ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCE
SCHOOL OF PUBLIC HEALTH

PREGNANCY OUTCOMES IN HIV INFECTED AND UNINFECTED WOMEN
ATTENDING ANC/PMTCT IN MEKELLE TOWN, TIGRAY REGIONAL STATE,
ETHIOPIA.

BY:

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ADVISOR:

FIKRE ENQUOSELASSIE (PhD, Associate professor)

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OF GRADUATE STUDIES

PREGNANCY OUTCOMES IN HIV INFECTED AND UNINFECTED WOMEN ATTENDING ANC/PMTCT IN MEKELLE TOWN, TIGRAY REGIONAL STATE, ETHIOPIA.

A COMPARATIVE CROSS SECTIONAL STUDY

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<td>Addis Ababa University</td>
</tr>
<tr>
<td>AIDS -</td>
<td>Acquired Immune Deficiency Syndrome</td>
</tr>
<tr>
<td>ANC –</td>
<td>Ante Natal Care</td>
</tr>
<tr>
<td>BMI –</td>
<td>Body Mass Index</td>
</tr>
<tr>
<td>EDHS-</td>
<td>Ethiopian Demographic and Health Survey</td>
</tr>
<tr>
<td>HAART –</td>
<td>Highly Active Anti Retroviral Therapy</td>
</tr>
<tr>
<td>HIV –</td>
<td>Human Immuno Virus</td>
</tr>
<tr>
<td>IUGR –</td>
<td>Intra-Uterine Growth Retardation</td>
</tr>
<tr>
<td>LBW –</td>
<td>Low Birth Weight</td>
</tr>
<tr>
<td>MDG -</td>
<td>Millenium Development Goal</td>
</tr>
<tr>
<td>PMTCT -</td>
<td>Prevention of Mother To Child Transmision</td>
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ABSTRACT

Background: Birth weight is a powerful predictor of infant survival, growth, long-term health and psychosocial development. Low birth weight has been defined by the World Health Organization (WHO) as weight at birth of less than 2,500 grams. Low birth weight (LBW) is a risk factor for infant mortality, morbidity, growth retardation, poor cognitive development and chronic diseases later in life. HIV infection during pregnancy may have a negative effect on birth weight, preterm birth and still birth.

OBJECTIVE: The main objective of this study is to determine the effect of HIV infection on birth outcome.

METHODOLOGY: Health facility based comparative cross sectional study was conducted to determine the effect of HIV infection on birth outcomes. A pretested data collection form was used to extract data from records of systematically selected pregnant women and their birth outcomes. Data was entered and validated using Epi-Info 3.5.1 for windows. Statistical analysis was performed using SPSS version 16 for windows. Bivariate analysis using student’s t-test was performed to compare means of continuous variables. Differences in proportions was analyzed using the chi-square test. Ethical clearance was obtained from the ethical review committee of the school of public health (SPH) and institutional review board (IRB) of College of Health Science of Addis Ababa University.

RESULT: A total number of 711 pregnant women, 237 (33.3%) HIV infected and 474 (66.7%) HIV uninfected and their newborn characteristics was extracted from ANC and delivery registers and analyzed. The overall LBW rate was 11.7% while mean birth weight was 2953 ± 20.98 (SE). Mean birth weight tends to be lower in infants born to HIV infected women compared to HIV uninfected women (2724.78 ± 41 grams VS 3064.55 ± 22 grams, independent t test, P<0.001). HIV infected women were more likely to have preterm births (OR = 1.534, 95% CI; 1.046, 2.249). Although not statistically significant, HIV infected women had higher proportion of still births (3.4%) compared to HIV uninfected women (1.9%) (X² = 1.47, P = 0.23).

CONCLUSION AND RECOMENDATION: HIV infected pregnant women are at increased risk for preterm birth and low birth weight. Therefore, we suggest promoting of HIV infection among reproductive age group.
1. INTRODUCTION

1.1. Background information
Weight at birth is a powerful predictor of infant survival, growth, long-term health and psychosocial development. Low birth weight has been defined by the World Health Organization (WHO) as weight at birth of less than 2,500 grams [1].

World wide, more than 20 million (15.5%) infants per year are born with low birth weight. The level of low birth weight in developing countries (16.5 %) is more than double the level in developed regions (7 %). The incidence of low birth weight varies across regions. Half of all low birth weight babies are born in South-central Asia. Low birth weight levels are 15%, 10%, 14% in sub-Saharan Africa, Central and South America and Oceania, and Caribbean respectively [1].

Low birth weight (LBW) is a risk factor for infant mortality, morbidity, growth retardation, poor cognitive development and chronic diseases later in life. Generally the risk of neonatal mortality for LBW infants approximately 20 times greater than for infants with birth weight exceeding 2500g, and it increases sharply as birth weight decreases. Therefore, the overall public health importance of LBW is determined by both the risks for subsequent morbidity and mortality, and its prevalence in a given population [1-3].

HIV infection may also have contributed to the burden of LBW, particularly in sub-Saharan Africa where the prevalence of HIV infection is high [4]. In Ethiopia, the prevalence of HIV among pregnant women is about 1% [5]. Several studies from Africa and other developing and developed countries suggested that HIV-infected women have a greater risk of LBW and its causes than do seronegative women. The incidence of prematurity and Intra Uterine Growth Retardation (IUGR) was higher in infants born to HIV infected women [6-10]. Low birth weight was significantly higher among HIV infected women [11-13]. In contrast some studies have reported no association between maternal HIV infection and birth weight [14].
1.2. Rationale of the study

The goal of reducing low birth weight incidence by at least one third between 2000 and 2010 is one of the major goals in ‘A World Fit for Children’. The reduction of low birth weight also forms an important contribution to the Millennium Development Goal (MDG) for reducing child mortality by two thirds by 2015. Low birth weight is therefore an important indicator for monitoring progress towards these internationally agreed-upon goals[1].

A 20 year study showed that significantly higher incidence of LBW was reported in 1990s than in 1980s and 1970s at Tikur Anbessa Hospital and authors the suggest that one of the contributors might be HIV epidemic [15]. A recent study in Gonder also reported a high LBW incidence of 15.4 percent[16].

Since low birth weight and its causes, prematurity and intra-uterine growth retardation (IUGR) are major determinants of child survival, growth and development it is important to assess the excess LBW, preterm delivery and intra uterine growth retardation (IUGR) attributable to HIV infection in populations in which low birth weight is common. However, little is known in Ethiopia about the association between HIV infection and birth weight. Thus, the aim of this study is to determine the effects of maternal HIV infection on the birth weight.

The study will give some baseline data for governmental and non-governmental organizations which work on the area of HIV/AIDS by providing basic information on the association of HIV infection with birth outcomes specially birth weight.
2. LITERATURE REVIEW

2.1. Impacts of low birth weight
Low birth weight (LBW) is a risk factor for infant mortality, morbidity, growth retardation, poor cognitive development and chronic diseases later in life. A study conducted in Nigeria indicate that children with low birth weight were more than 37 times more likely to die during infancy compared to those born with normal weight (hazard ratio = 1.37; 95% CI; 1.09, 1.72) [17].

A study conducted in United States showed that, adult women born with low birth weight have about two times higher risk of developing Type 2 diabetes mellitus than who were born with normal birth weight (RR=1.83, 95% CI; 1.55-2.16) [18]. Another retrospective study from the same country, indicated that women born with low birth weight had higher risk of developing non fetal cardiovascular diseases including myocardial infarction, stoke and coronary revascularisation during adulthood than normal birth weight counter parts (RR=1.49, 95% CI; 1.05-2.1) [19]. Similarly, a study done in America indicated that compared with women in middle category of birth weight the age adjusted odds of hypertension among low birth weight women is 1.39 (95% CI; 1.29-1.50) [20]. Another study in Norway showed that low birth weight adults have 1.7 (95% CI; 1.2-1.9 P=0.002) risk of developing End Stage Renal Disease compared to normal birth weight adults [21].

Study done in Scottland to examine the relation beteween birth weight and cognitive function showed that mean score on Moray House Test increased from 30.6 for low birth weight to 44.7 at 4001–4500 g, after correcting for gestational age, maternal age, parity, social class, and legitimacy of birth [22].
2.2. Determinants of low birth weight

LBW is caused by either a short gestation period or retarded intrauterine growth (or a combination of both). Factors with well-established direct relationships with intrauterine growth include infant sex, racial/ethnic origin, maternal height, pre-pregnancy weight, paternal weight and height, maternal birth weight, parity, history of prior low-birth-weight infants, gestational weight gain and caloric intake, general morbidity and episodic illness, malaria, cigarette smoking, alcohol consumption, and tobacco chewing. For gestational duration, only pre-pregnancy weight, prior history of prematurity or spontaneous abortion, inutero exposure to diethylstilbestrol, and cigarette smoking have well established relationships, and the majority of prematurity occurring in both developing and developed country settings remains unexplained [2].

Study done in Mexico city found that, low socioeconomic status is the most and independent of other factors, including those related to reproduction and nutrition, smoking, morbidity during pregnancy, accessibility to health services and prenatal care risk factor for LBW (OR 2.68; 95% CI 1.19, 6.03) [23].

Study conducted in Iran indicated that, compared to mothers with university level of education mothers with primary education have odds of 6.83 more likely to deliver LBW neonates (OR=6.83; 95% CI, 2.35-7.34). The same study also showed that birth interval of less than or equal to one year is significantly associated with LBW compared to birth interval of greater than one year [24].

Study done in Brazil found that maternal nutrition or body mass index (BMI) of less than 19.8 is significantly associated with LBW (OR = 1.72 ; 95% CI, 1.52- 1.93) compared to mothers between 19.8 and 26.0 body mass index. The study also showed that high blood pressure during pregnancy is significantly associated with LBW (OR =2.82 ; 95% CI, 2.40-3.32) [25]. Another study done in Taiwan showed that mothers diagnosed with TB have significantly higher odds of delivering LBW neonates (OR =1.35 ; 95% CI, 1.01-1.81) [26].

Study conducted in Sudan showed that, maternal anaemia (OR=9.0 ; 95% CI, 3.4-23.8) and lack of antenatal care (OR=5.9 ; 95% CI, 1.4-24.1) are the main risk factors for LBW after controlling for maternal age, parity, education and anthropometric measurements [27].
2.3. HIV infection and low birth weight

Several studies suggested that HIV infection has contributed to higher risk of LBW. Study done in Tanzania showed that HIV positive pregnant women were two times more likely to give birth to LBW neonates as compared with HIV negative ones and the difference between the two groups is statistically significant (OR=2.43; 95% CI, 1.15-5.07). Gestational age, infant sex, marital status, antenatal care (ANC), body mass index (BMI), occupation, ethnicity, malaria, anemia, pre-eclampsia, hypertension, eclampsia, tuberculosis and thromboembolism were also associated with birth weight [28]. Another study also showed that, HIV infection during pregnancy was associated with an increased risk of LBW even after adjusting for the effects of drug use, health care delivery, and other social and medical risk factors and increase nearly three fold odds of LBW among full-term deliveries (OR=2.7; 95% CI, 1.6-4.3) [13]. Similarly a study done in rural Mozambique reported that, the proportion of low birth weight babies was higher and median birth weight was lower among HIV infected pregnant women[29].

A Study done in urban Malawi showed that infants of HIV infected women have higher incidence of IUGR (7.5% versus 4.4%; P<0.02), preterm delivery (12.5% versus 3.8% P<0.001) and LBW (20.1% versus 8.3%, P<0.001) than HIV uninfected mothers [6]. A study done in Rwanda showed that, HIV infected women have nearly doubled risk of having full-term newborn with LBW (RR=1.8; 95% CI, 1.1-2.9) and IUGR (RR=2; 95% CI, 1.1-3.8) [9].

Another systematic review of literature and meta-analysis study showed that, HIV infected mothers have higher odds of LBW (OR=2.09; 95% CI, 1.86-2.35), IUGR (OR=1.7; 95% CI, 1.43-2.02), preterm delivery (OR=1.83; 95% CI, 1.63-2.06) and still birth (OR=3.91; 95% CI, 2.65-5.77) [8].

The use of highly active antiretroviral therapy (HAART) is now standard care to prevent mother-to-child HIV transmission. While the primary concern is to reduce the risk of maternal-to-child transmission there is controversy about its impact on preterm birth and low birth weight. Highly active antiretroviral therapy (HAART) for pregnant HIV-positive women reduces the risk of mother-to-child transmission, but is associated with an increased risk of preterm delivery and intrauterine growth retardation [30, 31]. In contrast other studies indicate no relation between intratamate exposure to HAART and intrauterine growth retardation [32].
2.4. Situational of HIV/AIDS and Low birth weight in Ethiopia

The HIV pandemic created an enormous challenge to the survival of mankind worldwide. Ethiopia is one of the countries most severely hit by the epidemic. According to calibrated single point estimate the national adult HIV prevalence was reported to be 2.1% (7.7% in urban and 0.9% in rural areas). The three highest prevalence regions in the country are Gambela (8.3% urban), Addis Ababa (7.5%) and Dire Dawa (4.2%). Other regions with HIV prevalence rates greater than the national estimate (2.1%) are Harari (3.2%), Amhara (2.7%) and Tigray (2.7%). Somali is the region with the lowest HIV prevalence estimate in the country (0.8%). Highest prevalence occurs in the 15-24 age groups and prevalence is higher among females than males in both urban and rural areas. Prevalence of HIV/AIDS among women of reproductive age was reported to be 2.6 percent. According to the Ethiopian Demographic and Health Survey prevalence of HIV/AIDS among pregnant women is about 1 percent [5, 33]. How ever, little is known about the impact of HIV infection on birth outcomes in Ethiopia.

A twenty years study in Addis Ababa reported an over all 8.4% of low birth weight with an increasing trend from 5.8% (95% CI 4.6%-7.3%) in the 1970s to 7.1% (95% CI 6.4%-7.8%) in the 1980s and to 11.3% (95% CI 10.2%-12.3%) in the 1990s [15]. Study conducted in Jimma reported low birth weight prevalence of 11.02 percent [34]. Different studies showed that maternal age, parity, antenatal care, maternal height, and gestational age are associated with birth weight [16, 34, 35].

In Ethiopia, only three percent of new borns are weighed at birth and the prevalence of low birth weight is 14 percent [5]. Another study conducted in Gondar reported low birth weight incidence of 15.4 percent [16].
3. OBJECTIVE

3.1. General objective
➢ To determine the effect of HIV infection on pregnancy outcome specially on birth weight

3.2. Specific objectives
➢ To compare the mean birth weight among HIV infected and uninfected mothers
➢ To compare the prevalence of low birth weight among HIV infected and uninfected mothers
➢ To compare the prevalence of preterm birth among HIV infected and uninfected mothers
➢ To assess factors affecting low birth weight
4. METHODOLOGY

4.1. Study area and period
The study was conducted in three Health institutions (Mekelle hospital, Mekelle Health center, Kasech Health center) in Mekelle town, which is the capital city of Tigray. Mekelle is located at about 775 Km North of Addis Ababa. According EDHS 2005 prevalence ANC follow up was 69% in urban areas and the prevalence of HIV infection among ANC attending women was 1%. The study was conducted from August 2010 to April 2011.

4.2. Study design
Health facility based comparative cross sectional study design was conducted to determine the effect of HIV infection during pregnancy on birth outcome.

4.3. Population

4.3.1. Source population: All pregnant mothers attending ANC/PMTCT and gave singleton birth from July 2008- November 2010 in the three health institutions.

4.3.2. Study population: All selected records of pregnant mothers whom attend ANC/PMTCT and gave singleton birth in the three health institutions. All multiple births during the study period were excluded from the study.

4.3.3. Sample size determination
Sample size was determined using the two sample proportion method using the following formula

\[ n_1 = \frac{z_\alpha/2 \sqrt{(1+1/r)p(1-p) + Z_\beta \sqrt{(1-p_1) + p_2(1-p_2)/r}}^2}{(p_1-p_2)^2} \]
Where:

\[ P = \frac{p_1 + rp_2}{1+r} \]

\[ Z_{\alpha/2} = 1.96 \text{(type I error)} \]

\[ Z_\beta \text{ is the } Z \text{ value at 80\% power}(0.84) \]

\[ r = \text{ratio of sample size } n_2 \text{ to } n_1 \text{ which is taken as 2.} \]

\( P_1 = \text{proportion of LBW among HIV infected women} \)

\( P_2 = \text{Proportion of LBW among HIV uninfected women} \)

By taking \( P_1 = 25\% \text{ (Rwanda)} \) and \( P_2 = 15.4\% \text{ (Gondar)} \)

A total sample of 645 (\( n_2 = 430, n_1 = 215 \)) was required

Adding 10\% for missing and unrecorded data to have the final sample size

711 (474\% HIV uninfected, 237 HIV infected)

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4.3.4 Sampling procedure

One hospital and two Health Centers were selected purposefully. Namely, Mekelle Hospital, Mekelle Health Center and Kasech Health Center since ANC/PMTCT and delivery services are given to most of the population. The total sample records of both the HIV infected women and uninfected women were allocated proportionally to the size of ANC/PMTCT attendants in each health facility. Records of study subjects were selected using systematic random sampling method.

4.4 Data collection methods

4.4.1 Study Variables

4.4.1.1 Dependent Variable: Birth weight

4.4.1.2 Exposure variable: HIV infection
4.4.1.3. Other Variables: Age, parity, weight, height, maternal occupation, marital status, Previous history of abortion, hypertension, diabetes mellitus, malaria, pre-eclampsia, eclampsia, anemia, sex of infant and gestational age.

4.4.2. Data collection procedures
Data collection form which is necessary to extract important information was prepared by the principal investigator. Records of women who had PMTCT/ANC follow up and gave singleton birth including maternal age, weight, height, parity, previous history of abortion, hypertension, pre-eclampsia, eclampsia, anemia and diabetes mellitus in the health facilities from July 2009 to November 2010 was extracted from the registers using the data collection form (see Appendix). New born characteristics including gestational age, sex, still birth, birth weight were also extracted from the registres. Data was extracted and filled on the data collection form by trained midwives and nurses who work on the ANC/PMTCT and delivery departments and those who handle the registers.

4.4.3. Data quality Control
The questionnaire (check list) was pretested ahead of the actual data collection and modifications was made according to the existing records in the health facilities. Midwifes and nurses who work on the ANC/PMTCT and delivery and those who handle the registers were recruited as data collectors and they were trained for two days how to extract the variables and fill on the data collection form. Every questionnaire (check list) was checked by the supervisor each day for completeness and consistency with the existing records. The principal investigator also strictly followed the process. Finally, data was entered and validated using Epi-Info and ready for analysis.
4.5. Data processing and analysis
Data was entered and validated using Epi –Info 3.5.1 software and statistical analysis was done using SPSS version 16. Frequencies and means with standard deviations were used to describe the variables. Student’s $t$ test was used to compare differences between means of continuous variables. Differences in proportions was performed using the chi-square test. Odds ratio was computed with 95% confidence interval to measure the strength of association. Multivariate Logistic regression was used to explain the effect of HIV infection and other variables on birth outcome.

4.6. Ethical considerations
Ethical clearance was obtained from the ethical review committe of the School of Public Health(SPH) and institutional review board(IRB) of College of Health Science of Addis Ababa University.A letter of support from the School of Public Health had been given to medical directors of Mekelle hospital, Mekelle health center and Kasech health center. As the study was conducted through record review, the individuals will not be subjected to any harm as far as the confidentiality is kept. To ensure the confidentiality nurses and midwifes working in ANC/PMTCT and those who handle the registers were extracted the data. Personal identifiers were not used on the data collection form and recorded data had never been accessed by third person.
5. RESULT

5.1. Sociodemographic, Medical and obstetric characteristics

During the period under review, July 2008 to November 2010, data on a total number of 711 pregnant women, 237 (33.3%) HIV infected and 474 (66.7%) HIV uninfected and their newborn characteristics was extracted from ANC and delivery registers and analyzed. Among the HIV infected women 79 (33.3%) of them had known HIV infection before the current pregnancy and 66 (83.5%) were started HAART before the current pregnancy.

Most mothers were recorded in Mekelle Hospital 396 (55.7%), and the remaining were from Mekelle Health Center 217 (30.5%) and Kasech Health Center 98 (13.8%). Six hundred ninety three (97.5%) were tigrea folllwed by amara 14 (2.0%) and afar 4 (0.6%). Maternal occupation was recorded for only 118 (49.78%) of HIV infected women and 255(53.79%) of HIV uninfected women.

Most 87.3% of the mothers were 20-35 years old, with mean age of 26.09 ±4.88 years. HIV infected women did not differ significantly from HIV uninfected women with respect to mean body weight (56.38 ± 7.34 VS 56.69 ± 6.53 kilogram, independent sample test, t=0.549 ). Most HIV uninfected women 389 (87.8%) were married and the remainig were unmarried 43 (9.7%), and widowed and divorced 11 (2.5%). One hundred seventy eight (78.4%) of HIV infected pregnant women were married followed by unmarried 31 (13.7%), and widowed and divorced 18 (7.9%). Last history of abortion was recorded among 46 (19.4%) HIV infected pregnant women and in 53 (11.2%) of HIV uninfected women.
Table 1. socio-demographic, obstetric and medical characteristics of pregnant women by HIV infection status, Mekelle town, July 2008 to November 2010.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>HIV Infected</th>
<th>HIV uninfected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>n(%)</td>
<td>n(%)</td>
</tr>
<tr>
<td>&lt;20 years</td>
<td>8(3.4)</td>
<td>51(11.3)</td>
</tr>
<tr>
<td>20-35 years</td>
<td>215(91.5)</td>
<td>384(85.2)</td>
</tr>
<tr>
<td>&gt;35 years</td>
<td>12(5.1)</td>
<td>16(3.5)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>178(78.4)</td>
<td>389(87.8)</td>
</tr>
<tr>
<td>Unmarried</td>
<td>31(13.7)</td>
<td>43(9.7)</td>
</tr>
<tr>
<td>Divorced&amp;widowed</td>
<td>18(7.9)</td>
<td>11(2.5)</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primiparous</td>
<td>101(42.8)</td>
<td>117(25.0)</td>
</tr>
<tr>
<td>Multiparous</td>
<td>135(57.2)</td>
<td>351(75.0)</td>
</tr>
<tr>
<td>Heamoglobin level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;10.9 g/dl</td>
<td>164(69.5)</td>
<td>391(83.0)</td>
</tr>
<tr>
<td>≤10.9 g/dl</td>
<td>72 (30.5)</td>
<td>80(17.0)</td>
</tr>
<tr>
<td>History of previous abortion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>46(19.4)</td>
<td>53(11.2)</td>
</tr>
<tr>
<td>No</td>
<td>191(80.6)</td>
<td>421(88.8)</td>
</tr>
<tr>
<td>Malaria during current pregnancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6(2.5)</td>
<td>9(1.9)</td>
</tr>
<tr>
<td>No</td>
<td>231(97.5)</td>
<td>465(98.1)</td>
</tr>
<tr>
<td>Number of ANC visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 3 ANC visit</td>
<td>75(31.6)</td>
<td>106(22.4)</td>
</tr>
<tr>
<td>≥ 3 ANC visit</td>
<td>162(68.4)</td>
<td>368(77.6)</td>
</tr>
</tbody>
</table>

Only 2 pregnant women one (0.4%) from HIV infected and one (0.2%) from HIV uninfected women had preeclampsia during the current pregnancy. Eclampsia was recorded in only one (0.2%) HIV uninfected women and only one (0.4%) HIV infected pregnant women had gestational diabetes mellitus. Two (0.8%) HIV infected women and four (0.8%) HIV uninfected women had chronic hypertention and chronic deliabete mellitus was recorded in six (1.3%) HIV uninfected women.
Table 2. Maternal Medical characteristics of pregnant women by HIV infection status, Mekelle town, July 2008 to November 2010.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>HIV infected, N=237</th>
<th>HIV Uninfected, N=474</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n(%)</td>
<td>n(%)</td>
</tr>
<tr>
<td>Pre-eclampsia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1(0.4)</td>
<td>1(0.2)</td>
</tr>
<tr>
<td>No</td>
<td>236(99.6)</td>
<td>473(99.8)</td>
</tr>
<tr>
<td>Eclampsia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0</td>
<td>1(0.2)</td>
</tr>
<tr>
<td>No</td>
<td>237(100)</td>
<td>473(99.8)</td>
</tr>
<tr>
<td>Gestational diabetes mellitus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1(0.4)</td>
<td>0</td>
</tr>
<tr>
<td>No</td>
<td>236(99.6)</td>
<td>474(100)</td>
</tr>
<tr>
<td>Chronic hypertension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2(0.8)</td>
<td>4(0.8)</td>
</tr>
<tr>
<td>No</td>
<td>235(99.2)</td>
<td>470(99.2)</td>
</tr>
<tr>
<td>Chronic diabetes mellitus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0</td>
<td>6(1.3)</td>
</tr>
<tr>
<td>No</td>
<td>237(100)</td>
<td>468(98.7)</td>
</tr>
</tbody>
</table>

5.2. Birth outcomes in HIV infected and HIV uninfected pregnant women

Birth weight was available for 690 singleton live births. Newborn sex was available for 687 of singleton live births. Three hundred eighty four (55.89%) were males and 303 (44.1%) were females. The overall LBW rate was 11.7% while mean birth weight and weighted mean was 2953±20.98(SE) and 2952.4 respectively. Sixteen (2.3%) infants were born with birth weight less than 1500 grams and only three infants were born with birth weight greater than 4500 grams. Gestational age was available for 697 deliveries. The overall proportion of preterm birth was 19.9%. Only 9(1.3%) of the deliveries had gestational age less than 34 weeks and 4(0.6%) had gestational age greater than 34 weeks. Seventeen (2.4%) stillbirths were recorded.

As shown in Table 3, the mean birth weight was significantly lower in infants born to HIV infected women compared to HIV uninfected women (2724.78 ± 41 grams VS 3064.55 ± 22 grams, independent sample t test, t = 7.26). Similarly the proportion of LBW was significantly higher in HIV infected women (23.9%) compared to HIV uninfected women (5.8%) ($X^2$= 4 7.92, P < 0.001). Infants born to HIV infected women were five times more likely to result in
LBW compared to infants born to HIV uninfected women (OR=5.08,  \( P < 0.001 \) 95% CI ; 3.09, 8.32).

The proportion of preterm births born to HIV infected women (24.7%) was significantly higher compared to HIV uninfected women (17.6%) (\( X^2 =4.84 \), \( P= 0.028 \) OR= 1.534 95% CI ; 1.046.2.23). HIV infected women were more likely to have preterm births (OR = 1.534, 95% CI; 1.046, 2.249). HIV infected women had higher proportion of still births (3.4%) compared to HIV uninfected women (1.9%) (\( X^2 =1.47 \), \( P = 0.23 \)).

Table 3. Birth outcomes of HIV infected and uninfected women in Mekelle town, July 2008 to November 2010.

<table>
<thead>
<tr>
<th>Newborn characteristics</th>
<th>HIV infected</th>
<th>HIV uninfected</th>
<th>OR</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth weight n(%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 2500 grams</td>
<td>54 (23.9)</td>
<td>27 (5.8)</td>
<td>5.08</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>≥2500 grams</td>
<td>171 (76.1)</td>
<td>437 (94.2)</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Gestational age n(%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 37 weeks</td>
<td>57 (24.7)</td>
<td>82 (17.6)</td>
<td>1.53</td>
<td>0.028</td>
</tr>
<tr>
<td>≥37 weeks</td>
<td>174 (75.3)</td>
<td>384 (82.4)</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Still birth n(%)</td>
<td>8 (3.4)</td>
<td>9 (1.9)</td>
<td></td>
<td>0.23</td>
</tr>
<tr>
<td>Birth weight mean(SD)</td>
<td>2724.78 ± 617</td>
<td>3064.55 ± 478</td>
<td></td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Gestational age mean(SD)</td>
<td>37.673 ± 2.33</td>
<td>37.82 ± 1.70</td>
<td></td>
<td>0.371</td>
</tr>
</tbody>
</table>

LBW was associated with sex and gestational age. Preterm infants (gestational age <37 weeks) were 7 times more likely to result in LBW compared to term deliveries (OR = 7.26 95% CI ; 4.42 , 11.92  \( P < 0.001 \)). Mean birth weight tend to be lower in female infants (2856.60 ± 31.71 grams) compared to male counterparts (3028 ± 27 grams) (independent sample t test , t = 4.09).

However, the proportion of LBW was not significantly higher in female newborns (14.2%) compared to male newborns (9.9%) (\( X^2 = 3.0 \), \( P= 0.083 \)).

Bivariate analysis showed that proportion of LBW was significantly higher in Primipara women (20.2%) compared to multipara women (8.2%) (\( X^2 = 19.86 \), \( P <0.001 \). Primipara women were more likely to give LBW infants compared to multipara women (OR= 2.829 , 95% CI; 1.766, 4.53). Married women were more likely to have LBW births compared to widowed and divorced (OR = 1.64, 95% CI; 0.37, 7.08). Although not statistically significant women in the age category greater than 35 years were more likely to give LBW infants (OR = 1.79, 95% CI; 0.658
Pregnant women who had a history of previous abortion were more likely to deliver LBW infants (OR = 1.84, 95% CI; 1.022, 3.297).

Anemia and number of ANC visit were strongly associated with LBW. Proportion of LBW was significantly higher in women with hemoglobin level less than or equal to 10.9 g/dl (18.1%) compared to mothers who had hemoglobin level greater than 10.9 g/dl (10.1) (X² = 6.83, P=0.009). Pregnant women who attend less than three ANC visit were more likely to have LBW neonates compared to those who attend greater or equal to three ANC visit (OR = 3.19, P < 0.001 95% CI; 1.98, 5.15). Multivariate logistic regression showed that HIV infected women were more likely to result in LBW compared to HIV uninfected women (AOR = 5.18, 95% CI; 2.66, 10.07) after controlling for parity, hemoglobin level, sex of newborn, number of ANC visit, maternal age, marital status, delivery place, year of delivery, last history of abortion and gestational age.
Table 4. Effects of maternal Sociodemographic, medical and obstetric characteristics on low birth weight, Mekelle town, July 2008 to November 2010.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>nLBW(%)</th>
<th>COR</th>
<th>95% CI</th>
<th>AOR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV infected</td>
<td>54(23.9)</td>
<td>5.08</td>
<td>3.09, 8.3</td>
<td>5.18</td>
<td>2.7, 10.1</td>
</tr>
<tr>
<td>HIV uninfected</td>
<td>27(5.8)</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gestational age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 37 weeks</td>
<td>44(33.8)</td>
<td>7.26</td>
<td>4.4, 11.9</td>
<td>6.1</td>
<td>3.2, 11.8</td>
</tr>
<tr>
<td>&gt; 37 weeks</td>
<td>36(6.6)</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primipara</td>
<td>42(20.2)</td>
<td>2.83</td>
<td>1.76, 4.3</td>
<td>1.67</td>
<td>0.86, 3.2</td>
</tr>
<tr>
<td>Multipara</td>
<td>39(8.2)</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex of the baby</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>43(14.2)</td>
<td>1.51</td>
<td>0.95, 2.4</td>
<td>1.4</td>
<td>0.79, 2.6</td>
</tr>
<tr>
<td>Male</td>
<td>38(9.9)</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANC Visit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 3 ANC visit</td>
<td>38(22.4)</td>
<td>3.2</td>
<td>1.9, 5.14</td>
<td>3.2</td>
<td>1.7, 6.13</td>
</tr>
<tr>
<td>&gt; 3 ANC visit</td>
<td>43(8.3)</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemoglobin level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 10.9 g/dl</td>
<td>26(18.1)</td>
<td>1.95</td>
<td>1.2, 3.24</td>
<td>1.69</td>
<td>0.84, 3.3</td>
</tr>
<tr>
<td>&gt; 10.9 g/dl</td>
<td>55(10.1)</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maternal age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;20 years</td>
<td>6(15.3)</td>
<td>1.42</td>
<td>0.66, 3.1</td>
<td>3.45</td>
<td>1.25, 9.4</td>
</tr>
<tr>
<td>20-35 years</td>
<td>65(11.2)</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;35 years</td>
<td>5(18.5)</td>
<td>1.79</td>
<td>0.6, 4.9</td>
<td>0.91</td>
<td>0.27, 3.0</td>
</tr>
<tr>
<td>Year of delivery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2008/9</td>
<td>28(14.07)</td>
<td>1.35</td>
<td>0.8, 2.2</td>
<td>2.25</td>
<td>1.14, 4.4</td>
</tr>
<tr>
<td>2010</td>
<td>53(10.79)</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>64(11.6)</td>
<td>1.64</td>
<td>0.34, 7.1</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Unmarried</td>
<td>6(8.2)</td>
<td>1.12</td>
<td>0.2, 5.9</td>
<td>0.92</td>
<td>0.33, 2.5</td>
</tr>
<tr>
<td>Widowed and divorced</td>
<td>2(7.4)</td>
<td>1.00</td>
<td></td>
<td>0.67</td>
<td>0.13, 3.4</td>
</tr>
<tr>
<td>Place of delivery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mekelle Hospital</td>
<td>68(18.3)</td>
<td>7.04</td>
<td>2.18, 23</td>
<td>3.22</td>
<td>0.8, 11.8</td>
</tr>
<tr>
<td>Mekelle Health Center</td>
<td>9(4.2)</td>
<td>1.38</td>
<td>0.36, 5.2</td>
<td>1.51</td>
<td>0.34, 6.7</td>
</tr>
<tr>
<td>Kasech Health Center</td>
<td>3(3.1)</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Last history of abortion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>17(18.1)</td>
<td>1.84</td>
<td>1.0, 3.3</td>
<td>1.33</td>
<td>0.6, 2.93</td>
</tr>
<tr>
<td>No</td>
<td>64(10.7)</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6. DISCUSSION

This study assessed the effect of maternal HIV infection on neonatal birth outcomes. The overall LBW rate was 11.7%. There was high rate of digit preference in recording birth weights in those health facilities, a phenomenon which has been reported in other area[36]. This might be contributed to the low percentage of LBW in this study than the national average and previous published study in different parts of Ethiopia[5, 16]. A twenty years study in Addis Ababa [15] reported an overall mean birth weight of 3126 ± 502 grams. Similarly, a study done by Y. Feleke and F. Enquoselassie [35] reported mean birth weight of 3065 ± 465 grams. Those findings are higher compared to our finding of the current study.

Mean birth weight was significantly lower in infants born to HIV infected women compared to HIV uninfected women (2724.78 ± 41 grams VS 3064.55 ± 22 grams, independent t test, P<0.001). This finding is similar to other studies that reported significantly lower mean birth weight in infants born to HIV infected women [9, 13]. The current study also showed that the proportion of LBW was significantly higher in HIV infected women compared to HIV uninfected women. Infants born to HIV infected women were five times more likely to result in LBW compared to infants born to HIV uninfected women (OR=5.08, P < 0.001 95% CI; 3.09, 8.32). The likelihood of HIV infected women to deliver low birth weight babies agreed with findings from a study done among pregnant women in African countries [6, 9].

As reported in a previous study, our study has also showed that preterm birth at < 37 weeks gestation occurred more frequently among HIV infected pregnant women [37]. HIV infected women had also higher proportion of still birth (3.4%) compared to HIV uninfected women (1.9%). ($X^2 = 1.47, p = 0.23$) which was also reported by a study done among pregnant women in Tanzania [7].

The current study has shown that, primipara women were more likely to give LBW infants compared to multipara women (OR= 2.829, 95% CI; 1.766, 4.53) which was also previously reported [36]. This could be explained by the fact that there is a general agreement that the pregnancy outcomes are more favourable for multiparae than primiparae.
Proportion of LBW was significantly higher in women with hemoglobin level less than or equal to 10.9 g/dl (18.1%) compared to mothers who had hemoglobin level greater than 10.9 g/dl (10.1) ($X^2 = 6.83$ $P=0.009$). Pregnant women who attend less than three ANC visit were more likely to give LBW neonates compared to those who attend greater or equal to three ANC visit. The likelihood of anemic women and women who had lower number of ANC visit to deliver high proportion of low birth weight babies was also shown by findings from a study done among pregnant women in African countries [27, 28].

Preterm infants, gestational age <37 weeks were 7 times more likely to result in LBW compared to term deliveries ($OR = 7.26$ 95% CI; 4.42, 11.92 $P < 0.001$). This finding is in line with study conducted in Tanzania among pregnant women [28]. This finding underlines the effect intrauterine growth restriction which is a common factor for low birth weight in developing countries.

Mean birth weight tend to be lower in female infants (2856.60 ± 31.71 grams) compared to male counterparts (3028 ± 27 grams) (independent t test, $P < 0.001$). This finding is similar to study conducted in Addis Ababa [35]. However, odds of LBW was not significantly higher in female newborns compared to male counterparts ($OR = 1.56$, 95% CI; 0.95, 2.398 $P= 0.084$) which was also previously reported [36].

Multivariate logistic regression showed that infants born to HIV infected women were more likely to result in LBW compared to infants born to HIV uninfected women ($AOR = 5.18$, 95% CI; 2.66, 10.07 $P < 0.001$) after controlling for parity, anemia, sex of newborn, number of ANC visit, last history of abortion, place of delivery, maternal age, marital status and gestational age. This finding is in accordance with study done in America [13].
STRENGTH AND LIMITATIONS OF THE STUDY

Strength of the study

- Strong power
- Comparative cross sectional
- Ability to adjust for several confounders
- Baseline for further studies

Limitations of the study

- Secondary data, where some of the data were incomplete
- Measurement validity can not be ascertained
- Unability to adjust maternal occupation, maternal nutritional status and stage of HIV/AIDS
- Generalizability is questionable since health facilities were selected purposefully.
CONCLUSION

The overall LBW rate was 11.7% while mean birth weight was 2953±20.98(SE). Materna HIV infection was strongly associated with birth weight. Mean birth weight was significantly lower in infants born to HIV infected women compared to HIV uninfected women. Bivariate analysis showed that the frequency of LBW was significantly higher in HIV infected women compared to HIV uninfected women. Infants born to HIV infected women were five times more likely to result in LBW compared to infants born to HIV uninfected women.

Maternal HIV infection was associated with stillbirth and gestational age. HIV infected pregnant women had significantly higher proportion of Preterm births compared to HIV uninfected women. HIV infected women were more likely to result in preterm infants. Although not statistically significant, HIV infected women had higher proportion of still birth compared to HIV uninfected women.

LBW was also strongly associated with anemia, parity, number of ANC visit and gestational age. Gestational age less than 37 weeks, anemia, primiparous and less than three ANC visits were significantly associated with higher odds of LBW.
RECOMMENDATION
Depending on the findings I would like to recommend the following points.

To the Health facilities

- The health facilities should introduce digital weighing scales to reduce the high preference of recording birth weight towards zero.
- Right information is the foundation for right planning and program evaluation. However, some of the data in the registries were incomplete. The ANC/ PMTCT and delivery service providers therefore need training and a subsequent and frequent supervision so that they would appropriately record patient information.

To Voluntary Counseling and Testing (VCT) service providers.

- Promote primary prevention of HIV among women and men of reproductive age.

To researchers

- I suggest researchers to conduct prospective studies in order to control for potential confounders such as maternal occupation and nutritional status.
REFERENCES

5. Ethiopian Demographic and Health Survey 2005.
APPENDIX I

CHECK LIST FOR HIV INFECTED WOMEN

Date -------------------------------------------------------------

Name of Health Facility ---------------------------------------------

Name of data collector----------------------------------------------

Name of supervisor--------------------------------------------------- Signiture---------------------------

I. Maternal Characteristics
1. Age of women--------------------------------------years
2. Marital status--------------------------
   1. Married
   2. Unmarried
   3. Widowed
   4. Divorced
   99. Unrecorded
3. Ethnicity
   1. Tigray
   2. Amhara
   3. Afar
4. Maternal Occupation
   1. House wife
   2. Merchant
   3. Government worker
   4. Non-government worker
   99. Unrecorded
5. Did the woman was Known HIV/AIDS before the current pregnancy
   1. Yes
   2. No
   No. 7

6. Did the woman started HAART before the current pregnancy
   1. Yes
   2. No

7. Did the woman started HAART during the current pregnancy
   1. Yes
   2. No

8. Weight of mother -----------------------------------------------(Kg)
9. Height of mother -----------------------------------------------(centimeter)

10. Parity
    1. One
    2. Two
    3. Three
    4. Four
    5. Greater than four
    99. Unrecored
11. Did the mother have a previous history of abortion
   1. Yes
   2. No
   99. Unrecorded

12. Did the mother have malaria during the current pregnancy
   1. Yes
   2. No
   99. Unrecorded

13. Did the mother have pre-eclampsia during the current pregnancy
   1. Yes
   2. No
   99. Unrecorded

14. Did the mother have eclampsia during the current pregnancy
   1. Yes
   2. No
   99. Unrecorded

15. Did the mother have gestational diabetes mellitus during the current pregnancy
   1. Yes
   2. No
   99. Unrecorded
16. What was the mother’s haemoglobin

   1. > 10.9 g/dl
   2. 10 ---10.9 g/dl
   3. 7—9.9 g/dl
   4. < 7 g/dl

   99. Unrecorded

17. Number of ANC Visit

   1. one
   2. Two
   3. Three

   99. Unrecorded

18. Did the mother had known history of hypertension

   1. Yes
   2. No

   99. Unrecorded

19. Did the mother had known history of Diabetes Mellitus

   1. Yes
   2. No

   99. Unrecorded
20. Mode of delivery
   1. Normal vaginal
   2. Ceserian Section
   3. Vaccum delivery
   4. Forceps delivery
   99. Unrecorded

II. New born characteristics

21. Year of delivery
   1. 2008
   2. 2009
   3. 2010
   99. unrecorded

22. Did the mother gave to a live birth
   1. Yes
   2. No
   99. Unrecorded

23. Birth weight---------------------------------------------grams

24. Gestational age ------------------------------------------weeks

25. Sex of new born
   1. Male
   2. female
   99. Unrecorded
APPENDIX II

CHECK LIST FOR HIV UNINFECTED WOMEN

Date ---------------------------------------------

Name of Health Facility -----------------------------------------

Name of data collector----------------------------------

Name of supervisor----------------------------------------- Signiture---------------------------

II. Maternal Characteristics

1. Age of women--------------------------years

2. Marital status------------------------
   1. Married
   2. Unmarried
   3. Widowed
   4. Divorced
   99. Unrecorded

3. Ethnicity
   1. Tigray
   2. Amhara
   3. Afar

4. Maternal Occupation
   1. House wife
   2. Merchant
   3. Government worker
   4. Non-government worker
   99. Unrecorded
5. Weight of mother -----------------------------------------------(Kg)
6. Height of mother -----------------------------------------------(centimeter)

7. Parity
   1. One
   2. Two
   3. Three
   4. Four
   5. Greater than four
   99. Unrecorded

8. Did the mother had previous history of abortion
   1. Yes
   2. No
   99. Unrecorded

9. Did the mother had malaria during the current pregnancy
   1. Yes
   2. No
   99. Unrecorded

10. Did the mother had Pre-eclampsia during the current pregnancy
1. Yes
2. No
99. Unrecorded

11. Did the mother had **Eclampsia** during the current pregnancy
   
   1. Yes
   2. No
   99. Unrecorded

12. Did the mother had **Gestational Diabetes Mellitus** during the current pregnancy
   
   1. Yes
   2. No
   99. Unrecorded

13. What was the mother’s **haemoglobin**
   
   1. > 10.9 g/dl
   2. 10 ---10.9 g/dl
   3. 7—9.9 g/dl
   4. < 7 g /dl
   99. Unrecorded

14. Number of ANC Visit
1. one
2. Two
3. Three
99. Unrecorded

15. Did the mother had known history of hypertension
   1. Yes
   2. No
   99. Unrecorded

16. Did the mother had known history of Diabetes Mellitus
   1. Yes
   2. No
   99. Unrecorded

17. Mode of delivery
   1. Normal vaginal
   2. Cesarian Section
   3. Vaccum delivery
   4. Forceps delivery
   99. Unrecored
II. New born characteristics

18. Year of delivery
   1. 2008
   2. 2009
   3. 2010
   99. Unrecorded

19. Did the mother gave to a live birth
   1. Yes
   2. No
   99. Unrecorded

20. Birth weight ------------------------------------------ grams

21. Gestational age -------------------------------------- weeks

22. Sex of new born
   1. Male
   2. Female
   99. Unrecorded
ASSURANCE OF PRINCIPAL INVESTIGATOR

The undersigned agrees to accept responsibility for the scientific ethical and technical Conduct of the research project and for provision of required progress reports as Per terms and conditions of the Research Publications Office in effect at the time of Grant is forwarded as the result of this application.

Name of the student: ________________________________

Date: ________________  Signature: ________________

Approval of the primary Advisor

Name of the primary advisor: ________________________________

__________________________________________________________

Date: ________________  Signature: ________________