SCHOOL OF PUBLIC HEALTH

COLLEGE OF HEALTH SCIENCE

ADDIS ABABA UNIVERSITY

Maternal risk factors for prematurity related neonatal mortality among preterm neonates admitted to Neonatal Intensive Care Unit of selected referral Hospitals in Addis Ababa, Ethiopia

By: Dirreba Gemeda

A THESIS SUBMITTED TO THE SCHOOL OF GRADUATE STUDIES OF ADDIS ABABA UNIVERSITY, FOR PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE MASTERS DEGREE OF PUBLIC HEALTH IN REPRODUCTIVE HEALTH

Nov, 2017.

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ADVISORS: Abiy Seifu, Dr. Asrat Dimtse

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APPROVED BY

_____	_____	_____
External Examiner	(Signature)	(Date)
_____	_____	_____
Internal Examiner	(Signature)	(Date)
_____	_____	_____
1st Advisor	(Signature)	(Date)
_____	_____	_____
2nd Advisor	(Signature)	(Date)

ACKNOWLEDGEMENT

I would like to acknowledge my advisors Abiy Seifu (School of Public Health) and Dr. Asrat Dimtse (School of Medicine), College of Health Sciences, Addis Ababa University for their kind approach, unreserved guidance and support they provided me with starting from the development of this research proposal to final thesis.

My deepest gratitude goes for prof. Lulu Muhe for his unreserved support he provided me with starting from the inception of the research idea and for arranging opportunity to integrate my research work with the SIP project. My heartfelt gratitude also goes to prof. Ameha Mekasha, Addis Ababa site sip project coordinator, for his vital role in assuring quality data in the project through regular follow up and meeting to solve any challenge that may encounter through discussion with research team members. My immense thanks also extend to w/o Beliyu Tlahun, supervisors at the three hospitals and all the SIP project members for their support during my proposal development and data collection.

Finally, I would like to express my deepest gratitude to the School of Public Health, College of Health Sciences of Addis Ababa University for giving me the opportunity to join graduate program.

List of Contents

List of Figures

List of Tables

ACRONYMS

ANC	Antenatal Care
GTPE	Growth and Transformation Plan of Ethiopia
IRB	Institutional Review Board
LBW	Low Birth Weight
PNC	Postnatal Care
PTB	Pre Term Birth
MDG	Millennium Development Goal
MOH	Ministry of Health
MOE	Ministry of Education
NICU	Neonatal Intensive Care Unit
PTD	Preterm delivery
PE	Preeclampsia
SIP	Sickness in preterm
UTI	Urinary Tract Infection
WHO	World Health organization

Abstract

Background: The neonatal period is considered high risk period in terms of mortality. Globally, approximately 15 million infants are born prematurely each year, which is more than one tenth of all newborn infants. Mortality due to complications of prematurity is the leading cause of neonatal and children under five age death. Little is known about specific maternal risk factors for prematurity related neonate mortality.

Objective: The aim of the proposed study was to identify risk factors for prematurity related neonate mortality.

Methods: A facility based nested unmatched case control study design was employed to identify maternal risk factors for prematurity related neonatal mortality. Cases were preterm neonates who died and controls were preterm neonates who survived 28 days of neonatal period among those admitted to NICU ward. The study was conducted from July 25, 2016 to May 29, 2017 at neonatal intensive care units of three Referral hospitals in Addis Ababa city. The total sample size was 471 with 157 cases and 314 controls. Data was entered using Epi Info 7 and analyzed by STATA 12. Bivariate and multivariate logistic regression models were applied to measure the associations between the prematurity related mortality and maternal risk factors.

Results: The mean/median gestational age of cases and controls were 30.6/30 and 33.6/34 weeks respectively. The mean (±SD) age of the mothers of cases was 25.8(±4.6) years and that of mothers of controls was 26.6(±4.7) years.

Having no formal education [AOR (95% C.I): 6.586 (2.467, 7.582)], ANC visit [AOR (95% C.I): 2.791 (1.604, 4.857)], maternal anemia during pregnancy [AOR (95% C.I): 2.921 (1.396, 6.112)], urine test suggesting infection [AOR (95% C.I): 3.513 (1.261, 9.787)], and antepartum hemorrhage [AOR: (95% CI): 3.151 (1.509 , 6.577)] were found to be risk factors for preterm neonatal mortality.

Conclusion and recommendations: Maternal education, poor antenatal care, maternal anemia, and ante partum hemorrhage have strong association with mortality among premature babies. Reduction of mortality among premature babies requires multi-sectorial response. The Ministry of Health (MOH) should give more emphasis to strengthening routine antenatal care and management of obstetric complications like antepartum hemorrhage. The Ministry of Education (MOE) on the other hand should pay special attention to women's higher education; Promotion of proper maternal nutrition could be enhanced through joint effort of the ministries of education and health.

Key words: - **Prematurity related neonatal mortality, maternal factors, Addis Ababa**

1. Introduction

1.1 Background

Each year more than 15 million infants are born prematurely. In other words more than one in every ten newborn infants globally is born premature. From this, 1.1 million Babies die from Preterm birth complications [1]. Preterm infants have a high risk of birth complications, including infectious diseases, respiratory insufficiency, intraventricular hemorrhage, neurosensory deficits, and other organ system complications [2]. Nevertheless, the death of 700 neonates and 15,000 under five each day is intolerable. In 2016 prematurity is the main killer for children under age of five accounting for 18% of all under-five deaths followed by pneumonia, intrapartum complication and diarrhea contributing to 16%, 12% and 8% of under-five deaths, respectively [3].

About 99 % of neonatal deaths were from low and middle income countries, of which 66 % (1.16 million deaths) are in Africa and Southeast Asia in 2013 [4]. South Asia and sub-Saharan Africa account for almost two-thirds of the world's preterm babies and over three-quarters of the world's newborn deaths due to infectious and preterm birth complications and is among the regions showing the least progress in reducing the neonatal mortality rate [5]. By 2016 this two regions account for 80% of 5.6 million under five children death burdens in the world [3].

The major direct causes of under-five mortality, based on the 2014 WHO/CHERG estimates in Ethiopia were pneumonia (18%), asphyxia (14%), prematurity (11%), newborn infection (9%), and diarrhea (9%). In 2013 neonatal death accounted for 44% (86,240) of under-five child death [6]. By 2016, Ethiopia was one of the six countries in the world to account for half the under-five child death Burden [3].

Approaches to reduce deaths among premature babies includes; management of preterm labor by tocolytics to slow down labor, antenatal corticosteroids, antibiotics for premature rapture of membrane and provision of essential and extra care for premature babies.

These extra care includes feeding support, neonatal resuscitation, Kangaroo Mother Care which is supposed to save 450,000 babies each year, Chlorhexidine, cord care, management of premature babies with complications, especially Safe oxygen management and supportive care for respiratory distress syndrome and, if appropriate and available, continuous positive airway pressure and/or surfactant, and treating infection with antibiotics [1].

The Ethiopian government has prioritized child and newborn health and aims to reduce under-five mortality level of 64/1,000 to 29/ 1,000, infant mortality from 44/1,000 to 20/1,000 and neonatal mortality from 28/1,000 to 11/1,000 live births by 2019/2020 [7]. These include improving the quality and coverage of basic health services, improving maternal and child health, increasing the supply of iodized salt, the reduction of malnutrition, and improving household sanitation. Currently there are initiatives to apply KMC for preterm neonates, a high impact cost effective strategy to reduce mortality among neonates. This is supposed to be achieved mainly through scaling up of community based interventions such as newborn and child survival interventions by health extension workers and health development army to achieve universal coverage with community based promotive, preventive and curative services via enhancing their capacities [6].

1.2 Statement of the problem

The health of Newborn plays a vital role to achieve sustainable development goals. Globally, the mortality rate of newborns is increasing accounting for 40% in 1990 to 45% under five child mortality in 2015 [8]. Prematurity is the leading cause of death for neonatal and under five child mortality accounting for 18% under five child mortality and 35% of neonatal mortality rate [3]. The neonatal target under Sustainable development goal (SDG) 3.2 is to reduce the neonatal mortality rate to 12/1000 live births in all countries by 2030 through the implementation of every newborn action plan endorsed by 194 countries. This cannot be achieved without addressing the problems associated with preterm birth. The motive of beyond survival for children's, adolescents and mothers relies on the health of mothers during the first hour of delivery [9].

Investment in women's and maternal health and care at birth will reduce stillbirth rates and improve outcomes for women and newborn babies, especially those who are premature.[1]

Mortality rates increase with decreasing gestational age, and babies who are both preterm and small for gestational age are at even higher risk. Babies born at less than 32 weeks represent about 16% of all preterm births[10].

In Ethiopia, neonatal mortality rate (NMR) remains high despite the government and other non-governmental organizations endeavors to reduce neonatal mortality. The neonatal mortality rates for the years 1996–2000, 2001–2005 and 2006–2011, 2012-2016 were 42, 39, 37 and 29 per 1000 live births, respectively. Currently neonatal mortality accounts for about 43% of under-five mortality. Neonatal death from prematurity related complication accounts for about 25% of neonatal deaths (< 1 month**)** [11-14]. Despite the larger share of premature neonatal mortality for under-5 mortality most studies in developing countries focused on infant and child mortality[15].

Previous studies documented different factors contributing to neonatal deaths. These include socio demographic factors, number of pregnancies the woman had, maternal morbidity, prematurity, mode of delivery, birth weight and sex of the fetus [16-20].

The studies conducted worldwide over the past ten years on the factors and causes of neonatal mortality were diverse in their findings on the level of their causation or association to adverse outcome. Some studies report that the adverse outcomes are due to physiological and anatomical factors associated with young maternal age, while others report that they are due to external factors such as socioeconomic status, social support, inadequate antenatal care and other behavioral determinants. [17, 21-27]

In Ethiopia there are limited studies done assessing the effect of maternal risk factors on prematurity related neonatal deaths.

The main aim of this study was to determine the maternal risk factors for mortality among premature newborns.

1.3 Significance of the Study

Conducting a study on maternal risk factors of prematurity related neonatal mortality will add to our understanding of neonatal deaths and risk factors which might help the government to formulate strategies on prevention of the maternal risk factors of prematurity related neonatal mortality.

Most of the studies conducted world-wide on neonatal morbidity or mortality are in developed nations where better living standard and health care system is observed contrary to developing nations such as Sub-Sahara Africa and south east Asia where increasing acute morbidities or long-term impairment associated with prematurity is prevailing. The finding of them may be different for comparison and designing appropriate implementation plan. Thus, this study could provide evidence that will contribute to knowledge base of prematurity related deaths.

The study may also lay basis for other researchers to conduct longitudinal studies to show the temporal relationship between maternal and obstetric factors and prematurity related deaths.

2. Literature review

This chapter provides evidences of different studies on Neonatal mortality particularly among premature infants and its associated factors. It clearly discusses different literatures related to preterm and contributing factors associated with it.

2.1 Scale of the problem- how common is mortality among preterm infants?

Worldwide 6.3 million children below 5 years of age died in 2013 and 44% of these deaths occurred during the newborn period i.e. an estimated 2.9 million neonates die each year. Preterm birth is the most common cause of neonatal deaths globally. An estimated 1.1 million Newborn babies die from preterm complications [4]. Preterm birth is a major determinant of neonatal mortality and morbidity and has long-term adverse consequences for health [28]. Concomitant lack of attention to important causes of neonatal mortality like preterm birth has resulted in neonatal deaths becoming an increasing proportion of under-5 deaths (from 37% in 1990 to 40% in 2010), and demonstrating a slower rate of decline than that for under-5 deaths. Hence forth solutions for newborns, and especially preterm newborns, are intimately linked to maternal health and care [29, 30]. Complications from preterm births are the leading direct cause of neonatal deaths accounting for 35% of all newborn deaths, and are also a contributing factor in an additional 40% to 60% of neonatal deaths. In Ethiopia, of the 91,700 neonatal deaths in 2010, 32, 700 or a little more than one-third were deaths from complications of preterm birth [5].

2.2. Factors for neonatal mortality.

There are a number of known causes of fetal death. Sometimes more than one of these causes may contribute to the baby's death. Common causes include: Birth defects, Placental problems, Poor fetal growth, Infections, Chronic health conditions in the pregnant woman &Umbilical cord accidents.

Risk Factors for Fetal Death includes :Maternal age over 35, Maternal obesity, Maternal Diabetes, Maternal Drug/Alcohol/Tobacco Use during pregnancy ,Multiple gestation (twins or more), African-American ancestry .The reasons Why do some women deliver too soon are similar to why some women have a higher risk for fetal death [31].

The biggest barrier to progress on MDG-4 has been the inability to reduce the number of neonatal deaths and deaths from prematurity. Prevention of preterm death is classified as primary (focusing on all women) secondary (focusing on women with a history of preterm birth), and tertiary (focusing on preterm neonates) [32].

In a study of perinatal mortality in India risk factors for neonatal deaths includes male gender, multiple gestation and major congenital anomalies. Breech presentation/transverse lie and no antenatal care were also significant risk factors for neonatal death [33].

The risk factors of perinatal deaths were increased in the presence of premature labor especially with early rupture of membranes, obstructed labor and hemorrhage. Maternal factors such as hypertensive disorders were five times more likely to cause perinatal deaths compared to women without hypertension (OR 5.04). Other factors were a history of previous adverse pregnancy outcome and less than 35 weeks gestational age (GA). Intra-partum events such as abruption placenta, cord accidents, prolonged or obstructed labor, pre-eclampsia/eclampsia and prematurity were identified underlying causes of perinatal death [34].

A study by Carl H. Backes et al indicates that preeclampsia is associated with significant maternal and neonatal morbidity and mortality. Premature delivery has a negative consequence on neonatal outcome not limited to the most premature infants, leaving physicians with incomplete data to guide their clinical decision making [35].

Ligia Maria Suppo et al study shows that most newborn complications are related to prematurity, although the data on the morbidity and outcome for preterm infants of women who have PE are conflicting, and few studies address this issue. PE remains an important cause of maternal and fetal morbidity and mortality [36].

A study by Ashish KC, et.al in Nepal indicated that there is a 12-fold increased risk of neonatal death among preterm infants compared to term [37].

Study by Abdu Jammeh et.al in rural hospital of Gambia found that the pattern of risk factors was similar for LBW and PTB and both were strongly associated with antepartum hemorrhage and hypertensive pregnancy disorders. Primi parity was a risk factor for both PTB and LBW [38]. Another study by Cristina C. Trilla , et al shows that Women with LPTB had more medical conditions , Prior preterm births, prior adverse obstetric outcomes than women with term births. And obstetric complications were also more frequent in LPTB than in term births. However, no differences were found in maternal medical conditions when spontaneous LPTB and medically-indicated. LPTB were compared. Women with medically-indicated LPTB were older (33.69 vs. 31.07;
P = 0.003) and mainly nulliparous (75.8% vs. 49.4%; P = 0.002). Obstetric complications were more frequent in medically-indicated LPTB than in spontaneous LPTB [24].

In a meta-analysis of studies done worldwide on selected maternal and fetal factors for perinatal mortality showed a strong association of perinatal mortality with lack of antenatal care (OR=3.2), prematurity (OR=7.9), low birth weight (OR=9.6), and marginal association with primigravidity (OR=1.5) and male sex (OR=1.2). The meta-analysis showed that there was no association between mode of delivery and perinatal mortality [16].

The study in North Gondar has found that number of pregnancies the women, had (AOR =3.76: 95% CI, 2.73- 5.20), maternal morbidity (AOR =5.43: 95% CI,2.90-10.17) and neonatal illness (AOR = 3.68: 95% CI, 2.41-5.62) were strongly associated with neonatal mortality [19].

A study in very preterm infants cared for in the Australian and New Zealand Neonatal Network indicated that , prematurity was the dominant risk factor, infants born at 25 weeks having 32 times greater odds of death than infants born at 31 weeks. Low Birth weight for gestational age also had a dose–response effect. Male sex was also a significant risk factor (odds ratio (OR) 1.55, 95%confidence interval (CI) 1.31 to 1.82). Maternal hypertension in pregnancy was protective (OR 0.46, 95% CI [39].

A Clinical Audit at Tikur Anbessa Hospital has reported that prematurity less than 37 weeks of gestation is the leading cause of death (57.3%, n= 35). Perinatal death among primigravide was 29 (47.5%) while 32(52 %) perinatal losses in multiparous women [22].

Study on Patterns of Neonatal Morbidity at Gondar University Hospital Neonatal Unit has revealed that Ten variables were found to have significant statistical associations with neonatal mortality after adjusting for demographic covariates: Prematurity ($p < 0.001$), Meningitis ($p < 0.001$), Hemorrhagic Diseases ($P < 0.001$), Hyaline Membrane Disease ($P<0.001$), Neonatal Sepsis ($p < 0.05$), Meningitis (<0.05), Perinatal Asphyxia ($p < 0.05$), Neonatal Seizure ($p < 0.05$), Home delivery ($p < 0.05$) and Meconium Aspiration ($p < 0.05$) [21].

Several studies indicated the association between neonatal mortality and young maternal age, short interpregnancy birth interval, low maternal education, use of ANC & House hold wealth index [1, 16, 18, 24, 26, 40].

In Ethiopia perinatal deaths were related to socioeconomic factors such as education, religion, accessibility of health services, socioeconomic status and demographic characteristics like, mother's age at birth, birth order and birth weight [41].

Generally in the above studies socio demographic factors, socio economic factors, were clearly stated; however, there is a gap regarding specific maternal risk factors for mortality among preterm neonates.

2.3. Conceptual frame work

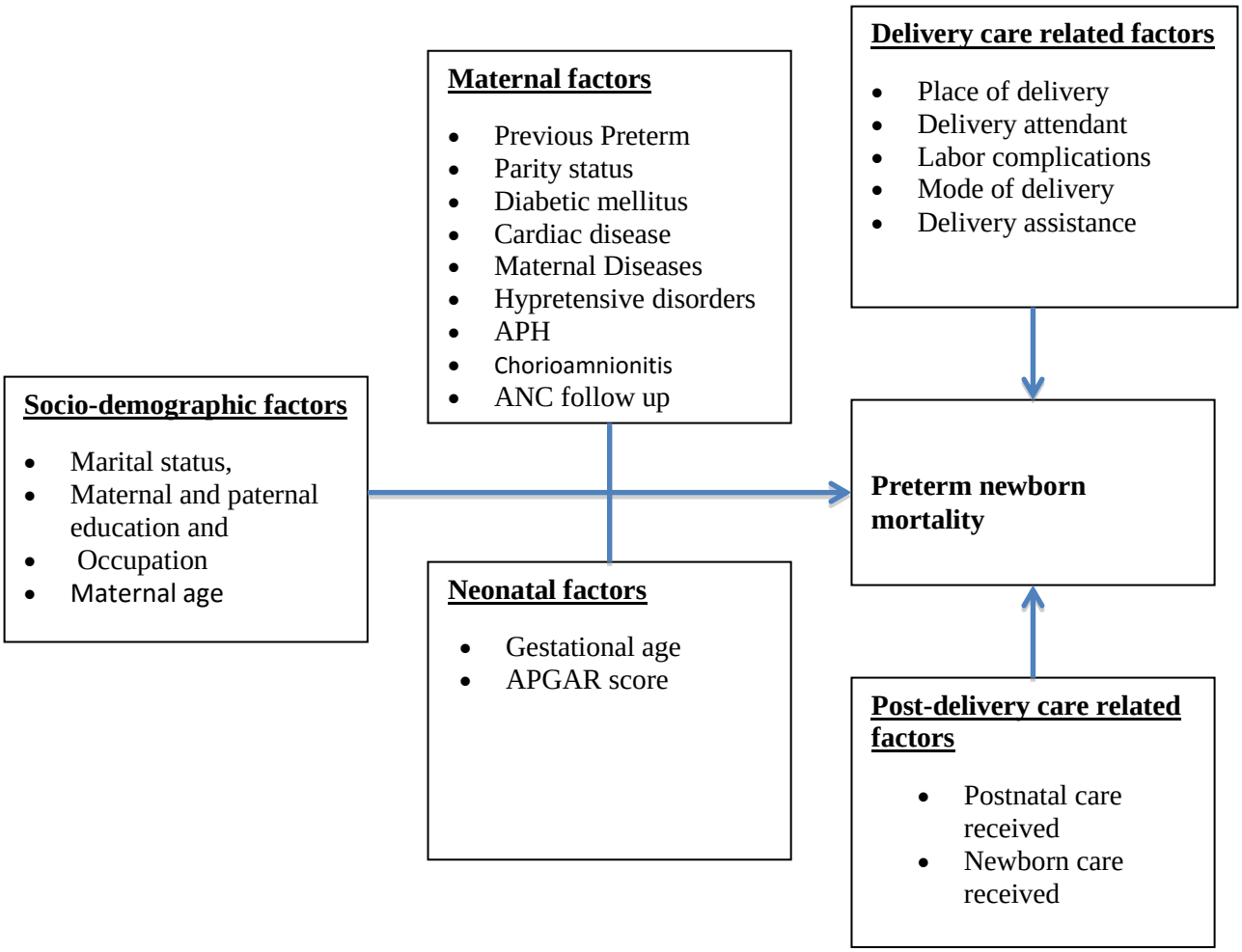

Figure 1: Conceptual framework with selected possible factors associated with prematurity related mortality. The framework was adapted from Mosley and Chen's conceptual framework for studies on child survival in developing countries [42].

2.4. Research Question & hypothesis

Research question

What are the maternal obstetric and medical risk factors for prematurity related neonatal mortality among premature babies who are admitted to NICU in selected referral hospitals in Addis Ababa?

Hypotheses

Obstetric & medical factors are associated with prematurity related neonatal mortality.

3. Objective

3.1 General Objective

The aim of this study was to determine maternal risk factors associated with mortality among preterm neonates admitted to in NICUs of selected hospitals of Addis Ababa.

3.2 Specific Objectives

- To determine obstetric risk factors associated with prematurity related neonatal mortality admitted to NICU.
- To determine Medical risk factors associated with prematurity related neonatal mortality admitted to NICU.

4. Methodology

4.1. Study design

A facility based nested unmatched case control study design was employed to identify maternal risk factors for prematurity related deaths in selected hospitals in Addis Ababa. The study was conducted from July 2016 to May 2017. A case is defined as a preterm neonate admitted to NICU in selected hospitals in Addis Ababa and died during neonatal period. A control is defined as a preterm neonate admitted to NICU and survived the neonatal period.

4.2. Study area and period

The data for this study was collected from July 25, 2016 to May 29, 2017. This study was conducted in Addis Ababa, the capital city of Ethiopia. It is located at 901'48'N latitude and 380 44'24'E longitudes. According to the population projection from 2007 census the city has an estimated total population of 3,194,999 in 2017 consisting of 1,515,001 male and 1,679,998 females. The study was conducted in Addis Ababa 3 Referral hospitals: Tikur Abbesses Teaching Hospital, Gandhi Memorial Hospital and St Paul's Hospital Millennium Medical College with well-organized neonatal care unit in the city.

The annual numbers of deliveries are about 6500, 10380 and 8400 in Tikur Abbesses Teaching Hospital, Gandhi Memorial Hospital and St Paul's Hospital Millennium Medical College respectively. Almost all high risk neonates and all preterm neonates are admitted to NICU and evaluated by the NICU team. The NICUs of the three hospitals have resuscitation corner, incubators, radiant warmer, phototherapy unit, and exchange transfusion equipment. Their units lack facilities for blood gas analysis and parenteral nutrition. The selection of the 3 hospitals is purposive for the reason that they have better organized manpower, services for neonates, client flow, and being part of the SIP Project with comparable follow up and treatment guideline for preterm neonates.

4.3. Source population

All mothers whose live birth preterm newborns were admitted to NICU of Addis Ababa Hospitals.

4.4. Study population

All mothers whose preterm newborns were admitted to NICU of the selected 3 referral hospitals in Addis Ababa under SIP Project and the inclusion & exclusion criteria applied on.

4.5 Study subjects

All mothers whose preterm newborns were admitted to NICU of the selected 3 referral hospitals in Addis Ababa under SIP Project and from whom the data was collected for this study.

4.6. Sample size Determination

Sample size was calculated based on a case control study design and assumptions were made based on findings from a case-control study done in Dare Salaam by Mpembeni et. al, (as there is no nationally available data regarding the proportion of specific maternal variable (risk factor) among cases or controls) [43]. The sample size calculated using the Fleiss Formula was.

Where: n_1 = Number of cases, n_2 = Number of controls

Z $\alpha/2$= Z-score for 2 tailed test based on alpha level (1.96)

Z $_{1-\beta}$= Z-score for one tailed test based on level (0.84)

r = cases with the assumption that at least 39% of controls had antenatal care compared to 53% of cases, an odds ratio of 1.79, at 95% level of confidence 80% power and alpha of 0.05: controls (1:2)

ρ_1= Proportion of cases with exposure (53% =0. 53)

q_1= 1- ρ_1 = 1- 0.534 =0.47

ρ_2 = Proportion of controls with exposure (39% =0.39)

$q_2 = 1 - \rho_2 = 1 - 0.39 = 0.61$

$\bar{\rho} = \rho_1 + (r\,\rho_2) / r + 1 = 0.53 + 2 \times 0.39 / 3 = 0.44$

$\bar{q} = 1 - \bar{\rho} = 1 - 0.438 = 0.56$

$$n_1 = \frac{[Z\,\alpha/2\sqrt{(r+1)\,\bar{\rho}\,\bar{q}} + Z_{1-\beta}\sqrt{r\,\rho_1\,q_1 + \rho_2\,q_2}]^2}{r\,(\rho_1 - \rho_2)^2}$$

$$n_1 = \frac{[1.96\sqrt{(2+1)\,(0.44 \times 0.56} + 0.84\sqrt{(2 \times 0.534 \times 0.466) + (0.39 \times o.61)}]^2}{2(0.534 - 0.39)^2}$$

$= 157$

$n_1 = 157 \qquad n_2 = r \times n1 = 2 \times 157 = 314$

The sample size estimated comprised of 157 cases and 314 controls. All available cases who meet the criteria were included in the study due to limited number of cases.

The total sample size included in the study was 157 cases plus 314 controls=471

4.7. Sampling procedure

Cases

One hundred and fifty-seven preterm live births (<37 weeks of gestational age) who died within 28 days of their life during the study from NICU admissions in the selected three referral hospitals in Addis Ababa were included in the study as cases. These were sampled consecutively during the study period until the required sample size was obtained.

Controls

On the other hand; preterm neonates who survived neonatal period (28 days of their post-natal life) were sampled to form the controls. Simple Random Sampling technique was applied to select study participants from study ID sheet. Random number generated by Microsoft excel 2010 was used to select three hundreds fourteen controls.

Inclusion criteria

- Mother delivered at or baby transferred to one of the participating study hospitals.
- Gestational age: < 37 weeks according to the algorithm shown in the table 2 & figure 2 below.
- No lower limit to gestational age
- Live born: cry, breathing or movement after delivery or Apgar >1
- Age: < 7 days when screened
- Consent given

Exclusion criteria

- Stillbirths, term neonates and premature newborns with incomplete information during the data collection.

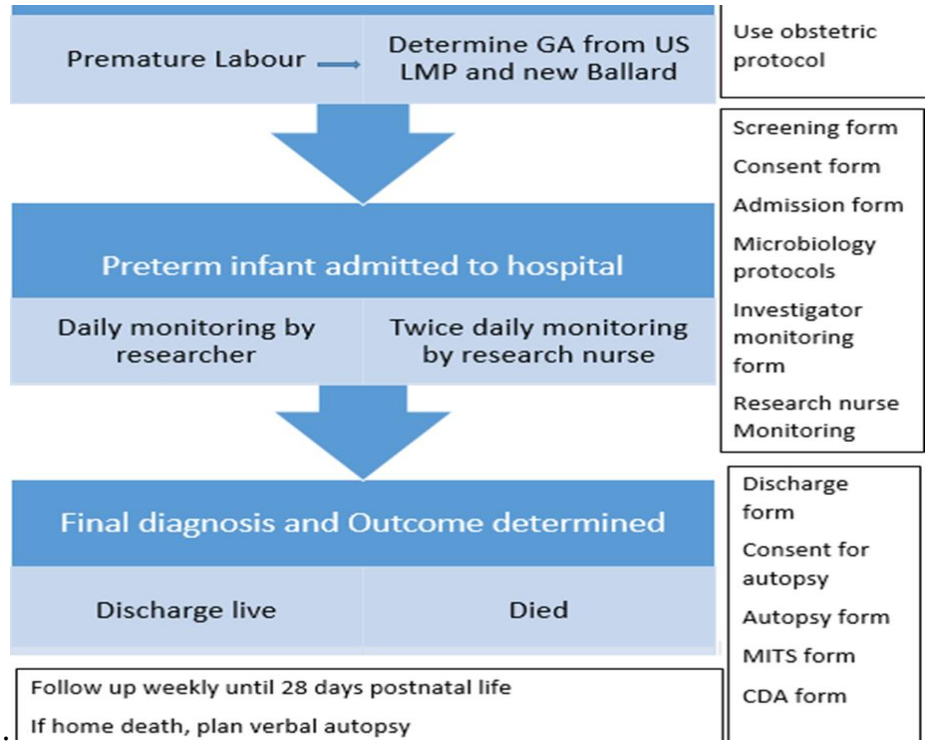

Figure 2: Roadmap of study patients enrolment and tools used (SIP project protocol)

4.8. Study variable

Dependent variable: mortality among premature newborn

Independent variable:

Table 1 .Factors and variables to be measured for preterm neonatal mortality in the selected hospitals in Addis Ababa, July 25, 2016 to May 29, 2017

Factor	Variables to be measured
Maternal socio demographic variables	Age, occupational status, level of education, marital status
Past pregnancy	Parity, abortion, preterm birth, Term birth, Number of living children.
Present pregnancy	ANC, Gestational age, Anemia, maternal ailments (HIV, Syphilis, UTI, Malaria), TT vaccinations, corticosteroid/dexamethasone, antibiotics use for UTI
Intra-partum factors and immediate post-partum	Labor complications, mode of delivery, delivery assistance, baby resuscitation
Obstetric Complications	Hypertension, ante partum hemorrhage, Chorioamnionitis
Medical disorders	Diabetes Mellitus, cardiac diseases, thyroid disease)

4.9. Operational definition

Standardizing definition of "preterm"

Three methods (ultrasound, last menstrual period [LPM], Ballard/Dubowitz scores) were applied for assessment of gestational age.

Preterm birth: -Neonate born at gestational age of less than 37 weeks determined by the three methods mentioned and included in the study according to Fig 2 above.

Table 2: Methods used to determine gestational age of preterm neonates by prospective study of SIP project 2016/2017.

Ultrasound was done at < 28 weeks	**GA at delivery <37 weeks**
If Ultrasound at >28 weeks **and** either valid LMP or Ballard	GA at delivery < 37 weeks
If no US, valid LMP **and** Ballard Exam done < 7 days after delivery	GA < 37 weeks
If no US, valid LMP and Ballard Exam is done < 7 days after delivery and discrepancy between the LMP and Ballard use hierarchy to determine GA	If the difference between GA by Ballard and LMP is not greater than 2 weeks, the LMP GA is correct; if the difference is greater than 2 weeks, use Ballard
If no US and no valid LMP, Ballard was done < 7 days after delivery	GA at Ballard exam <37 weeks. Note: If Ballard indicates category 36-3 8wks, Baby not eligible for SIP
Gestational age is ≥37 weeks or GA was not taken	Ineligible

Cases-All preterm neonates who were admitted to NICU ward of SIP follow up study and died within 28 days of their neonatal life regardless of place of death (in hospital or home after discharge.)

Controls-Selected preterm neonates who were admitted to NICU ward of SIP follow up study and survived till 28 days of their neonatal life.

4.10 . Data collection tool and procedure

A pretested questionnaire developed by the SIP project was used for data collection. Data was collected through retrospective chart review and interviewer administered questionnaires. Information on maternal age, parity, prior uterine surgery, history of PTB, and obstetric history was recorded. Presence of pre-existing maternal medical disorders was reviewed. Hypertensive, endocrinological (diabetes), congenital heart diseases and infectious conditions were also recorded.

Pregnancy-related complications such as hypertensive disorders of pregnancy (gestational hypertension and, gestational diabetes, and bleeding in the second half of pregnancy (abruption placentae, placenta Previa) were recorded. Other pregnancy-related complications (e.g. urinary tract infections, maternal anemia) were also documented. Maternal antenatal care was recorded.

4.11 Data quality management

A pretested questionnaire was used for data collection and cross-checked for completeness on daily basis by the team supervisor. The research nurses took consent form, enrolled the study infants, obtained obstetric history and continuously documented nursing care, at least twice daily until the infant was discharged or has died during neonatal period (28 day) as part of the project protocol. A three days training for data collectors (nurses who routinely carry out their tasks in the care of preterm neonates admitted to NICU ward); clinicians who reviewed the clinical and laboratory findings and the progression of the illness to decide on the primary cause of mortality and the contributory maternal and infant causes of mortality following the WHO guidance on certification of causes of death; data clerks, and supervisors was given by the project coordinators (professors) to make them familiar with the objectives and procedures of this multicenter prospective study specifically on interviewing techniques, patient privacy, how to fill different formats and over all patient data handling and reporting according to the project protocol. Pretest and posttest assessment on data collection was conducted and adjustments made on tools accordingly.

4.12 Data analysis procedure

Data was entered using Epi Info 7 and analyzed by STATA 12. Descriptive statistics such as frequency distribution, mean, and standard deviation were computed to characterize the major independent and dependent variables. Bivariate analysis was run to identify the relationship between preterm neonatal mortality and the potential independent variables without adjusting for other explanatory variables. All determinants with p-value less or equal to 0.25 in bivariate analyses were entered into a multivariate logistic regression model to assess their association with the dependent variable.

Odds ratios (OR) with 95% confidence intervals (CIs) were computed using logistic regression models to assess the relationship between preterm neonatal mortality and each selected variables. In the final model all variables with p-value <0.05 was considered as having statistical association with preterm mortality.

4.13 Ethical considerations

This study is part of the well-resourced SIP project in Ethiopia. As a result close monitoring and follow-up was made by the research staff to ensure safety of enrolled children in study. Ethical approval to carry out the study was obtained from College of Health science IRB. Separate ethical approval was obtained from the School of Public Health Research and Ethics Committee for this sub-study.

During the data collection this aim of the study was explained to all the study participants and informed written consent was obtained. Participants were given adequate time to go through the consent form if they were literate. When they were not literate data collectors have read the forms for them. Participants were informed that they were free to withdraw at any time without giving reasons. A decision not to participate was respected and the participants assured that non-participation would not affect the health care they receive in anyway.

4.14 Dissemination of the results

The finding of this study would be presented to Addis Ababa University College of Health Sciences School of Public Health, and SIP project. And it would be disseminated to MOH. Finally, the manuscript will be submitted to reputable scientific journals.

5. Results

5.1 . Characteristics of study participants

5.1.1 Socio-demographic characteristics of mothers of the preterm babies

The study included 471 (157 cases and 314 controls) mother-newborn pairs who gave birth and admitted to NICU ward in the selected hospitals in Addis Ababa from July 2016 to May 2017.

The mean (±SD) age of the mothers of cases was 25.8(±4.6) years and that of mothers of controls was 26.6(±4.7) years. Most of the mothers of the cases 194 (61.8%) and that of controls 85 (54.1) % were in the age group 25-34 years (p=0.259**)**. They were not significantly different with respect to maternal age. Most of the mothers of cases 144 (91.7%) and that of control 303 (96.5%) were married. More mothers among the controls were married compared to the cases; this was statistically significant different (p=0.026). Forty (25.5%) of mothers of the cases and 58 (18.5%) of controls have no formal education. Cases were statistically significantly different from controls on their educational status (p=0.019). Most mothers of the cases 109 (69.4%) and controls 198 (63.1%) were employed (Table-3).

Table 3: Socio-demographic characteristics of mothers of preterm Neonates Admitted to NICU ward who died within 28 days postpartum or who survived, in a prospective study under SIP project of selected Referral Hospitals in Addis Ababa, Ethiopia from July 2016 to May 2017

Variables	**Cases (n=157)**		**Controls (n=314)**		**P.Value**
	Frequency	**Percent**	**Frequency**	**Percent**	
Age at birth (in years)					0.259
15-24	61	38.9	99	31.5	
25-34	85	54.1	194	61.8	
35-49	11	7.0	21	6.7	
Marital status					0.026
Married	144	91.7	303	96.5	
Others*	13	8.3	11	3.5	
Formal education of mother					0.019
None/not able to read and write	22	14.0	43	13.7	
None/able to read and write	18	11.5	15	4.8	
Primary	52	33.1	117	37.3	
Secondary	50	31.8	86	27.4	
Higher	15	9.6	53	16.9	
Mothers' occupations					0.171
Employed	109	69.4	198	63.1	
Unemployed	48	30.6	116	36.9	

* Widowed, divorced, single

5.1.2 Reproductive characteristics of the respondents

Regarding the obstetrics information of the study participants, 99 (63.1%) of mothers of cases and about 200 (63.7%) of mothers of the controls were primiparous (p=0.892). Among mothers of the cases, about 34 (21.70%) gave prior preterm birth babies as compared to that of 64 (20.4%) mothers of controls who gave prior preterm Birth (p=0.933). Among mothers of the cases who have ANC for their last pregnancy, most 103 (65.6%) had 1-3 visits while mothers of the controls who had 1-3 times ANC visits were 188 (59.9%) (p=0.357). Most of the mothers of the controls 111 (70.7%) and of that of cases 251 (79.9%) had two doses of Tetanus toxoid vaccination for their current pregnancy, which is statistically significantly different (p=0.001). Twenty-five mothers (15.9%) of cases and 18 (5.7%) mothers of controls had last hemoglobin level of 8-11 mg/dl, which was statistically significantly different hemoglobin level (p=0.000). The major type of birth among cases 133 (84.8) and controls 272 (86.6) was singleton (p=**0.**892). Fourteen (8.9%) among mothers of cases were found to have urine test suggesting infection as compared to 8 (2.5%) among mothers of controls (p=0.002). Caesarean section was mode of delivery for 64 (63.8%) of cases and 116 (36.9%) of controls. The mean/median gestational age of cases and controls are 30.6/30 and 33.6/34 weeks respectively. Thirty-two (20.4%) cases and 30 (19.1%) controls have not taken antenatal steroids (p= **0.**417**)** (table-4).

Table 4: Reproductive characteristics of Mothers of preterm Neonates Admitted to NICU ward who died within 28 days postpartum or who survived, in a prospective study under SIP project of selected Referral Hospitals in Addis Ababa, Ethiopia from July 2016 to May 2017.

Variables	Cases (n=157)		Controls (n=314)		P.value
	Frequency	Percent	Frequency	Percent	
Primiparous					0.892
No	99	63.1	200	63.7	
Yes	58	36.9	114	36.3	
Prior pregnancies ending at <20 weeks					0.933
0	128	81.5	260	82.8	
1	24	15.3	44	14.0	
≥2	5	3.2	10	3.2	
Previous preterm births					0.326
0	117	74.5	227	72.3	
1	34	21.7	64	20.4	
≥2	6	3.8	23	7.3	
Previous term births					0.800
0	99	63.1	189	60.2	
1	33	21.0	74	23.6	
≥2	25	15.9	51	16.2	
At least One ANC Visit for last pregnancy					0.000
No	19	12.1	2	0.6	
Yes	138	87.9	312	99.4	
Number of ANC Visits for last pregnancy					0.357
No visits at all (0)	19	12.1	2	0.6	
1-3 Visits	103	65.6	188	59.9	
≥4 Visits	35	22.3	124	39.5	
Hemoglobin Level					0.000
<8 mg/dl	15	9.6	18	5.7	
8-11 mg/dl	25	15.9	19	6.1	
≥ 11mg/dl	117	74.5	227	88.2	
VDRL					0.570
Reactive	1	0.6	3	1.0	
Nonreactive	156	99.4	311	99.0	
HIV/AIDS sero-status					0.475
Positive	4	2.5	5	1.6	
Negative	153	97.5	309	98.4	
Urine test suggesting infection					0.002
No	143	91.1	306	97.5	
Yes	14	8.9	8	2.5	

Table-4: Continued.

Variables	Cases (n=157)		Controls (n=314)		P.value
	Frequency	Percent	Frequency	Percent	
TT vaccination					0.001
No	21	13.4	18	5.7	
Yes (2 doses), this pregnancy	111	70.7	251	79.9	
Yes (2 doses), pre-pregnancy	12	7.6	36	11.5	
One dose	13	8.3	9	2.9	
Complication during labor and delivery*					0.590
No	146	93.0	291	92.	
Yes	11	7.0	23	7.3	
Mode of delivery					0.562
Vaginal	93	59.2	64	40.8	
Cesarean section	64	63.8	116	36.9	
Dexamethasone					0.417
None	111	70.7	213	67.8	
1-3	14	8.9	41	13.1	
≥4	32	20.4	60	19.1	
Antibiotics					0.648
No	82	52	50.0	4	
Yes	75	157	500		
Gestational age at birth					0.007
Extremely preterm (<28 weeks)	13	8.3	8	2.5	
Very preterm (28 to <32 weeks)	49	31.2	84	28.8	
Moderate to late preterm (32 to <37 weeks)	95	60.5	222	70.7	

*Maternal fever, cord prolapse, ruptured uterus baby resuscitation

5.1.3 Medical Disorders and Obstetric Characteristics of the respondents

Regarding obstetric related information of the study participants 52 (33.1%) of the mothers of cases and 59 (18.8%) of mothers of controls had one type of hypertensive disorders during pregnancy like preeclampsia, eclampsia, superimposed preeclampsia and chronic hypertension. Cases had statistically significantly higher maternal hypertension compared to controls (p=0.007). Forty-five (28.7%) mothers of cases and 66(21%) of that of controls had developed pre-eclampsia during current pregnancies showing statistical difference among the two groups (p= 0-001). Chorioamnionitis was noted on about 9 (5.7%) mothers of cases as compared to 26 (8.3%) of control mothers, which was not statistically significant difference (p= 0.320). About 23(14.6%) of mothers of cases had antepartum hemorrhage in their current pregnancies which was statistically significantly higher as compared to 18 (5.7%) mothers of controls (p= 0.001) (TABLE 5).

Table 5 .Medical disorders and obstetric characteristics of mothers of preterm neonates admitted to NICU ward who died within 28 days postpartum or who survived, in a prospective study under SIP project of selected referral hospitals in Addis Ababa, Ethiopia from July 2016 to May 2017.

Variables	Cases (n=157)		Controls (n=314)		P.value
	Frequency	**Percent**	**Frequency**	**Percent**	
Hypertensive disorders of pregnancy*					0.007
No	105	66.9	255	81.2	
Yes	52	33.1	59	18.8	
Pre-eclampsia					0-001
No	112	71.3	248	79	
Yes	45	28.7	66	21	
Eclampsia					0.153
No	152	96.8	310	98.7	
Yes	5	3.2	4	1.3	
Superimposed pre-eclampsia					0.203
No	154	98.1	312	99.4	
Yes	3	1.9	2	0.6	
Chronic hypertension					0-219
No	155	98.7	313	99.7	
Yes	2	1.3	1	0.3	
Antepartum hemorrhage (APH)					0.001
No	134	85.4	296	94.3	
Yes	23	14.6	18	5.7	
Chorioamnionitis					0.320
No	148	94.3	288	91.7	
Yes	9	5.7	26	8.3	
Cardiac disease					0.525
No	156	99.4	310	98.7	
Yes	1	0.6	4	1.3	
Diabetes mellitus					0.112
No	15o	95.5	308	98.1	
Yes	7	4.5	6	1.9	
Thyroid disease					0.525
No	156	99.4	310	98.7	
Yes	1	0.6	4	1.3	

* Pre-eclampsia, Eclampsia**,** Superimposed pre-eclampsia**,** chronic hypertension

5.2. **Multivariate logistic regression**

Hierarchical multivariate analysis was used to assess the relative effect of the descriptive factors on the outcome variable (mortality among preterm neonates).

From the socio-demographic factors educational status was the only variable that was associated with deaths among premature babies. Compared to preterm neonates of mothers who attended higher education preterm neonates of mothers who had no education but merely can read and write and who attended secondary education were 6.5 times and 2.5 times to die, respectively. Other education level categories did not show statistically significant difference between cases and controls.

Number of ANC visits, hemoglobin level and urine test result had statistically significant association with preterm neonatal mortality. The odds of dying during neonatal period was 2.8 times [AOR (95% C.I): 2.791 (1.604, 4.857)] and 2 times [AOR (95% C.I): 1.997 (1.153, 3.461)] higher among preterm neonates whose mothers had no ANC visit at all and 1-3 times ANC visits, respectively, compared preterm neonates whose mothers had $\geq$4 ANC visit.

The odds of death among preterm neonates whose mothers last hemoglobin level was 8-11 mg/dl was 2.9 times compared to preterm neonates whose mother had hemoglobin level of > 11mg/dl [AOR (95% C.I): 2.921 (1.396, 6.112)]. However, the odds of death among preterm neonates whose mother had <8mg/dl was not significantly higher compared to preterm neonates whose mothers had hemoglobin level of >11mg/dl.

Death was 3.5 times higher among neonates whose mothers' urine test suggested infection compared to preterm neonates of mothers with negative urine test result [AOR (95% C.I): 3.513 (1.261, 9.787)].

Among obstetric and medical factors, only antepartum hemorrhage was significantly associated with the prematurity related neonatal death. Premature neonates whose mothers had antepartum hemorrhage for their current pregnancy were about 3.2 times more likely to die compared to preterm neonates whose mothers didn't experience antepartum [AOR: (95% CI): 3.151 (1.509 , 6.577)] (Table 6).

Table 6: Multivariate logistic regression analysis of the adjusted effect of selected maternal socio-demographic, reproductive related factors, medical and obstetric associated with preterm mortalities among 471 preterm live born infants admitted to NICU of selected referral hospitals under SIP project in Addis Ababa Ethiopia, from July 25, 2016 to May 29, 2017.

Variables	Adjusted OR (AOR) with (95%CI)			Condensed Model AOR (95%CI)
	Model-1	Model-2	Model-3	
Part 1. Socio demographic characteristics				
Marital status (RG- Married)				
(Single Vs. Married)	2.44 (1.047,5.704)*	0.646(0.202,2.068)		
Educational status (RG- Higher Education)				
None/not able to read and write	1.843 (0.85,3.996)	1.803 (0.773, 4.204)	1.748 (0.738, 4.139)	1.809 (0.773, 4.230)
None/able to read and write	4.089 (1.662,7.061)	6.121 (2.314, 6.192)	6.521 (2.421, 7.569)*	6.586 (2.467, 7.582) *
Primary	1.587 (0.817,3.082)	1.490 (0.723, 3.072)	2.144 (1.008, 1.008)	1.556 (0.750, 3.229)
Secondary	2.130 (1.084,4.186)*	2.182 (1.049, 4.539)*	20.563 (4.393, 96.239	2.464 (1.174, 5.174)*
Part 2. Socio demographic + Reproductive related factors				
Number of ANC Visits (RG- ≥ 4)				
No visits at all (0)		2.700 (1.543, 4.724)	2.642 (1.495, 4.669)	2.791 (1.604, 4.857)**
1-3 Visits		1.861 (1.075, 3.222)*	2.099 (1.197, 3.681)*	1.997 (1.153, 3.461)**
Hemoglobin Level (RG- ≥ 11mg/dl)				
<8 mg/dl Vs. RG		1.651 (0.424, 6.439)	2.019 (0.897, 4.545)	1.810 (0.818, 4.005)
8-11 mg/dl Vs. RG		3.455 (1.412, 8.457)*	2.577 (1.216, 5.459)*	2.921 (1.396, 6.112)*

RG- Reference Group, * Significant at p- value <0.05, ** significant at p- value <0.001

Table 6:Cont.

Variables	Adjusted OR (AOR) with (95%CI)			Condensed Model AOR (95%CI)
	Model-1	Model-2	Model-3	
Urine test suggesting infection (No- RG)				
(Yes Vs. RG)		3.295 (1.175, 9.236)*	3.198 (1.058, 9.669)*	3.513 (1.261, 9.787)*
TT vaccination RG-Yes (2 doses), this pregnancy				
(No. Vs. RG)		0.621 (0.175, 2.198)		
Yes (2 doses), pre-pregnancy Vs. RG)		0.527 (0.193, 1.440)		
(One dose Vs. RG)		0.319 (0.096, 1.062)		
Gestational age at birth (moderate to late preterm (32 to <37 weeks)- RG)				
Extremely preterm (<28 weeks) Vs. RG		1.343 (0.241, 7.483)		
Very preterm (28 to <32 weeks) Vs. RG		0.836 (0.452, 1.544		
Part 3. Socio demographic, + Reproductive related factors + Medical disorders and Obstetric Characteristics				
Hypertensive disorder of pregnancy* (No- RG)**				
(Yes Vs. RG)			0.696 (0.210,3.217)	
Pre-eclampsia (No- RG)				
(Yes Vs. RG)			3.086 (0.920, 10.353)	
Eclampsia (No- RG)				
(Yes Vs. RG)			5.755 (0.924,35.864)	
Antepartum hemorrhage (APH) (No- RG)				
(Yes Vs. RG)			3.227 (1.528, 6.814)*	3.151 (1.509, 6.577)*
Diabetes mellitus (No- RG)				
(Yes Vs. RG)			0.827 (0.188, 3.635)	

RG- Reference Group *: Significant at p- value <0.05, ** significant at p- value <0.001, ***: Pre-eclampsia, Eclampsia, super imposed preeclampsia, Chronic hypertension

6. Discussion

The main aim of this study was to determine maternal risk factors associated with mortality among preterm neonates in selected hospitals of Addis Ababa admitted to NICU from July 2016 to May 2017.

The finding from the study shows that maternal education was associated with the likelihood of preterm neonatal death. A study that analyzed DHS data in Ethiopia showed similar result (AOR = 1.89, CI: 1.32 - 2.72). We also found a study from Indonesia that reported consistent findings [18]. Our finding challenges findings from previous studies that widely documented that maternal social status (education) does not have effect on survival of her preterm neonate once the mother reached hospital [16, 17, 44, 45]. While large-scale study employing prospective design may be needed to confirm this, our finding has brought into light the importance of maternal education in reduction of neonatal death among preterm births. Our finding imply that in addition to improving access to quality maternal and neonatal care the government needs to increase coverage of secondary and higher education for girls and women to reduce risk of deaths of preterm babies among mothers who have no education. In the short term provision of enhanced counseling of mothers with low level of education during antenatal contact could be considered [46].

The study also revealed that the risk of preterm neonatal death is increased with decreased frequency of maternal antenatal visit. This finding was in line with studies done in other developing countries [17, 24, 33]. While our finding underlines the importance of more frequent ANC visits for reduction of death among preterm neonates it did not specifically assess which care during ANC visits contribute to lowering risk of preterm neonatal death. This finding imply that health facilities need to continue encouraging mothers to receive more frequent ANC visits, which also emphasized in the WHO recommendation on ANC[1, 38, 47]. It also calls for the need to conduct more researches looking at which care during ANC visits specifically contribute to lowering risk of preterm neonatal death.

The multivariate analysis showed that death among preterm neonates whose mothers' hemoglobin level was 8-11 mg/dl was higher compared to those who had hemoglobin level of > 11mg/dl. However, the mortality risk for neonates whose mothers' hemoglobin level was <8gm/dl was not statistically different from neonates of mothers with hemoglobin level of >11gm/dl. This could have been due to a combination of factors, such as inadequate maternal nutrition, inadequate weight gain during pregnancy, [33, 44]. These factors were not investigated in the present study.

Certain urinary tract infections caused by virulent pathogens are capable of impairing feto-maternal barriers or incidentally infect the neonate from birth canal during childbirth and causing adverse effect in the already less immune competent preterm neonates in mothers who hadn't adequate treatment for the infection [44]. Consistent with this, in our study we found that there was high risk of death among preterm neonates whose mothers' urine test suggesting infection compared to those preterm neonates with mothers' negative urine test result.

Preeclampsia was not associated with preterm neonatal mortality in our study. Previous studies highlighted that the long term effect of maternal preeclampsia on neonatal outcomes are Conflicting [36, 39]. The preeclampsia finding of current study may be ascribed to the fact that mothers good control of their hypertensive status in this referral hospitals might have contributed to the reduced long adverse effect on preterm neonatal outcomes. This needs to be approved through longitudinal community based study for better characterization of infants of women who have PE and to aid in predicting risks in their neonatal and later outcome.

But mothers who had antepartum hemorrhage had higher risk of preterm neonatal death than those who didn't experience antepartum hemorrhage. Similar findings have been reported in other study showing that the occurrence of antepartum hemorrhage were found to increase the likelihood of neonatal mortality by nearly five times [44].

The variation in the magnitude of this finding is due to the fact that the current study identified the specific effect of antepartum hemorrhage among preterm neonates while other studies emphasized the association of aggregate maternal complications to both term and preterm neonates. Contrary to this the study by Evans et.al in the Australian and New Zealand Neonatal Network indicated that APH was not significantly associated with neonatal mortality [39]. .

Other studies conducted in Spain Barcelona indicated that no statistical difference was observed with respect to APH between spontaneous late preterm and medically indicated neonates [24]. This is because women with medically-indicated late preterm were more likely to be older and nulliparous and obstetric complication is more common in late preterm births as compared to term ones. Mortality associated with these factors may be amenable through effective antenatal and intrapartum care.

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7. Strengths and Limitation of the study

7.1 . Strengths of the study

- This study's strengths include the use of high-quality data collected by trained research staff as part of their routine tasks applying standardized methods.
- The use of prospectively collected data has presumably limited the probability of selection bias and misclassification of covariates and outcomes.
- The use of the hierarchical modeling method helps to assess the hierarchical impacts of covariates on mortality and final factor supposed to be associated with preterm mortality.
- All preterm neonates legible for the study get similar care and follow up in NICU ward by the data collectors/duty nurses until 28 days postnatal or discharge to minimize possible effect of health facility related factors on preterm neonatal mortality.

7.2 Limitations of the study

- This study was not able to examine variability among mothers quality of care by professionals which are additional possible contributors to variation in the preterm outcome.

8. Conclusion And recommendations

8.1 . Conclusion

The result of this study showed maternal education, number of ANC visits, Urine test suggesting infection, maternal anemia, and Ante-partal hemorrhage, were identified as determinants of preterm neonatal mortality.

Mothers with no formal education were at increased risk of preterm Neonatal mortality as compared to those with secondary school education and above.

The preterm neonatal death was increased with decreased frequency of maternal Antenatal Visit and maternal Anemia was also found to be associated with Preterm neonatal survival.

Mothers with Antepartum hemorrhage had increased odds of preterm neonatal mortality.

However, further comprehensive community based study/longitudinal is required in the study area before drawing conclusions about the relation between this maternal risk factors and Preterm neonatal mortality.

8.2 . Recommendations

- The MOH needs to address the importance of increasing ANC Visit frequency to at least 4 visits of WHO recommendations to avert complications through effective counseling programs as one of preterm neonatal survival interventions.
- Health extension workers should strengthen home to home visit and advice of all pregnant women for ANC follow up.
- The MOE needs to give emphasis on women's education to continue their educational level secondary school and higher.
- Assistance need to be extended to this vulnerable group of mothers newborn pairs, to see a reduction in the incidence of adverse preterm neonatal outcomes.
- More research is needed to identify and determine other factors associated with mortality among preterm infants.

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Annexes

Annex *I*: English version participant's information sheet

Hello. My Name is _____. I am a candidate of post graduate student from the school of public health. The title of my study is "maternal risk factors for prematurity related neonatal mortality among preterm neonates admitted to Neonatal Intensive Care Unit of selected referral Hospitals in Addis Ababa". The research has gone through ethical approval process. Ethical clearance has been accepted from the school of public health. The aim of this study is to determine maternal risk factors associated with mortality among preterm neonates in selected hospitals of Addis Ababa admitted to NICU from July 25, 2016 to May 29, 2017.

You are purposely selected to participate in the study because of being a member of study participant during the study period. You can decline partially or totally to give information any time you hesitate. No payment is incurred and hence it is voluntary to improve mortality especially among preterm. Participation in this study has no any health risk to you and your preterm neonate. However, genuine information you provide us is useful to improve both the health of mothers and their neonates for decision makers and stakeholders. Confidentiality will be assured through not recording your name, use of code, and your permission. No access to the data will be confirmed through keeping it in a locked cabinet except whom it may concern legally. You can ask me freely any question any time you didn't understand or you have hesitation about. If you ask me question that needs further clarification, I'm a principal investigator on this Topic and ready to discuss with my research team coordinators and advisors so that a consensus will be arrived at and you get un ambiguous explanation.

Annex II: Informed consent form

Informed Consent

Hello. My name is _____.and I am part of the data collectors who are gathering data on "Maternal risk factors for prematurity related Neonatal mortality in _____ of NICU (Show a letter of approval from the school). I would Very much like to appreciate your participation in this study. I would like to ask you some questions and it will take 20 minutes. Your answers will remain confidential, and we will not write down your name so your answers will be anonymous.

Participation in this study is voluntary and you can choose not to answer any individual question or all of the questions. However I hope that you will participate in this important study and play your role towards neonatal mortality reduction by providing genuine response since your views are important. If you have any question now or later you can contact me in person or thorough my personal address as appropriate to you. Take time and think over it for better decision to take part in the study or not since it is based on voluntary and payment free participation.

Cell phone- 0913140330

Email- dirogemeda@gmail.com

At this time, do you want to ask me anything about the study?

May I begin the interview

Start time____:___-End Time ____:_____Date_____/_____/_____.

Respondent agrees to be interviewed Respondent Doesn't agree to be interviewed

End!

Annex III- Questionnaire- English version

NB- A five pages pretested Questionnaires Developed by Prof. Lulu Muhe was employed for data collection as this is one of the study packages on Preterm Newborn mortality in Ethiopia under SIP Project.

S. No	**ETHIOPIA STUDY OF ILLNESS IN PRETERMS (SIP)**	
	Question	**Answer**
	Obstetric form	**02**
	Page	
001	**Interview Date**	/__/__/ /__/__/ /__/__/__/__/ **Date Month Year**
002	HOSPITAL Name	
003	Study ID:	|__|__ |___|_|__|__|
004	MEDICAL RECORD	
005	NAME	

Part 0. : Address

S.no	The obstetric form should be completed following delivery at enrollment for all women with an infant participating in the SIP project by the study nurse. All dates should be recorded in the Ethiopian Calendar.		
	Question	Answer	Skip
101.	How old are you in completed years?	1. |__|__| years	
102.	What is your current marital status?	*1.* ☐Married *3.* ☐Divorced *2.* ☐Single 4. ☐Widowed 5. ☐Don't Know	
103.	What is the Educational status of the respondent?	*1.* ☐None/not able to read and write *2.* ☐None/able to read and write *3.* ☐Primary 5. ☐Higher Education *4.* ☐Secondary 6.☐Don't Know	
104.	What is the Occupation of mother?	*1.* ☐Housewife 4. ☐Farmer *2.* ☐Government/Company 5. ☐Other:____ *3.* ☐Self-employed 6. ☐Don't Know	

PART1. SOCIODEMOGRAPHIC DATA

PART 2. Maternal factors associated with mortality among Preterm neonates

2.1. PAST PREGNANCY HISTORY

S.no	Question	Answer	Skip
201.	Is this mother's first pregnancy?	1☐Yes – Skip to Section C 2☐No 3☐Don'tKnow	
202.	Prior pregnancies ending at <20 weeks 202.1Spontaneous abortions: 202.2 Medical/induced abortion:	|__|__|(if no prior pregnancies <20 wks.' indicate 00) |__|__|(if none, code 00) |__|__|(if none, code 00)	
203.	Number of prior pregnancies that appeared preterm (20-37 weeks)	|__|__|(if none, code 00)	
204.	Number of prior pregnancies that appeared term > 37 weeks		
205.	Number of living children:	|__|__| (if no living children, code 00)	

2.2. CURRENT PREGNANCY

S.no	Question	Answer	Skip
206.	Antenatal care (ANC) received? 205.1 If yes number of visits whether in this or other hospital/clinics:	1 ☐ Yes 2 ☐ No/Don't Know |__|__|	
207.	Last Hemoglobin level (Hgb)	|__|__|.|__| or 2 ☐ Not done/Don't Know	
208.	Last HCT level	|__|__|.|__| or 2 ☐ Not done/Don't Know	
209.	Blood group	1.☐ A 2. ☐ B 3. ☐ AB 4. ☐ O 5. ☐ Don't Know	
210.	Rh factor	1. ☐ Positive 2. ☐ Negative 3. ☐ Not done/Don't Know	

211.	VDRL	1. ☐Reactive 2. ☐Nonreactive 3. ☐Not done/Don't know	
212.	HIV/AIDS sero-status	1. ☐Positive 2. ☐Negative 3☐Not done/Don't know	
213.	History of tuberculosis	1. ☐yes 2. ☐No 3. ☐Not done/Don't know	
214.	Urine test suggesting infection	1. ☐Yes 2. ☐No 3. ☐Not done/Don't know	
215.	Malaria during the current pregnancy?	1. ☐Yes 2. ☐No 3. ☐Not evaluated/Don't know	
216.	TT vaccination	1. ☐ Yes (2 doses), this pregnancy 2. ☐ Yes(2 doses), pre-pregnancy 3 . ☐ One dose 4. ☐ No 5. ☐Don't know	
217.	Gestational age when the baby was born	------Weeks/-----days	

2.3. Events *leading to delivery*

S.no	Question	Answer	Skip
218.	Spontaneous labor	1. ☐Yes 2. ☐No 3. ☐Don't know	
219.	Spontaneous ROM	1. ☐Yes 2. ☐No 3. ☐Don't know	
220.	Induction of labor	1. ☐Yes 2. ☐No 3. ☐Don't know	
221.	If induced, specify indication	1. ☐Fetal distress 2. ☐IUGR/SGA 3 ☐Preeclampsia/eclampsia 4. ☐ Macrosomia 5. ☐ Other specify:_____	
222.	C-Section	1 ☐Yes 2 ☐No 3☐Don't know	
223.	If Cesarean section, specify indication	1☐Fetal distress 7☐Breech 2☐IUGR/SGA 8☐Multiple pregnancy 3☐Preeclampsia/eclampsia 9☐Prolonged or obstructed labor 4☐Cord prolapsed 10☐Elective Cesarean section 5☐Prior Cesarean section 11☐ Other specify:__ 6☐Macrosomia 12☐ Don't know	

224.	Is pregnancy:	1. ☐Singleton 2. ☐Twins 3. ☐Triplet 4. ☐ Other		
		Presentation 1=Vertex 3=Transverse 2=Breech 4=Other cephalic (face, brow) 5=Don't know	**Delivery Mode (Mark ALL)** 1= SVD 4=Assisted Breech 2 = Forceps 5=C-Section 3=Vacuum 6 = Don't know	
225.	Singleton ***or*** if twin/triplets, Baby A			
226.	If twin/triplets, Baby B			
227.	If triplets, Baby C			
228.	Other (4+)			
229.	229.1 Date and time of delivery (record or if multiple birth, record time of first) (Ethiopian Calendar): Date: |__|__|-|__|__|-|__|__|__|__| Time: -|__|__|- |__|__| 1☐AM 2☐PM (dd-mm-yyyy) (Hr) (Min) 3 ☐Don't know 229.2 Date and time of delivery (if multiple birth, record time of second): Date: |__|__|-|__|__|-|__|__|__|__| Time: -|__|__|- |__|__| 1☐AM 2☐PM (dd-mm-yyyy) (Hr) (Min 3 ☐Don't know) 229.3 Date and time of delivery (if multiple birth, record time of third): 1☐AM 2☐P Date: |__|__|-|__|__|-|__|__|__|__| Time: -|__|__|- |__|__| 1☐AM 2☐PM (dd-mm-yyyy) (Hr) (Min 3 ☐ Don't know 229.4 Date and time of delivery (if multiple birth, record time of fourth): Date: |__|__|-|__|__|-|__|__|__|__| Time: -|__|__|- |__|__| 1☐AM 2☐PM (dd-mm-yyyy) (Hr) (Min 3 ☐Don't know) 229.5 greater than 4 *specific*_____		
230.	Apgar Score of singleton/Baby	A: 1st min |__| 5min |__| ☐Don't know		
	Apgar Score of singleton/Baby	b: 1st min |__| 5min |__| ☐Don't know		
	Apgar Score of singleton/Baby	c: 1st min |__| 5min |__| ☐Don't know		
	Apgar Score of singleton/Baby	d: 1st min |__| 5min |__| ☐Don't know		
231.	If labor, overall duration in hours and minutes	|__|__| days |__|__| (Hr) |__|__|Min (ENTER '0' if no labor)		
232.	Duration of rupture of membrane in hours and minutes	|__|__|-|__|__|(Hr) - (Min) (Record '0' if at delivery)		
233.	Did delivery occur during:	1. ☐Working Hours (8AM-5PM weekdays) 2. ☐Doctor duty hours (after 5PM weekdays,		

		holidays/weekend) 3.☐Don't know	
234.	Delivery attendant (Indicate most senior care giver present at the delivery):	1. ☐Nurse/midwife 2. ☐Physician 3. ☐Students(Medical or midwifery) 4. ☐Resident 5. ☐Intern 6. ☐TBA 7. ☐ Other/Don't know	

2.4 COMPLICATIONS DURING LABOR AND DELIVERY AND IMMEDIATE POST NATAL CARE

.S.no	Question	Answer	Skip
235.	Maternal fever prior to delivery	1. ☐Yes 2. ☐No 3. ☐Don't know	
236.	Cord prolapse:	1. ☐Yes 2. ☐No 3. ☐Don't know	
237.	.Ruptured Uterus	1☐Yes 2 ☐No 3 ☐Don't know	
238.	Other If YES	1. ☐Yes 2. ☐No 3. ☐Don't know SPECIFY:_____	
239.	Intra-partum FHR monitoring If Yes	1. ☐Yes 2. ☐No 3. ☐Don't know 1. ☐Intermittent auscultation 2 .☐Continuous CTG monitoring	
240.	Was baby resuscitated with bag and mask?	1. ☐Yes 2. ☐No 3. ☐Don't know	
	If Yes,	1☐Intermittent auscultation 2☐Continuous CTG monitoring	

2.5 MATERNAL MEDICATIONS PRIOR TO DELIVERY

S.no	Question	Answer	Skip
241.	Antibiotics	1. ☐Yes 2. ☐No 3. ☐Don't know	
242.	1If yes to Question No.241, check whether antibiotics are given for following indications		
	242.1 PROM	1. ☐Yes 2 ☐No 3 ☐Don't know	
	242.2 Chorioamnionitis	1. ☐Yes 2 ☐No 3 ☐Don't know	
	242.3 Maternal urinary tract infection	1. ☐Yes 2 ☐No 3 ☐Don't know	
	242.4 Prophylaxis for C-Section	1. ☐Yes 2 ☐No 3 ☐Don't know	
	242.5 Other maternal infection	1. ☐Yes 2 ☐No 3 ☐Don't know	
	242.5.1 If Yes,	Specify_____	
243.	Dexamethasone given for fetal lung maturation	1. ☐Yes 2 ☐No 3 ☐Don't know	
	243.1 If Yes, Number of doses	|__| or 3 ☐Don't know	
	243.2 If Yes, time from the last dose of steroid to delivery	|__|__|days |__|__| hours or 3 ☐Don't know	
244.	Magnesium sulfate	1. ☐Yes 2 ☐No 3 ☐Don't know	
245.	Diazepam	1. ☐Yes 2 ☐No 3 ☐Don't know	
246.	Pethidine	1. ☐Yes 2 ☐No 3 ☐Don't know	
247.	Other medication	1. ☐Yes 2 ☐No 3 ☐Don't know	
	247.1 If Other,	Specify _____	

Part 3: Maternal medical and obstetric related

3.1. MATERNAL MEDICAL DISORDERS

S.no	Question	Answer	Skip
301.	Cardiac disease?	1. ☐Yes 2. ☐No 3. ☐Don't know	
302.	Diabetes mellitus? 302.1 If Yes,	1. ☐Yes 2. ☐No 3. ☐Don't know 1. ☐Pre-gestational 2. ☐Gestational 3. ☐Don't know	
303.	Thyroid disease? If Yes	1. ☐Yes 2. ☐No 3. ☐Don't know 1. ☐Hyperthyroidism 2. ☐Hypothyroidism 3. ☐Don't know	
304.	Other disorders? If Yes,	1. ☐Yes 2. ☐No/Don't Know Specify:_____	

3.2. OBSTETRIC DISORDERS

S.no	Question	Answer	Skip
305.	Hypertensive disorders of pregnancy? **305.1** If yes, check type (TICK ALL THAT APPLY):	1. ☐Yes 2. ☐No 3. ☐Don't know 1. ☐Pre-eclampsia 3. ☐Superimposed pre-Eclampsia 2. ☐eclampsia 4. ☐Chronic hypertension 5. ☐Don't know	
306.	. Antepartum hemorrhage (APH)? (TICK ALL THAT APPLY)	1☐Yes 2. ☐No 3. ☐Don't know 3. ☐Other Hemorrhage, specify _____ 4. ☐Don't know	
307.	Chorioamnionitis?	1. ☐Yes 2. ☐No 3. ☐Don't know	

SECTION 4 COMPLETION OF FORM

401. Name of person completing this form: _____|___|___|___|

402. Name of person reviewing this form: _____ |___|___|___|

403. Date Completed Form Reviewed: |__|__|-|__|__|-|__|__|__|__| (dd-mm-yyyy) (Ethiopian Calendar)

Annex IV- Amharic version participant's information sheet

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ANNEX V- QUESTIONNAIRE- Amharic Version

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