and your baby. I'll also amine your baby. First, let me start by asking about your baby's health d feeding.

01a. How is the baby today? (Can I see him/her?)

Alive 1
Dead . . . . . 2 [GO TO Q3114]

01b. Is the baby crawling/walking about?

Yes, Crawling 1
Yes, Walking 2
No 3

02a. [Check Previous Interview] The baby was being breastfed at the time of the last visit.

Yes 1
No 2

02b. Are you currently breastfeeding the baby?

Yes, daily, several times/day . . . 1 [GO TO Q3102d]
Yes, daily, once or twice/day . . . 2 [GO TO Q3102d]
Occasionally, ____ days/last week . 3 [GO TO Q3102d]
Not any more 4
Don't Know . . . . . 9 [GO TO Q3103]

02c. [IF BREASTFEEDING PREVIOUSLY BUT NOT NOW, ASK] When did you stop breastfeeding the baby?

Date ____________ [GO TO Q3103]

02d. [IF BREASTFEEDING NOW BUT NOT PREVIOUSLY, ASK] When did you start breastfeeding the baby?

Date ____________

103.

	a. [Check Previous Interview] The Baby was getting the following items. [11=YES, 00=NO]		b. [Now Ask] What have you given the baby in the last week other than breast milk? [11=YES, 00=NO]			
	Previous		Stop		Start	Now
ɔthing						
lain Water						
ıgar Water						
ɔney						
ıimal Milk						
ɔwdered Milk						
ther Liquid ( )						
cuits						
emi Solid						
olid Food						
ther ( )						

c. [For any item given at previous visit but not now, Ask] When did you stop giving this item to the baby? [Write Date]

d. [For any item given now but not previously, Ask] When did you start giving this item to the baby? [Write Date]

103e. How many days in the past week and how frequently did the baby receive the item?

	DAYS	≥3 times/day Y	N
Plain Water	_____	1	2
Sugar Water	_____	1	2
Honey	_____	1	2
Animal Milk	_____	1	2
Powdered Milk	_____	1	2
Other Liquid	_____	1	2
Fruits	_____	1	2
Semi Solid	_____	1	2
Solid Food	_____	1	2
Other_____	_____	1	2

.03f. Do you give anything to the baby to drink from a bottle?

Yes 1
No 2
Don't Know 9

F THIS IS THE 3 MONTH VISIT, THEN GO TO Q3105]

3.sha

104a. Did the baby have generalized and progressing rash mostly on the face and trunk at any time since my last visit?

Yes 1
No . . . . . 2 [GO TO Q3105a]
Don't Know . . . . . 9 [GO TO Q3105a]

104b. For how many days did the rash last?

_____ Days

104c. Did the baby have fever for a few days (>1 day) before and after the rash appeared?

Yes, before 1
Yes, after 2
Yes, both before & after . . 3
No 4
Don't Know 9

104d. Was there water inside the rash (blisters)?

Yes 1
No 2
Don't Know 9

104e. Did the rash fade accompanied by dark discolouration and/or peeling of the skin?

Yes 1
No 2
Don't Know 9

104f. During this illness, did the child have cough?

Yes 1
No 2
Don't Know 9

104g. During this illness, did the child have red or runny eyes?

Yes 1
No 2
Don't Know 9

104h. During this illness, did the child have running nose?

Yes 1
No 2
Don't Know 9

105a. Is your baby suffering from any illness today?

Yes 1
No . . . . . 2 [GO TO Q3106]
Don't Know . . . . . 9 [GO TO Q3106]

3105b. Please describe what is wrong? [WHAT, WHEN, HOW LONG]

_____

_____

_____

QUESTIONS 3106-3108, 3110a AND 3111 ARE EACH FOLLOWED BY A TABLE. IN THE ABLES, INDICATE THE PRESENCE OR ABSENCE OF THE RESPECTIVE DISEASE SYMPTOM R SIGN ON EACH OF THE PREVIOUS 15 DAYS INCLUDING TODAY (11=YES, 00=NO)]

106. Did the baby have fever at all in the past 2 weeks?

Yes 1
No 2
Don't Know 9

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

107. Did the baby have cough at all in the past 2 weeks?

Yes 1
No 2
Don't Know 9

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

3108a. Did the baby have difficulty in breathing in the past 2 weeks?

Yes 1
No 2
Don't Know 9

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

3108b. Did the baby have chest indrawing in the past 2 weeks?
[CHEST INDRAWING = INWARD MOVEMENT OF THE LOWER CHEST WHEN BREATHING IN]

Yes 1
No 2
Don't Know 9

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

08c. Did the baby have short rapid breaths in the past 2 weeks?

Yes 1
No 2
Don't Know 9

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

F THERE WAS NO COUGH OR DIFFICULT BREATHING OR CHEST INDRAWING OR RAPID EATHING GO TO Q3110]

09a. Was the baby not able to drink because of breathing difficulty?

Yes 1
No 2
Don't Know 9

09b. Was the baby abnormally sleepy, difficult to wake, limp or unconscious during this illness?

Yes 1
No 2
Don't Know 9

09c. Did the baby's lips become dark or bluish at any time during this illness?

Yes 1
No 2
Don't Know 9

09d. Did the baby make noise from the chest when breathing during this illness?

Yes 1
No 2
Don't Know 9

09e. Did the baby's nostrils move and spread out while breathing during this illness?

Yes 1
No 2
Don't Know 9

110a. Did the baby have diarrhoea and/or bloody stool at any time in the past 2 weeks? **[DIARRHOEA: FREQUENT UNUSUALLY LOOSE STOOL]**

Yes, loose 1
Yes, liquid 2
No . . . . . 3 [GO TO Q3110]
Don't Know . . . . . 9 [GO TO Q3110]

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

10b. If yes, what was the maximum number of stools on the day the diarrhoea was worst?

_____

10c. Was there any blood in the stools?
[THE ANSWER IS YES EVEN IF BLOOD WAS SEEN JUST ONCE]

Yes 1
No 2
Don't Know 9

110d. Was there any mucus in the stools?
[THE ANSWER IS YES EVEN IF MUCUS WAS SEEN JUST ONCE]

Yes 1
No 2
Don't Know 9

110e. At the time of the diarrhoea, was the baby at any time weak, limp or drowsy?

Yes 1
No 2
Don't Know 9

110f. At the time of the diarrhoea, did the baby also have intense thirst?

Yes 1
No 2
Don't Know 9

10g. At the time of the diarrhoea, did the baby also have dry mouth and tongue?

Yes 1
No 2
Don't Know 9

10h. At the time of the diarrhoea, did the baby also have loose skin?

Yes 1
No 2
Don't Know 9

10i. At the time of the diarrhoea, did the baby also have a depression in the front of the head?

Yes 1
No 2
Don't Know 9

10j. At the time of the diarrhoea, did the baby also have sunken eyes?

Yes 1
No 2
Don't Know 9

10k. At the time of the diarrhoea, how was the baby's urine?

Normal 1
Less frequent than normal . . . 2
No urine in last 8/12 hours . . 3
Don't Know 9

91. Did you give ORT to the baby?

No 1
Packet 2
Home made 3
Don't Know 9

11. Did the baby have spasms or convulsions at any time in the past 2 weeks?

Yes 1
No 2
Don't Know 9

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

12a. Did the baby have any other illness or symptoms in the past 2 weeks?

Yes 1
No . . . . . 2 [GO TO Q3113]
Don't Know . . . . . 9 [GO TO Q3113]

112b. Please describe the illness/symptoms? [WHAT, WHEN, HOW LONG]

_____

_____

_____

13a. Have your received any treatment or medicine for your baby?

Yes 1
No . . . . . 2 [GO TO SECTION II]
Don't Know . . . . . 9 [GO TO SECTION II]

13b. For what condition was the baby treated? _____

_____

13c. Who gave you treatment or medicine? _____

13d. What kind or treatment or medicine did you receive?

_____

GO TO SECTION II]

/END: MODULE ON INFANT DEATH

114. When did the baby die?

Date of Death _________

115. Was the baby crawling/walking about before death?

Yes, Crawling 1
Yes, Walking 2
No 3

116. [CHECK Q3114] Death occurred in the past 14 days?

Yes 1
No . . . . . 2 [GO TO Q3125]

QUESTIONS 3117-3119, 3121a & 3122 IS FOLLOWED BY A TABLE. IN THE TABLES, NDICATE THE PRESENCE OR ABSENCE OF THE RESPECTIVE DISEASE SYMPTOM OR SIGN I EACH OF THE DAYS PRECEDING DEATH BUT NOT EARLIER THAN 14 DAYS PRIOR TO ATE OF VISIT (11=YES, 00=NO)]

117. Did the baby have fever before death but during the last 2 weeks?

Yes 1
No 2
Don't Know 9

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

118. Did the baby have cough before death but during the last 2 weeks?

Yes 1
No 2
Don't Know 9

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

119a. Did the baby have difficulty in breathing before death but during the last 2 weeks?

Yes 1
No 2
Don't Know 9

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

119b. Did the baby have chest indrawing before death but during the last 2 weeks? **[CHEST INDRAWING = INWARD MOVEMENT OF THE LOWER CHEST WHEN BREATHING IN]**

Yes 1
No 2
Don't Know 9

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

119c. Did the baby have short rapid breaths before death but during the last 2 weeks?

Yes 1
No 2
Don't Know 9

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

F THERE WAS NO COUGH OR DIFFICULT BREATHING OR CHEST INDRAWING OR RAPID EATHING GO TO Q3121]

20a. Was the baby not able to drink because of breathing difficulty?

Yes 1
No 2
Don't Know 9

20b. Was the baby abnormally sleepy, difficult to wake, limp or unconscious during this illness?

Yes 1
No 2
Don't Know 9

20c. Did the baby's skin/lips become dark or bluish at any time during this illness?

Yes 1
No 2
Don't Know 9

20d. Did the baby make noise from the chest when breathing during this illness?

Yes 1
No 2
Don't Know 9

120e. Did the baby's nostrils move and spread out while breathing during this illness?

Yes 1
No 2
Don't Know 9

121a. Did the baby have diarrhoea and/or bloody stool before death but during the last 2 weeks? **[DIARRHOEA: FREQUENT UNUSUALLY LOOSE STOOL]**

Yes, loose 1
Yes, liquid 2
No . . . . . 3 [GO TO Q3122]
Don't Know . . . . . 9 [GO TO Q3122]

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

121b. If yes, what was the maximum number of stools on the day the diarrhoea was worst?

_____

121c. Was there any blood in the stools?
[THE ANSWER IS YES EVEN IF BLOOD WAS SEEN JUST ONCE]

Yes 1
No 2
Don't Know 9

21d. Was there any mucus in the stools?
[THE ANSWER IS YES EVEN IF MUCUS WAS SEEN JUST ONCE]

Yes 1
No 2
Don't Know 9

21e. At the time of the diarrhoea, was the baby at any time weak, limp or drowsy?

Yes 1
No 2
Don't Know 9

21f. At the time of the diarrhoea, did the baby also have intense thirst?

Yes 1
No 2
Don't Know 9

121g. At the time of the diarrhoea, did the baby also have dry mouth and tongue?

Yes 1
No 2
Don't Know 9

121h. At the time of the diarrhoea, did the baby also have loose skin?

Yes 1
No 2
Don't Know 9

121i. At the time of the diarrhoea, did the baby also have a depression in the front of the head?

Yes 1
No 2
Don't Know 9

21j. At the time of the diarrhoea, did the baby also have sunken eyes?

Yes 1
No 2
Don't Know 9

11k. At the time of the diarrhoea, how was the baby's urine?

Normal 1
Less frequent than normal . . . 2
No urine in last 8/12 hours . . 3
Don't Know 9

11. Did you give ORT to the baby?

No 1
Packet 2
Home made 3
Don't Know 9

12. Did the baby have spasms or convulsions before death but during the last 2 weeks?

Yes 1
No 2
Don't Know 9

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

13a. Did the baby have any other illness or symptoms before death but during the last 2 weeks?

Yes 1
No . . . . . 2 [GO TO Q3124]
Don't Know . . . . . 9 [GO TO Q3124]

13b. Please describe the illness/symptoms? **[WHAT, WHEN, HOW LONG]**

_____

_____

_____

14a. During the past 2 weeks but before death, did you receive any treatment or medicine for your baby?

Yes 1
No . . . . . 2 [GO TO Q3125]
Don't Know . . . . . 9 [GO TO Q3125]

14b. For what condition was the baby treated? _____

_____

14c. Who gave you treatment or medicine? _____

24d. What kind or treatment or medicine did you receive?

_____

F THIS IS THE 3 MONTH VISIT, THEN GO TO SECTION II]

25a. Did the baby have generalized and progressing rash mostly on the face and trunk at any time since my last visit?

Yes 1
No . . . . . 2 [GO TO SECTION II]
Don't Know . . . . . 9 [GO TO SECTION II]

25b. For how many days did the rash last?

_____ Days

25c. Did the baby have fever for a few days (>1 day) before and after the rash appeared?

Yes, before 1
Yes, after 2
Yes, both before & after . . 3
No 4
Don't Know 9

125d. Was there water inside the rash (blisters)?

Yes 1
No 2
Don't Know 9

125e. Did the rash fade accompanied by dark discolouration and/or peeling of the skin?

Yes 1
No 2
Don't Know 9

125f. During this illness, did the child have cough?

Yes 1
No 2
Don't Know 9

125g. During this illness, did the child have red or runny eyes?

Yes 1
No 2
Don't Know 9

25h. During this illness, did the child have running nose?

Yes 1
No 2
Don't Know 9

O TO SECTION II]

CTION II. INFANT & MATERNAL ANTHROPOMETRY, & INFANT PHYSICAL EXAMINATION

F INFANT IS DEAD, THEN GO TO Q3203]

w I would like to your baby's weight, length, arm, chest and head. I uld like to measure your weight and arm. This is very simple and quick.

01. **Infant Anthropometrics:**

ight _____gms

ngth _____cms

Mid-upper Arm Circumference _____mms

Chest Circumference _____mms

Head Circumference _____mms

202. **Physical Examination of the Baby:**

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

FINDINGS	CODING CATEGORIES
Temperature	_____°F
Respiration Rate	_____/minute
Chest Indrawing	Normal . . . . . 1 Indrawing present 2
Hydration Status	Normal . . . . . 1 Moderate Dehydration . . . . 2 Severe Dehydration 3

03. **Maternal Anthropometrics:**

eight _____gms

Mid-upper Arm Circumference _____mms

O TO SECTION III]

ECTION III: MATERNAL PREGNANCY STATUS

ow I will ask you some questions about you.

301. Do you think you are pregnant again?

	Yes	1
___	No	2 [GO TO Q3401]

302. When did you last start menstruating?

____/____/____
dd mm yy

ECTION IV: EXPOSURE TO SMOKE

401. Who takes care of the baby most of the time?

Mother	1
Father	2
Grand mother	3
Grand father	4
Sister	5
Brother	6
Uncle	7
Aunt	8
Relative/Neighbour . .	9
Other_____ . .	10

3402a. Does that person smoke?

Yes	1
No	2 [GO TO Q3403]

3402b. How many cigarettes per day does that person smoke?

_____

1403a. Does anybody else, who stays at home most of the time, smoke?

Yes	1
(relation_____)	
No	2

3403b. How many cigarettes per day does that person smoke?

_____

404a. What type of oven do you use?

Gas	1
Kerosene	2
Firewood/leaves/twigs	3
Cow-dung	4
Garbage/scraps	5
Rags/clothes	6
Other_____	7

04b. Where is the oven located?

Inside main structure	1
Adjoining main structure	2
Separate structure	3
Open	4
Other_____	5

404c. Does the cooking area fill up with smoke when used?

Always	1
Sometimes (≥once/day)	2
On occasions	3
Never	4

404d. How many hours is spent cooking meals for the family?

_____ hours

404c. Does the child's caretaker do most of the household cooking?

Yes	1
No	2

404d. Where does the child usually stay while cooking is in progress?

Cooking area	1
Close to cooking area	2
Main Structure (cooking area not in main structure)	3
Outside, in the open (not exposed to smoke)	4

ank you for spending so much time telling us about yourself and your baby.
IF 12 MONTH VISIT, THEN DO NOT SAY THE FOLLOWING]
e will come back in three months to see how you and the baby are doing.

[redacted]