

**FACTORS CONTRIBUTING TO MORBIDITY AND
MORTALITY AMONG PRETERM NEONATES ADMITTED AT
TWO MAJOR HOSPITALS IN RWANDA**

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SN/PGMNH/07/14

**THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE
REQUIREMENT FOR THE AWARD OF THE DEGREE OF
MASTERS OF SCIENCE IN NURSING (MATERNAL AND
NEONATAL HEALTH)**

MOI UNIVERSITY

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DECLARATION

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DEDICATION

To

My family

My friends

All persons born preterm

This work is dedicated.

ABSTRACT

Background: Prematurity is one of the highest global health challenges of the 21st century and has been named the first killer of young children. In Rwanda, it is the leading cause of death in neonates. It is expedient to explore the factors contributing to the observed high morbidity and mortality to plan appropriate interventions.

Objective: To identify factors contributing to morbidity and mortality among preterm neonates and neonatal outcomes at discharge.

Methodology: Adopting the descriptive design and quantitative approach, 125 preterm babies admitted in the Neonatal Intensive Care Unit (NICU) of the University Teaching Hospital of Kigali and Muhima hospital over eight weeks were recruited in the study using consecutive sampling method. Interviewer administered questionnaire to the mothers, files of mothers and babies were used as sources of data. Frequencies, chi-square, and logistic regression were used for analysis. A p-value <0.05 was considered significant.

Results: Marital status of mothers, mother's participation in the care of her baby, and APGAR score ≤ 6 with a p-value (0.007), (0.02), (0.002) respectively, were statistically significantly associated with mortality. Controlling for confounders, neonates with APGAR score ≥ 6 had a lower odds of dying compared to those with an APGAR score ≤ 6 (OR=0.268 CI:0.102,0.700). Morbidities and mortality was high as gestational age, and birth weight decreased. The main morbidities were neonatal sepsis (88.8%), and Respiratory Distress Syndrome (RDS) (62.4%).

Conclusion: Characteristics of preterm neonates, care received by baby, maternal and obstetrical characteristics are critical factors thereafter neonatal sepsis and RDS accounting for highest morbidities in preterm babies.

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ACKNOWLEDGEMENT

I express my sincere gratitude to the Almighty God for His generosity, for giving me the power, courage, perseverance, and accomplishment of this study.

I wish to extend my special appreciation, and my sincere gratitude to my supervisors; Mr. Amos Getanda, and Prof. Simon Kangethe for their invaluable and careful guidance, support, encouragement, and accessibility that made this research successful.

I thank the University of Rwanda for availing me the opportunity of a study leave to pursue my studies.

I also extend a vote of thanks to the staff and students of Moi University most notably the School of Nursing, Department of Midwifery and Gender for granting me the opportunity to learn.

My gratitude goes to the staff and the mothers of preterm babies at hospitals in which this study was dedicated. Without their support and participation, this research could not have been completed.

My utmost gratitude also goes to my husband, Emmanuel Mahirane for his moral and financial assistance, interest and his immeasurable support.

To my friends especially my classmates, I confirm my admiration for all the support they gave.

I am grateful to my children Alvin Xan Hira, Alvine Hira and Alvia Hira for their constant support and flexibility through this period of this study.

ACRONYMS/ABBREVIATIONS

AGA	Appropriate for gestational age
AIDS	Acquired immunodeficiency syndrome
ANC	Antenatal care
APA	American Psychologists Association
APGAR	Aspect, pulsation, grimace, activities, respiration
AWHONN	Association of Women's Health, Obstetric and Neonatal Nurses
BAM	Becoming a mother theory
BCG	Bacillus of Carmelette and Guerin
BM	Breast milk
BW	Birth weight
C/S	Caesarian section
CDC	Center for Disease Control
CHUK	Centre Hospitalier et Universitaire de Kigali
CI	Confidence interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CMHS	College of medicine and Health Sciences
CPAP	Continuous Positive Airway Pressure
EAC	East African Community
EDD	Expected date of delivery
ELBW	Extremely low birth weight (>1000 grams)
FAS	Fetal Alcohol Syndrome
FM	Formula milk
GAPPS	Global Alliance to Prevent Prematurity & Stillbirth
GCAPR	Global Coalition to Advance Preterm Birth Research
HINARI	Health InterNetwork Access to Research Initiative
HIV	Human Immunodeficiency Virus
HRIS	Human Resources Information System
ICD	International Classification of Disease
IRBs	Institutional Review Boards
IREC	Institutional research and ethical committee
IUGR	Intra-uterine growth retardation
IVH	Intraventricular Hemorrhage

KMC	Kangaroo Mother Care
LBW	Low birth weight (1501-2499 grams)
LGA	Large for Gestational Age
LLINs	Long-lasting insecticide-treated nets
LMP	Last menstrual period
MDGs	Millennium Development Goals
Mg SO₄	Magnesium of Sulphate
MoH	Ministry of Health
Mr	Mister
MSN	Masters of Sciences in Nursing
NEC	Necrotizing enterocolitis
NGT	Nasogastric tube
NICU	Neonatal Intensive Care Unit
NMR	Neonatal Mortality Rate
OR	Odds ratio
PGMNH	Post-graduate in maternal and neonatal health
PPROM	Preterm Premature Rupture of Membranes
Prof.	Professor
PROM	Premature Rupture of Membranes
PTBi	Preterm Birth Initiative
RDS	Respiratory Distress Syndrome
Reg. No	Registration number
RWF	Rwandan francs
SDGs	Sustainable Development Goals
SGA	Small for Gestational Age
SN	School of Nursing
SPSS	Statistical Packages for Social Scientists
Sqmi	Square meter
STIs	Sexually Transmitted Infections
SVD	Spontaneous Vertex Delivery
TB	Tetracycline Eye ointment
TORCHs	Toxoplasmosis, Rubera, Cytomegalovirus, Herpes simplex2
TTN	Transient tachypnea of a newborn

UCSF	University of California at San Francisco's
UNICEF	United Nations Children Emergency Fund
UR	University of Rwanda
US	United States
US \$	United states dollar
UTI	Urinary tract infections
Vit.	Vitamin
VLBW	Very low birth weight (1000-1500 grams)
WHO	World Health Organization
WPD	World Prematurity Day

OPERATIONAL DEFINITION OF TERMS

1. Factors

In this study factors are any attribute, characteristic or exposure that increases the likelihood of preterm neonates to develop a disease or lead to death. The factors assessed in this study are variable within socio-economical, obstetrical, behavioral, fetal, maternal, paternal age, environmental and care-characteristic to the newborn.

2. Morbidity

In this study morbidity is a measure of disease, illness, injury or disability within preterm neonates. Morbidity among preterm neonates can be measured by the presence of diagnosed conditions, as well as by length of hospital stay (Center for Diseases Control, 2013). In this study morbidities of interest are for example RDS, neonatal sepsis, neonatal asphyxia among others.

3. Mortality: In this study mortality means death during neonatal period and also only during hospitalization in NICU. It has to be computed based on neonatal mortality rate which is can be death from a particular disease

4. A premature baby is a baby born earlier 37 ended week or less than 259 days of gestation (Brown et al., 2014). A birth weight of at least 500 grams or a pregnancy duration of at least 22 weeks are the minimal thresholds recommended as declared World Health Organization (WHO) (Blencowe et al., 2013)

5. NICU: This is an acronym of Neonatal Intensive Care Unit often pronounced shortened "Nick-yoo". This unit takes care of preterm neonates who are incapable of surviving without assistance and monitoring. Also, it is designed for ill newborn babies (British Association of Perinatal Medicine, 2010).

6. Outcomes: In this study, outcomes means, any good or bad change experienced by a neonate at birth during hospitalization and the endings at the exit time of the baby from NICU. This includes conditions experienced or not, weight gain/ loss, discharged alive or dead.

CHAPTER ONE

INTRODUCTION

1.1. Background to the study

Morbidity and mortality among preterm newborns is a global challenge documented as one of the highest health challenges of the 21st century (United Nations Children Emergency Fund, 2014). The complications related to prematurity exceed the total of other causes of deaths in children under-five years, and prematurity was recently named as the first killer of children younger than five years (UNICEF, 2014). World Health Organization reported that the morbidity among babies born prematurely remains high in all countries worldwide especially in lower-income countries (WHO, 2015).

Nearly 15.1million babies, which translates to one out of ten babies born every year, are born pre-term of whom 1.1million of them die. In Africa and South-Asia, prematurity accounts for more than 60% (WHO, 2015). Other high-income countries have higher averages of under-five deaths directly stemming from prematurity even above 17%, which is the global average (UNICEF, 2014). However, the real causes of preterm birth or events leading to preterm birth are not yet completely understood. For this reason, the global agencies, associations, and universities are working together in four core-study initiatives to discover the origins of preterm deliveries as well as how to prevent and limit the consequences (UNICEF, 2014).

Rwanda is among few African countries that achieved Millennium Development Goal 4 (MDG), but neonatal mortality rate remains high and contributes to 30% of mortality of children under-five years. Prematurity is the leading cause contributing up to 36% of these deaths. Mortality among preterm babies was 10.6% (Blencowe et

al,2012). Generally, prematurity was the main cause of deaths in the general population in all health facilities in Rwanda and accounted for a total of 43% of all deaths as documented by the Ministry of Health in 2014. However, in Rwanda, like many low income countries, there is dearth of data on many critical issues about preterm neonates.

Furthermore, premature birth is a primary root of continuing loss of human potential in survivors in all stages of life, and also loss of money (Blencowe et al, 2013). Therefore, newborns' health takes its place among the unfinished agendas of the MDGs and thus becomes a priority in Sustainable Development Goals (SDGs). The WHO is concentrating its effort in reducing the premature neonatal deaths because two-thirds of these deaths could be prevented (WHO, 2014). The WHO has a goal of reducing 50% deaths in preterm babies by the year 2025 and the global Sustainable Development Goals (SDG) have set a target of terminating preventable illness in neonates by 2030 (WHO, 2015).

All preterm newborns are at risk due to immaturity of their organs (Basso and Wilcox, 2010). The outcomes in newborns are related to several interactions of characteristics or factors thus health of a newborn is highly correlated to the mother's health especially as such relate to the intrapartum and postpartum attention received by the mother (Vandresse, 2006) (Austin et al, 2014). This study investigated various factors associated to the health outcomes among preterm neonates.

1.2 Problem Statement

Although progress in evidence-based practices has been made, prematurity remains highly related to high morbidity and mortality in the world therefore it is being termed as the leading killer of children less than five years old, whereby about 28% of

newborns succumb due to prematurity (UNICEF, 2014; Khan et al., 2012). Globally, morbidity in preterm babies remains high especially in lower-income countries resulting in high mortality (WHO, 2015). Blencowe et al, 2013 states that prematurity is a significant source of permanent loss of human potential in survivors in all stage of life. Globally each year 1.1 million newborns die due to prematurity-related complications. In Africa about 350,000 premature babies die from those complications. In Rwanda, about 10.6% of neonates born preterm lose their lives (Blencowe et al., 2012). A report from Ministry of Health in Rwanda has shown that prematurity-related complications are the leading causes of mortality in general population and in all hospitals (MOH, 2014). However, Rwanda has insufficiency of data concerning preterm neonates.

1.3 Scope of the study

The scope of this study was limited to the description of various factors contributing to morbidity and mortality among preterm newborns admitted to NICU at two major hospitals in Rwanda and possible outcomes at the time of NICU exit. The study was built on the adapted and adjusted conceptual model of Vandresse (2006) where various characteristics (socio-economic, age of both parents, environmental, behavioral, maternal, obstetrical, care to the newborn baby as well as neonatal characteristics) cover different variables associated to the outcomes of interest (morbidity and mortality) in the preterm neonates.

1.4 Research Questions

1. What are the factors associated to morbidity and mortality among preterm neonates admitted to NICU at two major hospitals in Rwanda?
2. What are the outcomes of preterm neonates at the time of exit from NICU at two major hospitals in Rwanda?

1.5 Research objectives

1.5.1. Broad objective

To determine the factors associated to morbidity and mortality among preterm neonates admitted to NICU of two major hospitals in Rwanda.

1.5.2. Specific objectives

1. To assess factors associated to morbidity and mortality among preterm neonates admitted to NICU at two major hospitals in Rwanda.
2. To determine the outcomes of preterm neonates at the exit from NICU at two major hospitals in Rwanda.

1.6. Justification

This study is one of a solution to the issue of prematurity which currently awakens researchers worldwide. This study is to determine the factors which are associated to morbidity and mortality and identify association between them and outcomes, then after Findings resulted from this study is a contribution to the body of knowledge. In addition Recommendations drawn will be translated into practices in the purpose of decreasing morbidity and mortality among these preterm babies. Furthermore prematurity is still being a burden in the clinical health system, but studies that were done concerning morbidity and mortality in preterm babies are not sufficient, in Rwanda there is shortfall of data in this field. For this reason, this study is the baseline and channel for progressive investigation in this area. Furthermore, no other similar research have been done in these hospitals, which automatically make this study to serve as reference for future similar studies

CHAPTER TWO

LITERATURE REVIEW

2.0 Introduction

In this chapter conceptual framework that guided this study was presented. The researcher has also reviewed empirical literature. It reflects different studies which have been done on factors of morbidity and mortality in preterm newborns. During the literature search, multiple electronic databases have been searched using keywords such as morbidity in premature "and" factors associated with morbidity in preterm neonates "and" mortality in preterm neonates "and" causes of morbidity in premature babies. The following databases were consulted via HINARI, PUBMED Central, CINAHL Google Scholar, Cochrane library. Elsevier lancet series called "Born too soon" were mostly searched. American Psychologists Association (APA) referencing style was used in the entire writing.

2.1 Conceptual framework

A conceptual model reveals a philosophical standpoint along with widely enlightening phenomena of concern (Burns and Grove, 2005).

The conceptual framework that guided this study was derived from a conceptual model of Vandresse regarding fetoinfant mortality (Vandresse, 2006). This study has two types of variables: dependent variables: preterm neonates' outcomes such as morbidities, length of stay, weight gain, mortality and independent variables as variables within Maternal characteristics, environment characteristics, behavioral characteristics, socio-economical characteristics, obstetrical characteristics, parental age characteristics, newborn characteristics and neonatal care characteristics.

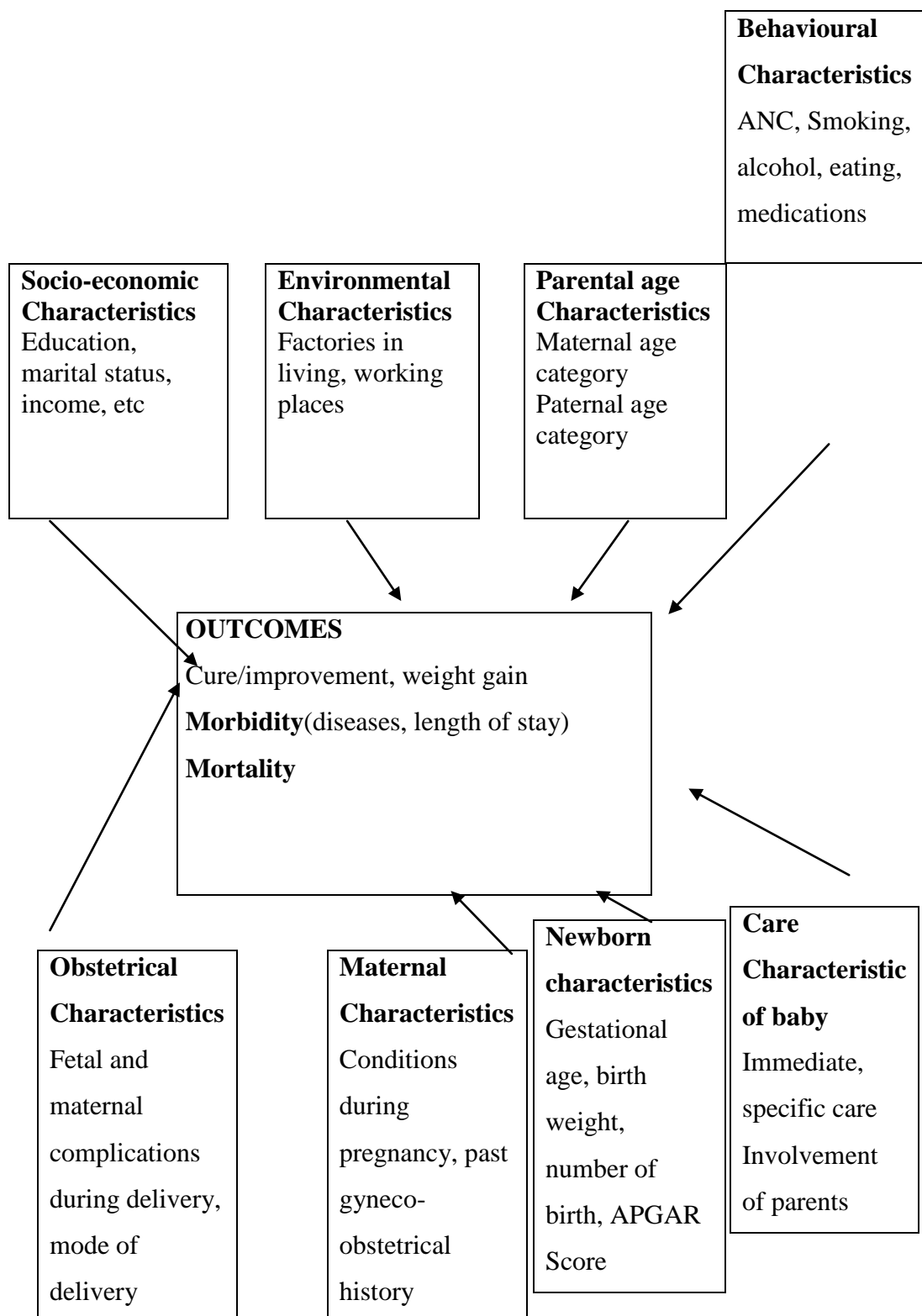


Figure 1: Factors of morbidity and mortality in preterm neonates: a conceptual model

Adapted and adjusted with permission from Vandresse (2006)

Vandresse (2006) classifies eight specific pathways as following:

1. The maternal characteristics:

Includes variables related to the general health status of the mother during pregnancy. The problems or conditions the mother had during pregnancy have an impact on her newborn babies. Research shows that a deficiency in folic acid and having diabetes are risk factors of congenital anomalies. Maternal fever, pre-eclampsia during pregnancy might also affect a newborn baby (Vandresse, 2006)

2. The fetal characteristics: Includes all the characteristics of the newborn. The fetal characteristics are the congenital anomalies which have a direct impact on fetal morbidity and mortality, and the physical features of the newborn. The physical features of the newborn include weight, sex, gestation duration, dysmaturity, multiple births, etc. Gestational age and relative weight at each gestational age are related to neonatal mortality. Some of the congenital anomalies influence the weight at birth or the gestation duration, the two most important physical characteristics of the newborn (Vandresse, 2006).

3. The obstetrical characteristics: include all variables linked to complications occurring during the delivery and the conditions of the delivery. The maternal complications and conditions in childbirth might both lead to neonatal morbidity and death. With congenital anomalies and preterm births, maternal complications during the delivery is a leading cause of neonatal morbidity and mortality (Vandresse, 2006)

4. Parents age: Vandresse, 2006 argues that maternal and paternal age can separately contribute to morbidity in newborns.

The natural course of becoming old is diverse for men and women where the risk is too high in case both parents have an advanced age. Different studies have shown an association between neonatal mortality and increased maternal age because of its direct impact on the maternal characteristics. Advanced maternal age also is the main

risk factor of infant death as well due to congenital anomalies such as Down's syndrome (Vandresse, 2006). Concerning paternal age, the Vandresse shows the link between paternal age and the quality of spermatozoa. There is a high risk of chromosome aberrations in older men over 40 years old, and this is related to genetic diseases such as Marfan Syndrome. Yet the outcome of paternal age on the physical characteristics of the newborn is controversially less documented (Vandresse, 2006)

5. The socioeconomic characteristics of the parents: include classical socioeconomic variables such as income, marital status, education level or occupation of the parents. Poor socio-economic conditions lead to unhealthy behaviors, exposure to stress and psychological reaction to stress which might consequently affect the child's characteristics at birth such as preterm delivery, low birth weight. The access to adequate medical care during and after the pregnancy might depend on couple's income (Vandresse, 2006).

6. The behavioral characteristics: Vandresse argues that these characteristics combine several behaviors of the parents during pregnancy which can affect the baby: smoking and drinking habits, nutrition, and depression among others. They also include attendance of prenatal care consultation (frequency and calendar). The pregnancy duration at first consultation is even more crucial than the number of consultations (Vandresse, 2006).

7. Environmental characteristics: including the chemical factors and occupational exposures gather the characteristics of the region of living or of working, such as pollution around a home or at work. Environmental pollution exposures significantly influence the risk of congenital anomalies. The transmission is through industrial pollution and food contamination (Vandresse, 2006). The relation between each variable is represented by an arrow indicating the causal relationship to the outcomes (Figure 1)

8. Newborn Care Characteristic

Those are usually cost-effective interventions from evidence-based care practices recommended by WHO to reduce morbidity and mortality in preterm neonates. These are immediate neonatal resuscitation after birth, thermal care to a newborn, baby feeding support, early detection and management of infections in neonates, cord care, basic respiratory support especially in preterm infants, administration of vitamin K and Tetracycline eye ointment to all neonates and immunization (National Perinatal Association, 2014).

2.2 Factors associated to morbidity and mortality among preterm neonates

The survival of preterm infants depends on the care given to them by their mother by the multi-professional team (midwife, pediatrician, an obstetrician and neonatal nurse) (Fraser et al., 2010). That care starts during the antenatal period, labour and birth, and continues until 28 days of life. For every preterm newborn baby, every minute counts. If there is any form of delay or a failure to provide adequate warmth after birth, plus lack of exclusive breastfeeding, hygiene, and resuscitation, the baby's condition can worsen quickly leading to mortality (Lawn et al., 2013) Kangaroo Mother Care (KMC) is cost-effectiveness method used to save lives of preterm neonates. This approach was introduced in the 1970s by a Colombian pediatrician, Edgar Rey, who sought it as an answer to incubator scarceness, high infection rates, and also rejection among preterm neonates in the hospital. Evidence on KMC reports that this method provides stable warmth, reduces morbidity and mortality, and facilitates breastfeeding. This simple approach, if used, can save approximately 450,000 premature neonates every year (Lawn et al., 2013). Antibiotics such as gentamicin have been approved to treat neonatal sepsis in premature babies but WHO (2015) states that their coverage level in low income countries remains extremely low.

Chlorhexidine use for cord care has been discovered to be effective in preventing neonatal sepsis but WHO has documented that its usage in lower income countries at a lower level. Death rates in preterm neonates have declined significantly since the introduction of antenatal steroid therapy and postnatal surfactant treatment and Continuous Positive Airway Pressure (CPAP) (Jo, 2014). The use of corticosteroids during premature labor reduce 50% of related respiratory complications in premature newborns and can reduce the risks of intraventricular hemorrhage (IVH) in premature babies as well as necrotizing enterocolitis in preterm newborns (Lawn et al., 2013). However, WHO claims that its implementation is still lacking especially in middle and lower income countries due the absence of this drug, or just lack of knowledge among health care providers.

It is important to involve family and providing health education to parents who have their babies in NICU. In the philosophy of neonatal care, both the baby and the family should be included (AWHONN, 2014). Therefore, a wide range of evidence argues that absence of contact between mother and her newborn becomes unconstructive to maternal identity. Otherwise, parents who have been participating in her newborns care during hospitalization get prepared and self-assurance to care their baby when discharged home. Therefore nurses are highly recommended to allow the mothers to be with their babies as much as possible and to participate in the care offered to their children (González et al., 2014).

Factors from baby which can be associated to morbidity and mortality are Low birth weight (LBW) contributes to approximately 65 % to 75 % of neonatal deaths. Gestational age and birth weight are highly associated, however. The notions of intrauterine growth retardation (IUGR) or small gestational age (SGA) have been consequently used to study the impact of weight independently of the gestation

duration. Moreover, a study that was done at the University of Texas showed that late preterm births are also associated with high increased newborn morbidities and deaths. However, morbidity decreased as gestational age increased (McIntire et al., 2008). Research done by Basso and Wilcox (2010) concludes that maternal factors that originate the preterm birth are associated with mortality in premature newborns. The authors argue that death in premature have different and many origins which can be immaturity itself and the causes by which have made that baby to be born too soon.

2.3. Outcomes in babies born preterm

Numerous preterm babies are prone to different conditions because their organs are immature hence suffer from other causes associated with the preterm birth itself (Basso and Wilcox, 2010). RDS (hyaline membrane disease) is a breathing condition that affects neonates predominantly those born six weeks before due date. It exclusively affects preterm infants and is highly associated with considerable morbidity and mortality in newborns. Different studies consider RDS as a primary cause of morbidity and mortality in babies born too soon and is associated with immature lungs with a lack of surfactant (Kawaza et al., 2014; Jo, 2014). Worldwide, above 50% deaths, of premature babies under 31 weeks of gestational age stem from the RDS where several of them develop this condition and decline considerably by 36 weeks. The studies also have documented that 80% cases of RDS are linked to both neonatal pneumonia plus neonatal sepsis (Kawaza et al., 2014). The common risk is immature lungs with deprivation of surfactant, and this makes lungs collapse further magnifying more force to expand. Maternal factors can be associated to RDS; maternal diabetes, elective caesarean section (C/s) where the labour-associated catecholamine and steroid surge do not occur thus causing decreased pulmonary surfactant release. However, studies claim that high morbidity of respiratory distress

syndrome in a baby born by elective cesarean delivery (Ramachandrapa, 2008). Also, birth asphyxia also reduces surfactant synthesis and causes leakage of protein and fluid into the alveolar space. The sex of the baby can be a risk factor where the male is more exposed than female, and maternal conditions during pregnancy are also a risk factor (Jo, 2014).

Intraventricular hemorrhage (IVH) is a condition that mainly affects preterm newborns. It is described by hemorrhage of the subependymal germinal matrix which is fragile (Khalessi et al., 2013). IVH is a major source of morbidity in preterm babies where up to 50% have been affected. However, with the recent use of antenatal steroids, this number is decreasing (Ballabh, 2010; Khalessi et al., 2013). Studies have detected that preterm babies with low birth weight are more likely to be exposed to this condition (LBW). Khalessi, 2013 and other researchers confirmed that male children are more exposed than female because most of their white blood cells are defenseless against preterm consequences. Also male baby organs appear to be weaker and unable to withstand adverse complications of prematurity. Survival of the baby in such circumstances becomes difficult and male baby mortality rises. Also, this research has been not able to show if the mode of delivery can be the risk factor IVH or not. There are controversies concerning the source of IVH (Khalessi et al., 2013; Pishva et al., 2012).

2.4 WHO recommendations and evidence-based practices to prevent morbidity and mortality in preterm neonates

A report from WHO (2015) has documented that most premature births (84%) occurred at 32 weeks of gestation, and argue that the morbidity would not be high, and the mortality can be prevented if the correct measures are put into place. The experts recommend family planning by avoiding pregnancy before 18 and after 35

years old as this can reduce preterm birth, avoiding unnecessary caesarean sections before 39 completed weeks of gestation to increase the prevention of infections. Use of antibiotics as methods which should help in preterm babies and mothers' survival is recommended (UNICEF, 2014). The studies came up with evidence-based recommendations to improve the outcome in babies. The recommendations are family planning; prevention and management of sexually transmitted infections (STIs); use of Long Lasting Insecticide Treated Nets (LLINs) and intermittent preventive treatment for malaria, identification and treatment of pre-eclampsia, and reduction of physical workload (Dean et al. 2013). The measures to tackle on issue of morbidity and mortality in neonates starts by preconception cares primarily family planning, teenager-friendly services, sexually transmitted infections hindrance, nourishment, and schooling promotion for girls. Antenatal care includes screening mothers of chronic diseases, as well as the advocacy of safety in daily activities. Their aim is to increase direct attention to the high-risk mothers. Another focus is the policy of health support like avoidance of exhaustive occupations and quitting smoking. Managing preterm labor comprises the use of tocolytics, corticoids administration, and antibiotics use if pre-labor premature rupture of membranes occurs (PPROM). For care of the preterm babies, WHO recommends resuscitation, Kangaroo Mother Care, breastfeeding, Chlorhexidine use for the cord care, the needed lively additional care depend on the baby's conditions or complications (WHO, 2015)

2.5 Knowledge gap, global initiative and new ongoing research on morbidity and mortality among preterm babies

Recently in the year 2014, prematurity has dramatically marked history by coming on 1st range among the causes responsible for killing children under the age of five. From that time, four major research initiatives have taken place with the aim of studying

about the real cause of preterm labor. Collaboration and network of global agencies together United States Government and public/private international and national professional have put an effort to create an initiative for reducing neonatal morbidity and mortality and is currently working in the three highest burden countries such as Ethiopia, India, and Nigeria. These have been created to support professionals in the progression of established interventions. The agencies involved are: the Global Coalition to Advance Preterm Birth Research (GCAPR), the March of Dimes, the University of California at San Francisco's (UCSF) Preterm Birth Initiative (PTBI), International Federation of Gynecology and Obstetrics (FIGO), finally the Global Alliance to Prevent Prematurity and Stillbirth (GAPPS). Furthermore, a public-private partnership (PPP) is the United States pediatric, Obstetricians/Gynecologists, and midwifery membership organizations (UNICEF, 2014)

2.6 Conclusion

From the literature reviewed above, there is still lack of researches that link factors from the whole process of before conception, during pregnancy, birth and after birth to the outcomes in preterm babies since many researchers merely highlight relationship between some factors associated to the outcomes among preterm birth. Therefore the investigator intends to cover that gap by conducting this study.

CHAPTER THREE

METHODOLOGY

3.0 Introduction

In this chapter methods were described, these include also study setting, study population, sample size, sampling techniques, research tools and technique, ethical considerations, limitations of the study, data management and analysis and presentation of findings.

3.1 Research design

Burns and Grove (2005) term a research design as a plan followed by the investigator to achieve the intended goal. Well-designed research is apt to enhance the strength of results (Jurs, 2005)

The design was cross-sectional descriptive. Burns and Grove (2005) argue that this model is used to examine groups of subjects in a variety of stages of development simultaneously with the target to describe changes in the phenomenon crossways stages. Descriptive research used consistently along with applied epidemiologic meaning is the basis for discovering the problems of premature babies (WHO, 2015). The descriptive design is used for identification of a problem, and it tends to enable the researcher to gain more information about the characteristics. It also describes the occurrence as it is, and tends to yield a new knowledge. Also, apart from being used as a basis for further researches, it is also used when there is little information (Mendes, 2007; Burns and Grove 2005). In this study, the quantitative approach was used.

3. 2 Study area and settings

This study was conducted at two NICU of two hospitals located in Kigali the capital city of Rwanda: University Teaching Hospital of Kigali mainly known as CHUK and Muhima hospital. The University Teaching Hospital of Kigali is the largest public teaching referral hospital in Rwanda. Its monthly average of neonates' admission in NICU is 50, whereby three-quarters of them have been born preterm. CHUK has a catchment area of 29 district hospitals. Within this hospital, there are 17 clinical departments. Each department is tasked with two or three services. In pediatrics department, there are general pediatrics and NICU. The health care providers working in NICU are two consultant pediatricians, three permanent pediatrician residents, 13 nurses and one midwife (12 of them have advanced diploma, and two are enrolled nurses). In every twelve-hour shift, three nurses should be on duty.

Concerning equipment, there are ten incubators, nine cots/cribs, three KMC beds and four radiant warmers. The bed occupancy is almost always 100%. Regarding Muhima hospital which has been in operation since 2001, the hospital has a catchment area of 302,778 populations from ten health centers. Muhima hospital is a primarily a maternal-child Hospital (MOH, 2015). Its monthly birth rate is 630 babies while the annual birth rate is 7563 babies. The average monthly number of admission in NICU is 125 where preterm neonates are 80. The health care providers are one consultant pediatrician, non-permanent registrar doctors, six nurses and five midwives (all have diploma level credentials). Working shift is 12 hours where three or four nurses should be on duty. Concerning equipment, there are 39 incubators, ten cots/cribs, 8 KMC beds and ten radiant warmers. Among routine care given to newborns after birth include immediate neonatal care such as administration of Vitamin K, Tetracycline Eye Ointment. Neonatal resuscitation, feeding. In NICU, there is provision of warmth,

oxygenotherapy, Intravenous fluid administration and medications administration according to specific baby's condition, health education to the parents. Actually mothers come for delivery after receiving antenatal care which include administration of albendazole, folic acid, tetanus toxoid immunization, provision of bednets, treatment of any existing conditions and health education.

3.3 Study Population

The study comprised of premature babies who were admitted during the study period of 2 months where "prematurity" was a medical diagnosis on admission to the NICU.

3.4 Sample size determination

The sample size was based on sample size calculation for logistic regression based on the work of Peduzzi et al (1996) which suggested the following guideline for the minimum number of cases to include in a study as $N = 10 \times k / p$. Where K is, the number of covariates and p is the proportion of cases in the population.

Then $10 \times 8 / 0.64 = 125$

P-Prevalence of morbidity among preterm neonates was based on the research that was done by Zamudio et al (2013) because no data concerning preterm deliveries was available in Rwanda.

3.5 Sampling methods

Burns and Grove (2005) define sampling as picking representative elements from the whole population which moreover possesses similar characteristics of interest. All consecutive preterm neonates (born before 37 completed weeks of gestation) admitted to two NICUs during the period of the study and were included in the study over a period of 2 months in each of the hospitals. The sampling process was beneficial in taking full advantage of a wide representation as well as reduction of biases. The

identity of the mothers was taken as a source of information, and each was selected based on their babies' enrollment.

3.5.1 Inclusion Criteria

Preterm newborns with gestational age less than 37 weeks and have less or equal to 28 days of life where prematurity are the main reason for medical diagnosis for admission.

Preterm newborns who were born in the two hospitals of interest (CHUK and Muhima), and admitted in NICU during the period of study.

3.5.2 Exclusion Criteria

Baby whose mothers were very sick and unable to participate or mother deceased

Babies whose gestational age was not clear

3.6 Data collection

3.6.1 Data Collection Tools

The tools were established based on all variables to be measured. The best way to interview people is to address them in their language. The questionnaire was designed in English then was translated to Kinyarwanda which is a language better understood by most of the participants. Also, a reverse translation to English was undertaken for checking originality.

A data extraction checklist was used to extract information from files concerning maternal health during pregnancy and childbirth, neonatal health and care received according to evidence-based practices from WHO guidelines was used to extract data from files (hospital files for preterm neonates and their mothers then antenatal booklets/cards).

An in-person interviewer-administered questionnaire developed according to concepts from the conceptual model was used and filled by the researcher.

3.6.2 Data Collection Process

After obtaining both approvals from Institutional Research Ethical Committee (IREC) and Rwanda Institutional Research Board (IRB), and permissions from research committees of CHUK and Muhima hospitals, the principal investigator visited the two NICUs and Maternity services separately but on the same day for each. The researcher described briefly about the study to the Unit managers; the investigator got the permission from them have been shown the Unit services to get familiar with them. The principal investigator carried out the pilot study at CHUK. After making the required amendments, the principal investigator came to train research assistance on the field (at Muhima Hospital). Research assistant has been trained concerning the confidentiality and privacy, and the whole process of collecting data.

The investigators started by identifying only preterm neonates who were admitted the first day of data collection; this was to prevent survivorship bias. The researcher listed appellation of preterm neonates from NICU by controlling the confounders which were mentioned in exclusion criteria and these appellation are always baby plus the mother's names which facilitated the research to identify their corresponding mother quickly from the maternity ward. Informed consent from respective mothers was obtained before collecting data. To reach the records with minimum derangement of care, information from the files was retrieved when they were not being used by health workers.

The mothers were asked by investigators of the suitable time to have in-person interviewing administered questionnaire, and this was filled by a researcher to decrease a burden of writing because some of them they might have undergone some procedures that interfered with handwriting ability. Briefly, in order to make the work

easy and straightforward, the process followed to fill each research tool (Appendix 3) was identification/recruitment of the participants from NICU registry, getting consent form from their respective mothers as well as getting information from them and their maternity files/antenatal card, retrieving data of preterm neonates in NICU file for the first time then at time of discharge, all remaining data including the outcomes was again documented for the second time at the exit of the baby from NICU in order to put an end to each questionnaire.

The initial of mother's name plus serial number have been used as a code on research instrument to recognize each preterm neonate's data, and this procedure was the same in both hospitals. The information that was extracted was about mothers' socio-demographic characteristics, health during pregnancy, information about delivery, care of the baby, topics taught to parents, etc. Clinical outcomes for each preterm were documented in the relevant checklist. In this study, no incentive has been offered.

The principal researcher was based at CHUK while the research assistant was based at Muhima Hospital; the principal investigator has been supervising the research assistant at the field twice a week plus by receiving a daily report.

3.6.3 Pilot Study

A pilot is a pre-test of research, and if well drawn and carried out, it can give an idea about the best study progression along with a prediction of outcomes (Burns and Grove, 2005).

The pilot study was conducted in CHUK before the beginning of a study, and ten preterm neonates admitted to NICU were recruited, and the research tool has been used to test and to detect for inconsistencies, sensitivity as well as estimation of needed time. These participants were not included in the final investigation.

3.7 Validity and Reliability

Validity refers to the accuracy of the study. Burns and Grove (2005) define the validity of research instrument as the strength of the extent to which that instrument measures what is purported to measure. Within this study, in the data collection tools content and construct validity was ensured based on study objectives and concepts in the conceptual framework to determine whether they appraise all the elements to be scrutinized. Empirical literature review supported by the conceptual model has eliminated potential confounders. WHO guidelines were also checked for updated recommendations about maternal and newborn care. Besides, the data collection tools have been reviewed by supervisors of this study.

To maximize the representatives, and ensure external validity diminishes biases, the study included all consecutive participants who met the inclusion criteria during the period of study. This could allow for generalization of the study findings in similar situations. The usage of a different source of information such as mothers of respective preterm neonates together with comprehensive hospital records files in study design has also increased validity to this study. Several variables have been assessed for their roles as confounders.

Burns and Grove (2005) define reliability as a measure of the consistency, stability of results obtained by using a particular instrument. As a means of testing reliability, the internal coherence of the research tool was ascertained by use of a test method before. Therefore ten preterm neonates arbitrary have been included for checking ambiguous, unnecessary as well as sensitive questions. Intra-observer and inter-observer reliability have been done on files records to maximize reliability.

3.8 Ethical considerations

Ethical approvals were sought from the Institutional Research and Ethical Committee (IREC) of Moi University, Eldoret, and the Institutional Review Board (IRB) of College of Medicine and Health Sciences (CMHS), Kigali. The supervisor within the country was officially available over the period of data collection. Permission was sought from the research committees of CHUK and Muhima hospital. Autonomy, confidentiality, anonymity, privacy, beneficence/non-maleficence and justice principles were assured. To ensure confidentiality in this study, the research tool which has been used for collecting data did not bear participants' identification details but just a code for purposes of data entry.

Data from the study was used for the purpose of completing this study; crude data was guarded confidentially in a locked place during the process of analysis and report writing after which it was kept in room under the key for a period of 7 years at the end of which they have to be disposed of in fire. Analyzed data was saved in computer files that are protected by a password that was only be known by the investigator.

3.8.1 Right to autonomy

The researchers have an obligation to respect the autonomy of the patient. For this research, the investigator fully explained to mothers of babies, the purpose, the process, the benefits/inconveniences of research as well as their right and freedom to withdraw. Then a signed written consent form was obtained for those who want their babies to participate.

3.8.2 Right to privacy

The researchers have an obligation to ensure that participants' privacy is maintained throughout the study period. This principle has been ensured by the omission of the participant's names on the research tool. Identification numbers which have been put

on the record review checklists were known only by the principal investigator and research assistant that had information of names and identification numbers.

3.8.3 Right to anonymity and confidentiality

The tools for collecting data did not hold participants' names but only a code for the reason of data entry. Crude data were guarded confidentially in a locked place during the process of analysis. Thereafter have to be kept in a room under the key for five years at the end of which they have to be disposed of into the fire. Analyzed data were saved in a computer with a password only known by the investigator.

3.9 Data management

The collected data were coded and entered into a Personal computer by using Statistical Packages for Social Scientists (SPSS) software version 20. The data were double entered by the principal investigator to minimize errors. After entry, the data were cleaned by scrutinizing the forms for inconsistencies, errors, and omissions. The information was stored and protected for their safeguard. Therefore was kept in a file code that had a password only known by the investigator and cannot be easily guessed. The antivirus, versions of all software in the computer was kept updated, and while connected to the internet the investigator was using a firewall. The data have been saved in a flash drive for backup in case the primary storage device destroyed.

3.10 Data analysis

Burns and Grove (2005) state that data analysis is carried out to reduce arrange, also, to give meaning to the data.

Socio-demographic data were summarized using descriptive statistics such as frequencies and percentages. Statistical test such as Chi-square was used to assess the relationship between categorical independent variables and outcomes in preterm babies in cases where the cell count was below five the Fishers' exact test was used.

Logistic regression was used to assess factors associated with neonatal outcome. Data were analyzed using STATA version 13 (Stata Corp). The level of significance was set at 0.05

Data was presented using pie charts, bar graphs and frequency, and percentage tables.

3.11. Limitations

To obtain the research approval from 2 Institutional Review Boards (IRBs) from two countries has taken longer and interfered with the work plan.

The study was completely not able to measure outcome regarding weight gain because this was not consistently taken at one of these hospitals especially at discharge.

Furthermore, the scope of the study was limited in a manner that it was only to determine factors which may affect the morbidity and mortality in preterm neonates while these are a complexity of interconnectedness of several dynamic characteristics. Hence this study was not able to establish a cause-effect because of the descriptive method. Also, the study was not able to compute the survival rate after a neonatal period because the investigator captured only the hospitalized cases and covered only the hospitalized period within the period of study.

The study sample was relatively small, and some predictors had small numbers. Therefore the results could not be generalized to other population apart from the population of these hospitals as this study was conducted only in the two major hospitals with a high level of neonatal care. Thus findings may not be generalizable to all preterm neonates in Rwanda.

3.12 Dissemination of findings

The findings from this study will be published in referred journal, will be presented in conferences and final copy will be a repository of library.

3.13 Summary

This study has used a single method research paradigm by the quantitative approach and descriptive design. The research area was two major hospitals in Rwanda. The tools and procedure of data collection were highlighted herein.

CHAPTER FOUR

RESULTS

4.0 Introduction

This chapter presents the analysis of findings. A total of 125 preterm neonates were included, of which 78 were from Muhima hospital while 47 were from CHUK. The findings portray various factors, and outcomes of interest and relationship between them.

4.1. Factors associated with morbidity and mortality in preterm neonates

4.1.1. Characteristics of preterm baby

The findings for characteristics of preterm neonates as they were retrieved from the hospitals records are displayed in table 4.1.

Table 1. Characteristics of preterm babies

Variable	Frequencies	Percentage
NOB		
Single	98.0	78.4
Twin	27.0	21.6
Gender		
Female	58.0	46.4
Male	67.0	53.6
APGAR		
6 and below	44.0	35.2
7 and above	81.0	64.8
Resuscitation		
No	61.0	48.8
Yes	64.0	51.2
GA		
24-28	12	9.6
29-33	64	51.2
34-36	49	39.2
BW		
<1000	7	5.6
1000-1500	28	22.4
1501-2499	84	67.2
2400-4000	6	4.8
BW to GA		
AGA	83	66.4
LGA	18	14.4
SGA	24	19.2

Source: Primary data from CHUK and Muhima Hospital, 2016

Among 125 preterm neonates, 27 (21.6%) were twins, and the majority were male 67 (53.6%). At birth, 81 of the neonates (64.8%) had APGAR score greater or equals to seven out of ten, (64.8%) had received some resuscitation. Most of newborns 64

(51.20%) were moderate preterm, with majority 84 (67.20%) having a low birth weight and a big proportion having birth weight appropriate for their gestational age 83 (66.40%).

4.1.1.1 Characteristics of the baby versus mortality

The cross-tabulation have been done between characteristics of baby and mortality.

Table 2. Characteristics of the baby versus mortality

	Discharge reason		Total	% of mortality
	Cured/improved	Dead		
Status of the baby				
Single	81	17	98	17.3
Twin	18	9	27	33.3
BW categories				
<1000	1	6	7	85.7
1000-1500	13	15	28	53.5
1501-2499	79	5	84	5.9
2500-4000	6	0	6	0
GA in completed weeks				
24-28	3	9	12	75
29-33	48	16	64	25
34-36	48	1	49	2
Gender				
Male	50	17	67	25.3
Female	49	9	48	15.5

Source: Secondary data from CHUK and Muhima hospital, 2016

Among babies born from multiple births, a rate of 33.3% had died whereas the mortality rate was 17.3% among those who were singletons. Mortality rate was respectively in severe preterm babies 75%, moderate preterm babies 25%, and late preterm babies 2%. Mortality according to birth-weight categories was respectively 85.7% in babies with extremely LBW, 53.5% in babies with VLBW, 5.9% in those with LBW and none of the baby with normal BW died. The deaths occurred more in males where 25.3% of them died. In females, the mortality rate was 15.5%.

4.1.1.2 Birth weight versus RDS

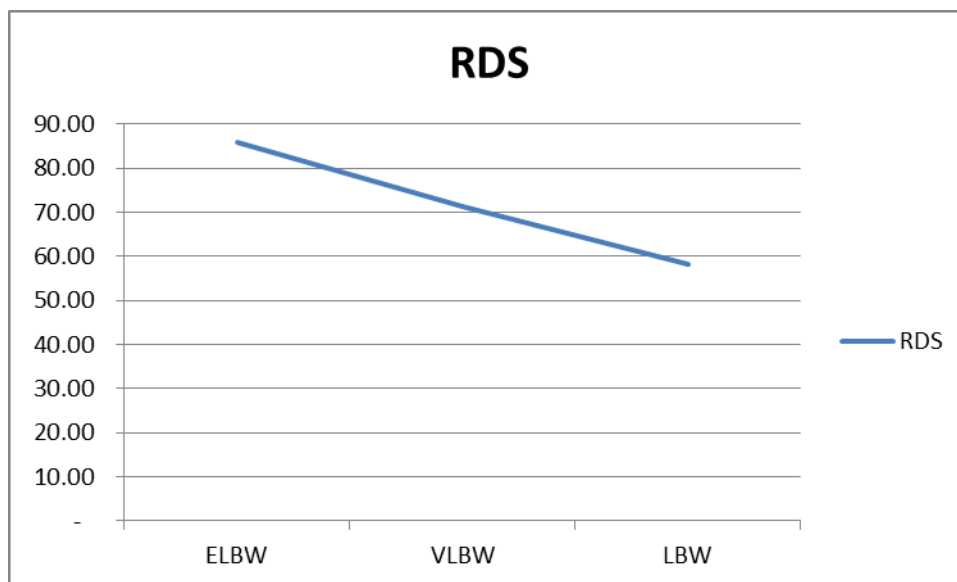


Figure 2. Birth weight versus RDS

Source: Secondary data from NICU files, 2016

RDS rate was increased as birth weight decreased. RDS developed as follows; ELBW babies (85.7%) VLBW (71.4%), LBW (58.3%)

4.1.1.3 Birth weight versus neonatal asphyxia

This figure shows relationship between BW and asphyxia

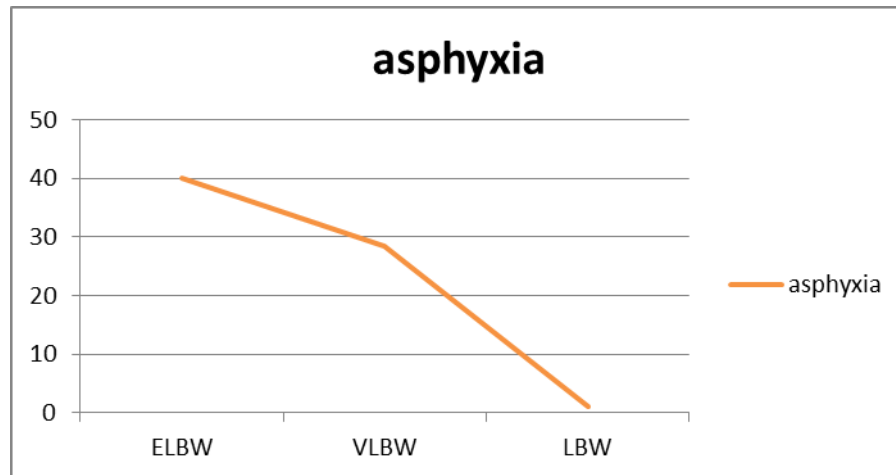


Figure 3. Birth weight versus neonatal asphyxia

Source: Secondary data from NICU records, 2016

Neonatal asphyxia was increased as the BW decreased where it was (40%) in ELBW, (28.5%) in VLBW, and (1.19) in LBW.

4.1.1.4. Gestational age versus RDS

Figure below shows relationship between gestational age with RDS

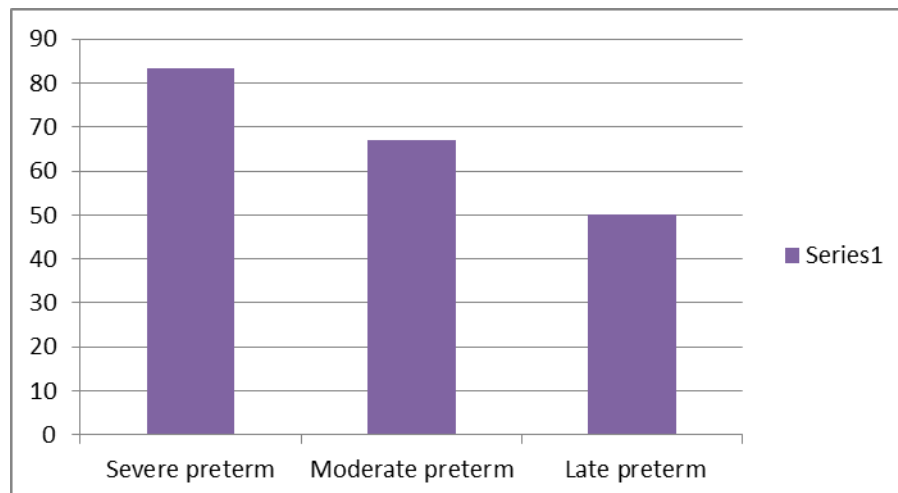


Figure 4. Gestational age versus RDS

Source: Secondary data from NICU files, 2016

RDS rate was high as gestational age decreased. In severe prematurity (83.3%), moderate prematurity (67.1%) and 50% in late prematurity

4.1.1.5 Gestational age versus neonatal asphyxia

This shows Gestational age vis a vis neonatal asphyxia

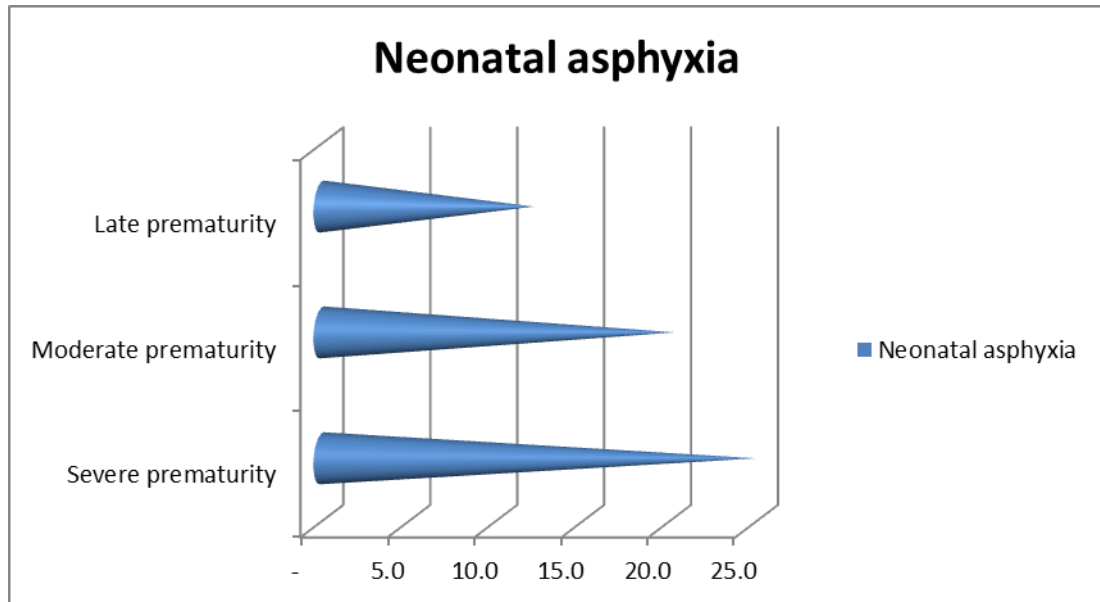


Figure 5. Gestational age versus neonatal asphyxia

Source: Secondary data from NICU records files, 2016

Neonatal asphyxia rate was also high as the gestational age decreased and was respectively (25%), (20.3%) and (12.2%) in severe, moderate and late preterm neonates. Mortality rate was 20.8%

4.1.2. Care characteristics in preterm neonates

As summarized in table below, findings are for types of care received by preterm neonates during the whole period of their admission in NICU.

Table 3. Care characteristics in preterm neonates

Variable	Frequency	Percentage
VitK/ TEO		
Both Given	100	80
VitK given only	10	8
None given at all	15	12
Warmth provision considering one method per individual		
Radiant warmer	103	82.4
Incubator	81	64.8
Crib	31	24.8
KMC		
Feeding	33	26.4
Breast milk only	103	82.4
BM +FM	12	9.6
FM only	10	8
Route of feeding only		
Oral/cup	69	55.2
NGT	56	44.8
Cord		
Not done	125	100
Immunization		
Not done	125	100
Mother participation		
At least every 3 hrs	94	75.2
Fewer than every 3 hrs	31	24.8
Health Education		
Hygiene	76	60.8
Baby feeding	79	63.2
Keeping baby warm	34	27.2
Not at all	38	30.4

Source: Secondary data from hospitals and Primary data from mothers of preterm babies

At birth, 15 (12%) of the neonates had not received both Vitamin K and tetracycline eye ointment. Methods of warmth provision included the use of radiant warmer, incubator, cribs and cots (wrapped in warm linen) and Kangaroo Mother Care. Therefore, neonates had received more than one mode of warmth provision. The

majority 103 (82.4%) had received radiant warmer with very few reporting use of crib 31(24.8%). Regarding feeding, most of the neonates 103(82.4%) were fed on breast milk with the main route of feeding being through the use of oral/cup 69(55%). None of the neonates received cord care with chlorhexidine or immunization. Seventy-five percent of the mothers reported having participated in the care of their newborn baby at least every three hours. However, 38 (30.4%) of these mothers did not receive any health education from nurses while (32%) reported having been educated on hygiene and breastfeeding.

Figure 6 shows the care provided in the NICU from the plot we observe that almost all the neonates 114(92%) received Intravenous fluid with very few neonates receiving nevirapine 14(11.2%)

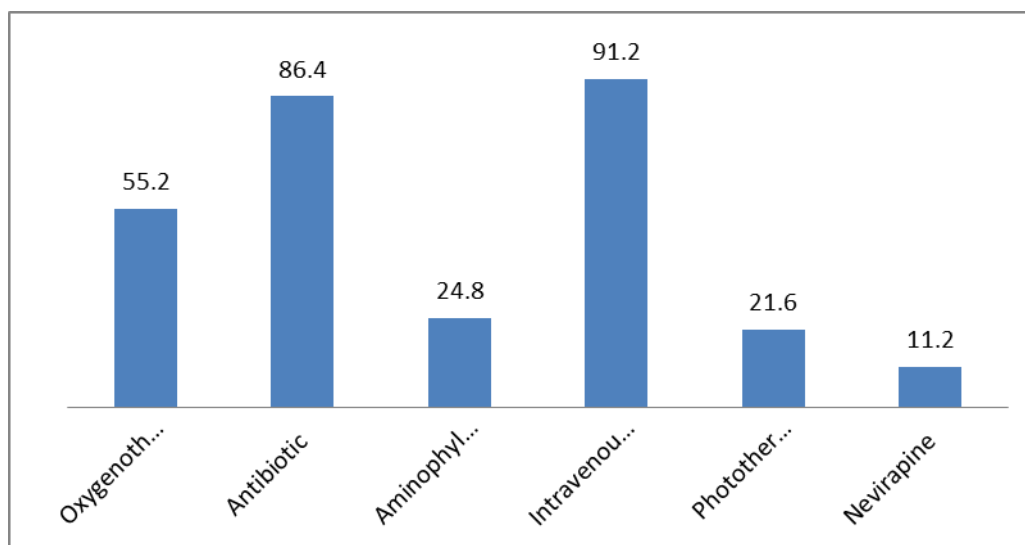


Figure 6: Care characteristics in preterm neonates

Source: Secondary data from hospitals, 2016

4.1.3 Parental age characteristics

The figure below portrays age of both mother and father of preterm babies

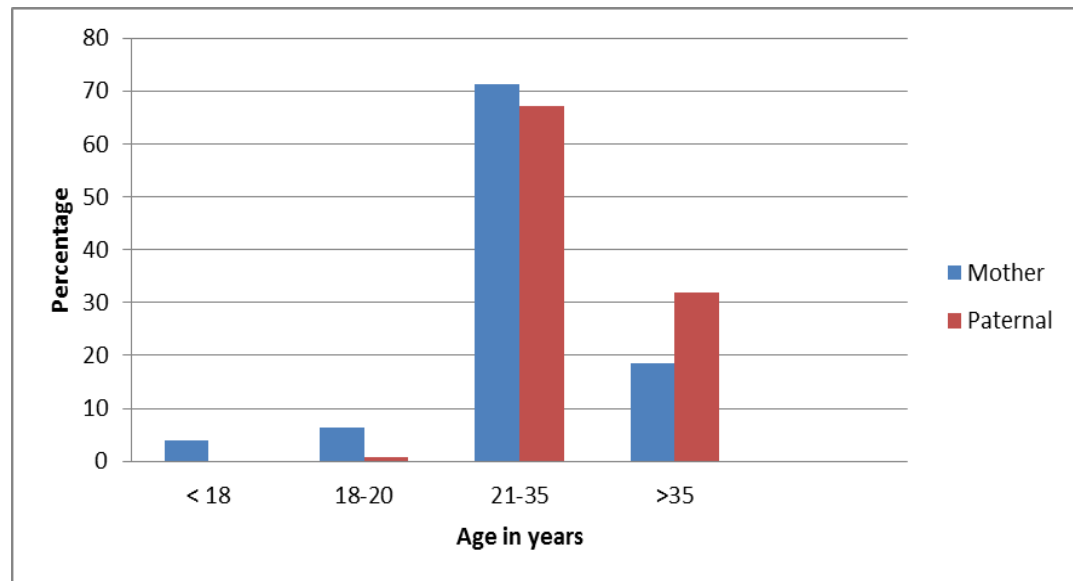


Figure 7. Parental age characteristics

Source: Primary data from mothers of preterm neonates

Overall 89 (71.2%) of mothers and 84 (67.2%) of fathers were aged between 21-35 years with a small proportion aged below 20 years.

4.1.4 .Mother's Socio-economic characteristics

As shown by table below, these are socio-economic of mothers of preterm neonates.

The findings were obtained by interviewer administered questionnaire to the mothers.

Table 4. Mother's Socio-economic characteristics

Characteristics	Frequency	%
Education level		
No level of education	15	12
Primary	64	51.2
Secondary	42	33.6
Tertiary	4	3.2
Marital status		
Cohabitation	60	48
Common-law marriage	48	38.4
Single	17	13.6
Occupation		
Casual work	53	42.4
Employed	8	6.4
Housewife	48	38.4
Self-employed	11	8.8
Student	5	4
Income		
<50,000	59	47.2
50,000-100,000	22	17.6
100,000-200,000	34	27.2
200,000-500,000	8	6.4
500,000-1,000,000	2	1.6

Source: Primary data from mothers of preterm neonates

Table 4 shows that majority of mothers 64 (51.2%) had a primary level education while 60 (48%) were living in cohabitation marital status. A large proportion of the mothers were casual workers 53(42.4%) with majority of them (47.2%) having a family income of under fifty thousand Rwandan francs (approximately 62.5\$) per month.

4.1.5 Environmental characteristics

During the current pregnancy 25 (20%) of mothers reported to have been living or working around the factories/industries.

4.1.6 Maternal characteristics

The findings below describe maternal reproductive history during pregnancy and problems during this pregnancy.

Table 5 Obstetrical characteristics

Characteristics	Frequency	%
Gravida		
G1	51	40.8
G2	23	18.4
G3	25	20
G4	13	10.4
G5	10	8
More than 5	3	2.4
Plan of pregnancy		
Planned but not attend preconception services	65	52
Unplanned and unaccepted	16	12.8
Planned and attended pre-conception services	2	1.6
Unplanned and accepted	42	33.6
Problems during pregnancy		
Malaria	44	35.2
Anaemia	29	23.2
UTI/Vaginal infections	55	44
HIV	14	11.2
Pre-eclampsia	24	19.2
Periodontal Infections	22	17.6
Psychological harassment/domestic abuse	27	21.6

Source: Secondary and primary data

The majority of mothers 51(40.8%) were primigravida, whereas 58 (56.4%) of the pregnancies were unplanned. Almost all mothers 123 (98.4%) did not attend preconception care while 16(12.8%) of the pregnancies were unplanned and unaccepted. Concerning problems of morbidities during the current pregnancy. The most prevalent conditions were: UTI/vaginal infections 55(44%), malaria 44(35.2%), anemia 29(23.2%), pre-eclampsia (19.2%), periodontal infections 22(17.6%) and HIV 14(11.2%)

4.1.6.1 Maternal morbidity versus mortality

The table below is to compare maternal conditions during pregnancy vis a vis mortality in their preterm babies.

Table 6. Maternal morbidity versus mortality

Maternal conditions during pregnancy	Discharge reason		Total	% of morbidity
	Cured/Improved	Dead		
Malaria				
Yes	36	8	44	18.1
No	63	18	81	22.2
Anemia				
Yes	28	1	29	3.4
No	71	25	96	26
UTIS				
Yes	45	10	55	18.1
No	54	16	70	22.8
HIV				
Yes	12	2	14	14.2
No	87	24	111	21.6
Pre-eclampsia				
yes	18	6	25	25
No	81	20	101	19.8

Source: Secondary data from NICU records files of preterm babies

Among babies born from mothers with malaria during pregnancy (18.2%) died compared to (22.2%) of babies died and were born from mothers without malaria. Mortality was high in babies born from mothers who did not have anemia during pregnancy (26%) compared to (3.4%) of mortality among babies born from mothers with anemia during pregnancy. Likewise neonatal mortality rate was high in babies born from mothers without UTI (22.8%) compared to mortality in babies born from mothers with UTI during pregnancy (18.1%). Mortality was also high in babies born from mothers without HIV(21.6%) compared to those born from mothers with HIV(14.2%). Contrary mortality rate was high in baby born from mothers with eclampsia (25%) compared to those from mothers who did not have it(19.8%).

4.1.6.2. UTI from mothers versus neonatal sepsis

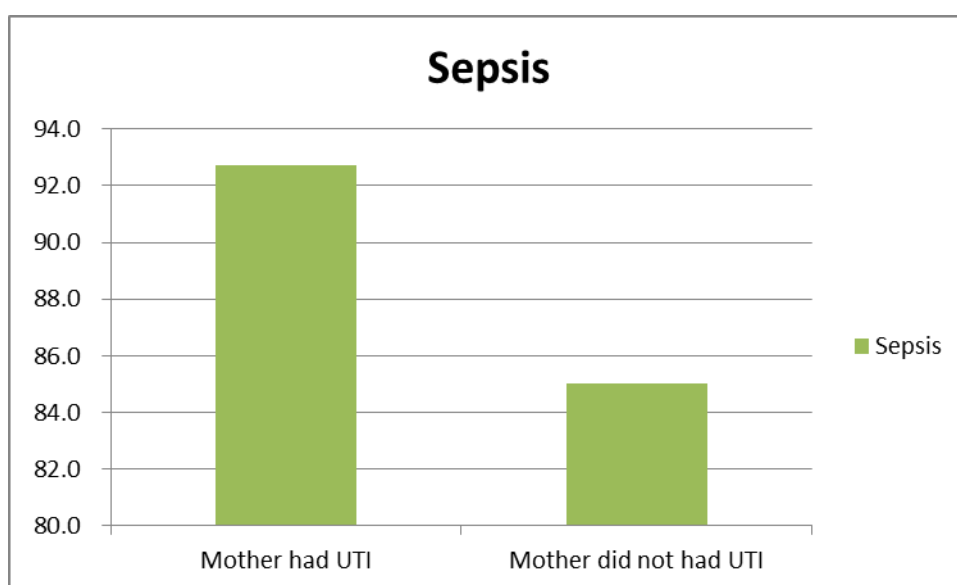


Figure 8. UTI from mothers versus neonatal sepsis

Source: Secondary data from maternity and NICU records, 2016

Neonatal sepsis was more prevalent in babies whose mother had UTI during pregnancy (92.7%) than the mothers who did not have UTI (85%)

4.1.7 Behavioral characteristics

The findings below indicate behavior of mothers during pregnancy which can affect health of the baby.

Table 4.7. Behavioral characteristics

Behavior of mother during pregnancy	Frequency	Percentage
Smoking, alcohol		
Drinking alcohol and passive smoking	15	12
Drinking alcohol in this pregnancy	15	12
None of the above	58	46.4
Passive smoking in this pregnancy	37	29.6
Pica		
No	117	93.6
Yes	8	6.4
Medication		
Both traditional and pharmaceutical	4	3.2
None	45	36
Pharmaceutical medications	63	50.4
Traditional medication	13	10.4
Food		
Once /day	20	16
2 times/ day	48	38.4
3 time/day	50	40
More than 3	7	5.6
ANC Visits		
1 ANC and start before 8 weeks, folic acid given	1	0.8
1 ANC, start after 8 weeks	23	18.4
2-3 ANC, start after 8 weeks	72	57.6
ANC 2-3 start before 8 weeks, folic acid given	12	9.6
4 ANC, start after 8 weeks	2	1.6
Above 4 ANC, start before 8 weeks, folic acid	2	1.6

given		
Above 4 ANC, start after 8 weeks	6	4.8
None	7	5.6
ANC		
All	25	20
Use of bednet during pregnancy	2	1.6
Deworming, folic acid	4	3.2
Folic acid	4	3.2
Folic acid, bednet	4	3.2
None	10	8
Updated immunization	7	5.6
Updated immunization, Deworming and	8	6.4
treated bednet		
Immunization and bednet	1	0.8
Immunization and deworming	3	2.4
Immunization and folic acid	22	17.6
Immunization, folic acid and deworming	30	24
Immunization, folic acid and treated bednet	5	4

Source: Primary and secondary data

The majority of the mothers 67(53.60 %) had either drunk alcohol or were secondary smokers during pregnancy while 8 (6.4%) had eaten non nutritious foods like soil. The majority of mothers 67 (53.6 %) had taken pharmaceutical medications while 17(13.6%) had taken traditional medications. Only 7 (5.6%) of the parents were reported to have eaten more than three meals per day during pregnancy. Among mothers who attend ANC, 124 (99.2%) started ANC visit after eight weeks of gestation, with most of them 72 (57.6%) having attended two to three ANC visits. Those who did not attend any ANC visits were 7 (5.6%). Concerning care given during ANC, the majority 30 (24%) had been offered three out four services together (up to date immunization, folic acid and deworming).Only 16 (20%) had gotten (LLINs) while 10(8%) did not get anything.

4.1.8 Obstetrical characteristics

The table below showing the complications and the eventual treatment received experienced by mothers during labor, delivery as well as mode of delivery.

Table 8. Obstetrical characteristics

Variable	Frequency	%
Labour complications		
PPROM	36	28.8
Fever of mother	9	7.2
Fetal distress	17	13.6
Treatment separately		
Antibiotics	53	42.4
Corticosteroids	29	23.2
MgSO ₄	19	15.2
Delivery		
C/S	47	37.60
SVD	78	62.40

Source: Secondary data from maternity record files, 2016

A proportion of 36 (28.8 %) mothers had PPRM, fetal distress was 17(13.6%) while 9 (7.2%) of mothers had fever. Among mothers who received treatment during labor, the majority had received antibiotics 53(42.4%), corticosteroids 29(23.2%) and MgSO₄ 19 (15.2%).The rate of C/s was 37.6%.

4.1.8.1. PPROM versus neonatal Sepsis

The figure below shows Neonatal sepsis rate vis a vis PPROM in their mothers.

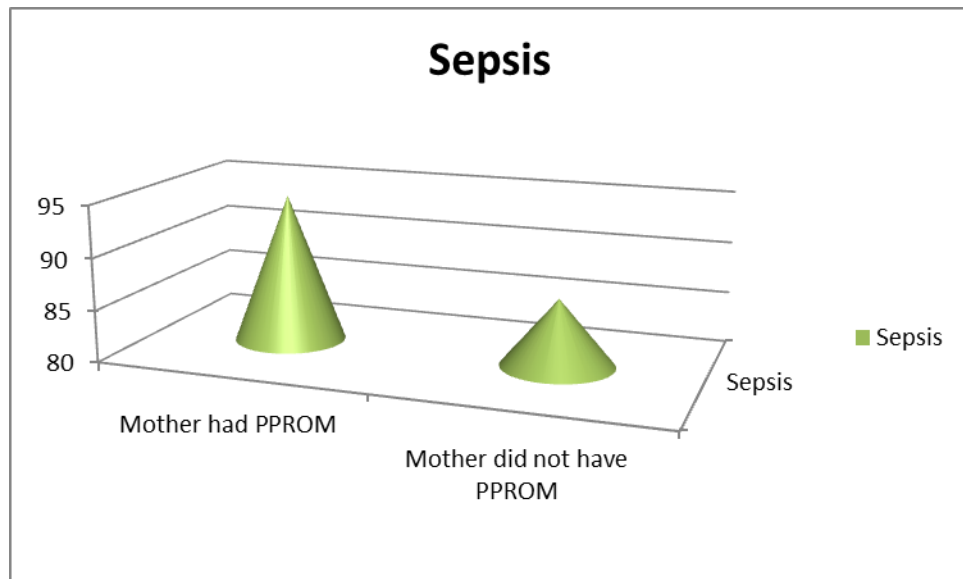


Figure 9. PPROM versus Sepsis

Source: Secondary data from maternity and NICU files, 2016

Neonatal sepsis rate was higher in babies born from mothers who had PPROM (94.4%) comparing to the those (86.5%) whose mother did not have it.

4.1.8.2 Mode of delivery versus mortality

The figure below shows mortality rate by mode of delivery.

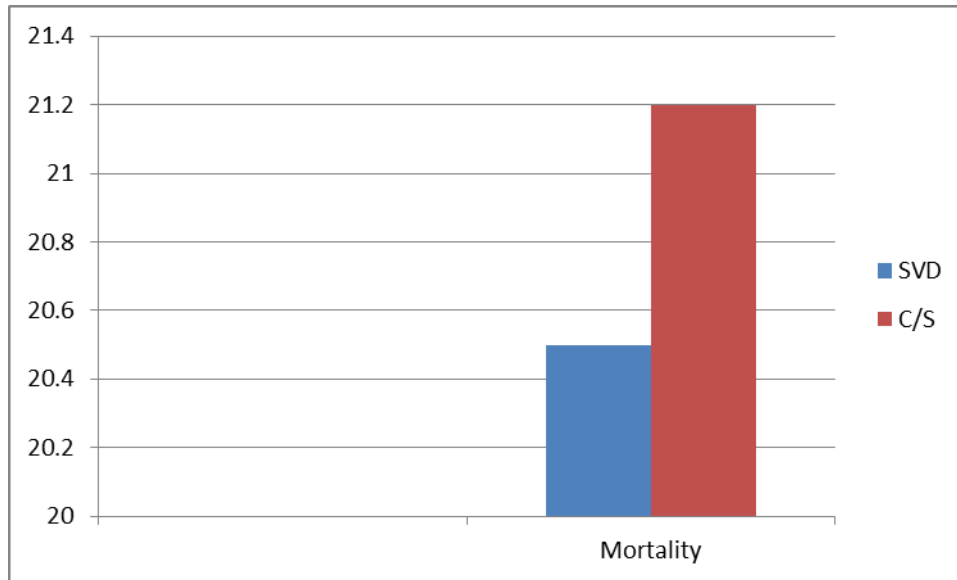


Figure 10. Mode of delivery versus mortality

Source: Secondary data retrieved from NICU records files for preterm neonates, 2016

Mortality was higher in babies born by CS (21.2) than in baby born by SVD (20.5%)

4.1.9 Relationship between factors and outcomes using statistical tests.

4.1.9.1 Factors associated with length of NICU

The table below displays any association existing between factors described above to length of stay as one of outcomes

Table 9. Factors associated with length of NICU

Variable	Length of stay in NICU		p-value
	<=7 Freq (Row %)	>7 Freq (Row %)	
NOB			
Single	51 (52)	47 (48)	0.085
Twin	9 (33.3)	18 (66.7)	
Gender			
Female	25 (43.1)	33 (56.9)	0.308
Male	35 (52.2)	32 (47.8)	
APGAR			
6 and below	20 (45.5)	24 (54.5)	0.675
7 and above	40 (49.4)	41 (50.6)	
BW to GA			
AGA	43 (51.8)	40 (48.2)	0.176
LGA	5 (27.8)	13 (72.2)	
SGA	12 (50)	12 (50)	
Mother's participation			
At least every 3hrs	44 (46.8)	50 (53.2)	0.642
Fewer than every 3 hrs	16 (51.6)	15 (48.4)	
Health Education			
None	22 (57.9)	16 (42.1)	0.143
Yes	38 (43.7)	49 (56.3)	
Maternal age			
18-20	9 (69.2)	4 (30.8)	0.069
21-35	37 (41.6)	52 (58.4)	

>35	14 (60.9)	9 (39.1)	
Marital			
Cohabitation	33 (55)	27 (45)	0.322
Common-law married	20 (41.7)	28 (58.3)	
Single	7 (41.2)	10 (58.8)	
Education			
Illiterate	9 (60)	6 (40)	0.588
Primary	32 (50)	32 (50)	
Secondary	17 (40.5)	25 (59.5)	
Tertiary	2 (50)	2 (50)	
Factories			
Factories around	11 (44)	14 (56)	
No factory around	49 (49)	51 (51)	0.654
ANC visits			
One	12 (50)	12 (50)	0.661
2-3	41 (48.8)	43 (51.2)	
4 and above	3 (30)	7 (70)	
None	4 (57.1)	3 (42.9)	
Smoking /drinking during pregnancy			
Smoking and drinking	9 (60)	6 (40)	
Drinking alcohol only	10 (66.7)	5 (33.3)	0.14
None of the above	22 (37.9)	36 (62.1)	
Passive smoking in this pregnancy	19 (51.4)	18 (48.6)	
Delivery			
C/S	26 (55.3)	21 (44.7)	0.204
SVD	34 (43.6)	44 (56.4)	

Source: Primary data from mothers, secondary data from maternity/NICU records, 2016

The Chi-square test was used to assess factors associated with length of stay in NICU, and in cases where the cell counts were below five the Fishers' exact test was used.

The table below shows the results. From the table, we observe that none of the variables was statistically significantly associated with length of stay in NICU.

4.1.9.2 Relationship between factors and mortality

The table below results from the Chi-square test to assess factors associated with mortality.

Table 10. Univariate analysis of factors associated with outcome

Variable	Outcome		p-value
	Cured/ Improved	Dead	
NOB			
Single	81 (82.7)	17 (17.3)	0.07
Twin	18 (66.7)	9 (33.3)	
Gender			
Female	49 (84.5)	9 (15.5)	0.176
Male	50 (74.6)	17 (25.4)	
APGAR			
6 and below	28 (63.6)	16 (36.4)	0.002
7 and above	71 (87.7)	10 (12.3)	
BW to GA			
AGA	66 (79.5)	17 (20.5)	0.089
LGA	17 (94.4)	1 (5.6)	
SGA	16 (66.7)	8 (33.3)	
Mothers participation			
At least every 3hrs	79 (84)	15 (16)	0.02
Fewer than every 3 hours	20 (64.5)	11 (35.5)	
Health Education			
None	27 (71.1)	11 (28.9)	0.138
Yes	72 (82.8)	15 (17.2)	
Maternal age			
18-20	12 (92.3)	1 (7.7)	0.468
21-35	69 (77.5)	20 (22.5)	
>35	18 (78.3)	5 (21.7)	
Marital status			
Cohabitation	41 (68.3)	19 (31.7)	0.007
Common-law married	41 (85.4)	7 (14.6)	
Single	17 (100)	0 (0)	
Education			
Illiterate	11 (73.3)	4 (26.7)	0.198
Primary	47 (73.4)	17 (26.6)	

Secondary	37 (88.1)	5 (11.9)	
Tertiary	4 (100)	0 (0)	
Factories			
Factories around	23 (92)	2 (8)	0.078
No factory around	76 (76)	24 (24)	
ANC visits			
One	21 (87.5)	3 (12.5)	0.188
2-3	63 (75)	21 (25)	
4 and above	10 (100)	0 (0)	
None	5 (71.4)	2 (28.6)	
Smoking			
Drinking and smoking	14 (93.3)	1 (6.7)	
Drinking alcohol in this pregnancy	13 (86.7)	2 (13.3)	0.392
None of the above	44 (75.9)	14 (24.1)	
Passive smoking in this pregnancy	28 (75.7)	9 (24.3)	
Delivery			
C/S	37 (78.7)	10 (21.3)	0.919
SVD	62 (79.5)	16 (20.5)	

Source: Primary data from mothers and secondary data from records from maternity, NICU, ANC cards, 2016

From the table, we observe that the variables: marital status, mother's participation, and APGAR score were associated with mortality.

4.1.9.3. Multivariate logistic regression analysis

The variables that were significant in the univariate analysis were subjected to multivariate logistic regression analysis the results are shown in the table below.

Since there were no deaths among the single, this group was dropped in the analysis.

Table 11. Multivariate logistic regression analysis

Variable	OR	95% CI	p-value
Apgar >6 versus ≤6	0.268	(0.102, 0.700)	0.007
Mothers participation (Less than 3 hours versus at least 3 hours)	2.359	(0.855, 6.511)	0.097
Married by common-law married versus cohabitation	0.395	(0.141, 1.107)	0.077

Source: Primary and secondary data, 2016

From the table, we observe that the only variable statistically significant in the multivariate analysis was APGAR score. Controlling for marital status and mother's participation neonates with APGAR score greater than 6 had a lower odds of dying compared to those with an APGAR score less than or equal to 6 (OR=0.268 CI:0.102,0.700).

4. 2. Outcomes among preterm neonates at time of exit from NICU

4.2.1 Mortality rate, weight and types of morbidities among preterm babies

Table 12 Outcome among preterm neonates at time of exit from NICU

Variable	Frequency	%
Outcome		
Dead	26	20.80
Cured/ improved	99	79.20
Weight		
No weight gain at discharge	33	26.60
Not taken	65	52.40
Weight gain at discharge	26	21.00
Main morbidities in babies		
Suspect/Confirmed sepsis	111	88.8
RDS	78	62.4
Jaundice	27	21.6
Asyphxia	22	17.6

Source: Secondary data from NICU records files, 2016

Most of the babies 111(88.8%) were suspected or confirmed to have sepsis and 78 (62.4%) had RDS. Other main morbidities causes were jaundice 27 (21.6%) and asphyxia neonatarum 22 (17.6%).

4.2.2. Frequency of morbidity

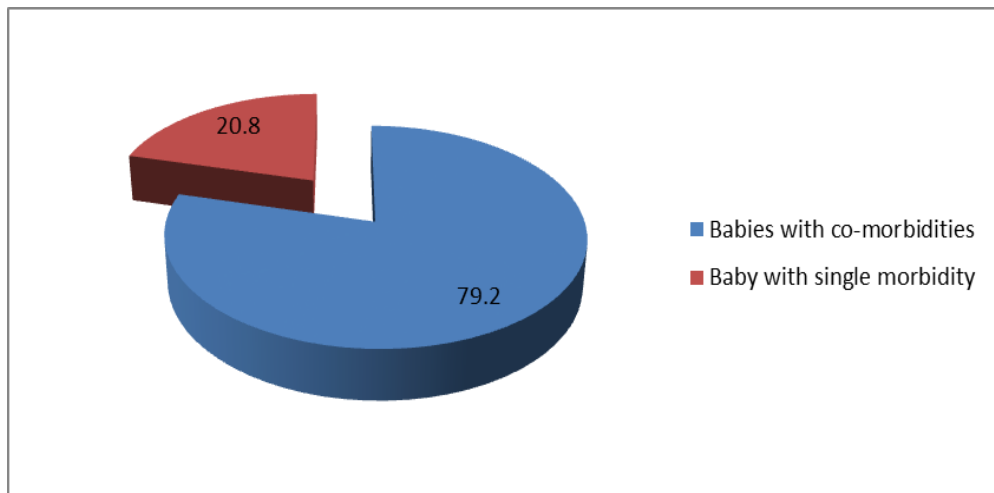


Figure 11. Frequency of morbidity

Source: Secondary data from records files from NICU, 2016

Most babies had co-morbidities 99 (79.2%), and 126 (20.8%) had single morbidity

4.2.3 Length of stay in NICU

The figure below describes length of stay as an outcome among others.

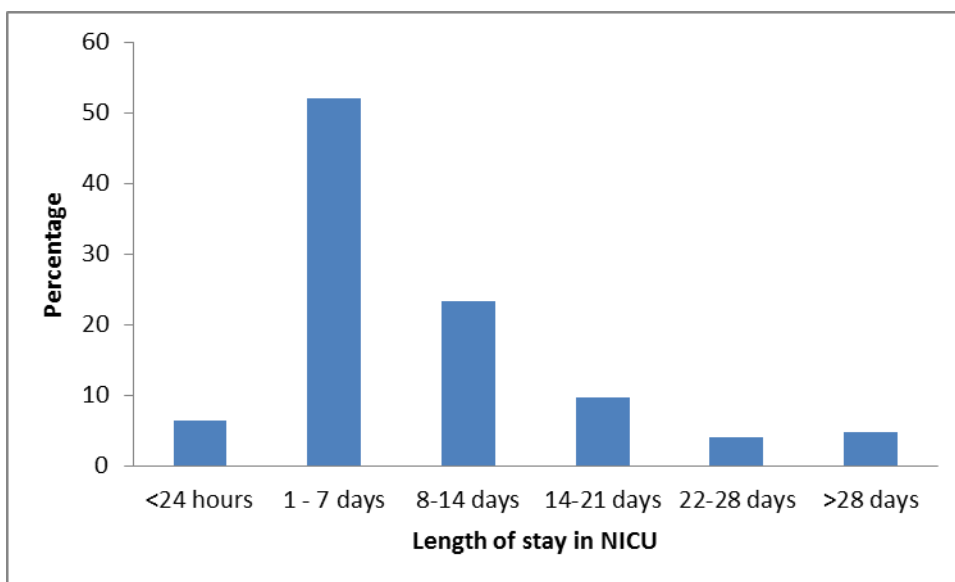


Figure 12. Length of stay in NICU

Source: Secondary data from NICU records files, 2016

Majority (56%) of the babies stayed in the NICU for less or equal to 7days

4.2.3.1. Length of stay in NICU versus mortality

Mortality was high as the length of stay was short. The deaths were 100% in babies who stayed less than 24 hours, 20% between 1 day to 7 days and 17.2% from 8 days to 14 days.

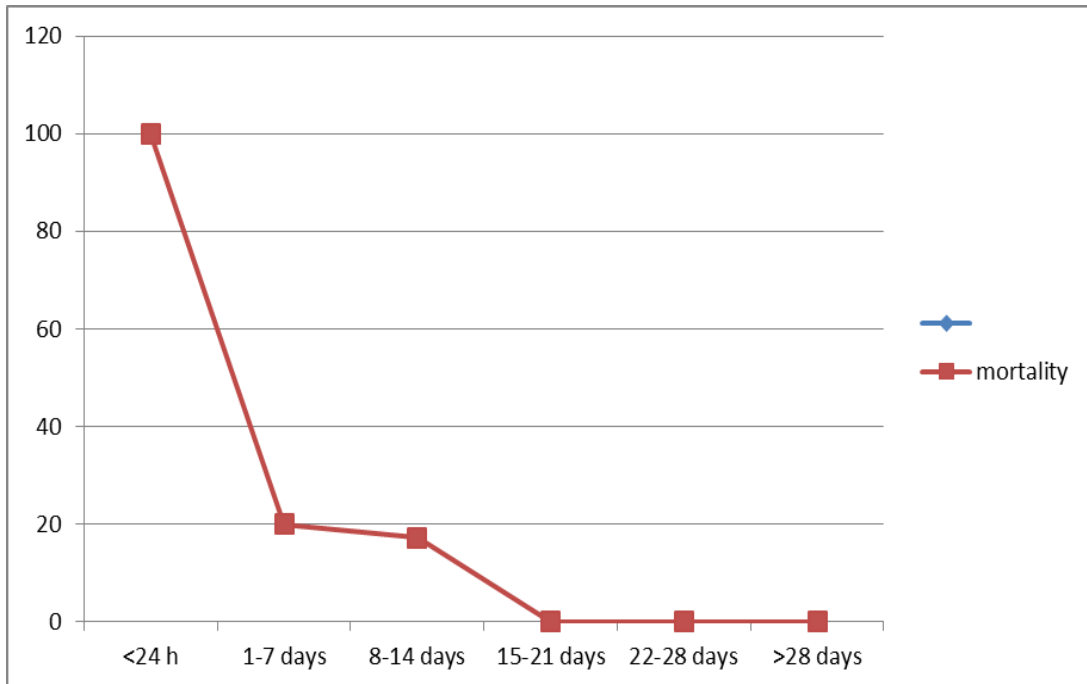


Figure 13. Length of stay in NICU versus mortality

Source: Secondary data from NICU files records, 2016

All babies who stayed less than 24 hours have died. Those who stayed between one to seven days, (20%) of them died, while those who stayed between eight days to fourteen days (17.2%) died, and from fifteen days and above none died.

CHAPTER FIVE

DISCUSSION

5.0 Introduction

This chapter presents the discussion of the results from the study done at two hospitals compared to previously published data, by explaining them and alluding to limitations of the study. The discussion is based on research objectives which focus on determining factors that contribute to morbidity and mortality in preterm neonates and to determine the clinical outcomes when these babies exit from NICU.

5.1 Factors associated with morbidity and mortality in preterm babies

5.1.1 Characteristics of preterm baby at birth

Results from this study showed that APGAR within one minute after birth, equal or lower than 6 is a factor of mortality in preterm neonates.

The majority of the preterm babies born were male; this is similar to the study done by Zeitlin et al., 2002 that showed that preterm birth was more common in boys occupying 55%. In this study, the majority (51%) was moderate preterm (born between 29 to 33 weeks of gestational) and this indication is controversial from another report from WHO (2012) which shows that worldwide, the majority (around 80%) of babies born are late preterm (born between 34 to 36 weeks of gestation). Babies born at less than 32 weeks are about (16%) of all preterm births (Blencowe et al., 2012). Around one in every five neonates was small for gestational age; this is similar to the study done in Nepal where one in every six infants was small at birth (Khan et al., 2014).

Though the majority of the participants in this study were appropriate for gestational age, almost all of them (95.20%) were below average birth weight. The disparity is similar to another research that was done with a close association between prematurity

and low birth weight (Blencowe et al., 2013). This study shows that mortality rate is inversely related to gestational age (mortality increases as gestational age decreases) where mortality was (75%) in severe preterm babies, (25%) moderate preterm babies and (2%) in late preterm babies.

This is similar to WHO (2012) report, where over 90% of preterm babies born before 28 weeks in low-income countries died within an early neonatal period. Similarly, this study evidenced that mortality is inversely related to birth weight (mortality increases as the gestational age decreases) where neonates with ELWB (85.7%) die, in VLBW (53.5%) died and in LBW (5.9%) died. In babies with a healthy weight, nobody died. This is similar to the findings from various studies (Blencowe et al., 2013; Zamudio et al., 2013). The death occurred mostly in male where among them, (25.3%) died. In females, the mortality rate was (15.5%). This is similar to the study done by Khalessi 2013 which argues that male babies are exposed than female because their organs are defenseless to preterm consequences.

5.1.2 Characteristics of care given to the preterm baby

A total of 64 (51.2%) of participants have been resuscitated (basic resuscitation, stimulation). A systematic review and meta-analysis study that was done by Lee et al., 2011, reports that immediate neonatal resuscitation reduces mortality by about 10%. In this study, the majority of preterm babies 103 (82.4%) were exclusively fed on breast milk. This is also similar to the study done by Maastrup, 2014 which reported that at discharge, 68% of the preterm infants were exclusively breastfed while (17%) were partially breastfed. Exclusive breast milk is beneficial to preterm infant immunologically and nutritionally perspective. Moreover, breastfeeding involves mother in care of her baby (WHO, 2012)

The findings from this study show that 12(9.6%) have been fed on breast milk adding fortified milk, this is supported by WHO and does recommend supplementation with iron, calcium, vitamin D and phosphorus and for very low birth weight neonates for boosting the weight (WHO, 2012). A total of 10 (8%) were exclusively fed on formula milk, according to studies done, formula feeding in preterm babies have been associated with high incidence of morbidity specifically necrotizing enter colitis (WHO, 2012). In this study, approximately half of babies 56 (44.8%) fed on Nasogastric tube while the remaining 69 (55.2%) were fed using a cup or directly sucking from the breast.

This is because the majority of babies were below 34 weeks and this leads to poor coordination, sucking, and swallowing reflexes with a higher likelihood to aspirate. Studies done reported that most premature babies need help with feeding with a cup, spoon or another device such as a nasogastric tube. Moreover, mothers had to express breast milk (WHO, 2012; Lawn et al., 2013). Findings from this study show that 12 (10%) of babies did not receive vitamin K and Tetracycline eye ointment. WHO recommend routine administration of vitamin K to all newborn because it specifically prevents preterm babies with lower birth weight from the risk of intraventricular hemorrhage while. A lack of TEO may contribute to neonatorum ophthalmia (WHO, 2012). Only a total of 76 (60.8%) mothers reported having been taught by nurses about hygiene (hand washing before touching the baby).

The World Health Organization recommends hand washing in NICU for the purpose of infection control (Blencowe et al., 2013). Among all participants, none had received cord care with chlorhexidine. Karumbi et al. 2013 say that healthcare providers diverge in their practice on cord care where some keep it dry, some use alcohol, methylated spirit or povidone iodine to clean it. Also, cluster-randomized

trials have shown benefits of chlorhexidine application to the baby's cord and associated with decreased mortality (El Arifeen et al., 2012; Soofi et al., 2012). Use of 4% chlorhexidine was found to be more effective if offered within the first 24 hours of birth, and it seems that even a single application is effective (Karumbi et al., 2013). A rate of 33 (23.4%) of the babies received warmth by Kangaroo Mother Care. In a systematic review and meta-analysis of numerous randomized control trials on KMC, and this came across on association of 51% in reduction in death for stable neonates weight more than 2,000g whether began in the first week (Lawn et al., 2010). Cochrane review also reported about KMC can reduce neonatal infections up to 60% and reduce hypothermia at 80%. Other benefits of KMC include increased breastfeeding, weight gain, mother-baby bonding and developmental outcome, for this reason, KMC improves to a becoming a mother process, baby's weight gain as well as reduces hospital stay (Conde-Agudelo, 2015).

5.1.3. Parental age characteristics

About 13(10.4%) were adolescent mothers; studies were done in different countries show that the risk of low birth rate is particularly high for younger teenager girls vis-a-vis women old 21 to 35 (Dean et al. 2013; Khashan, 2010)

5.1.4 Socio-economic characteristics

The findings showed that majority of mothers had low socio-economic status where (51.2%) had primary education level, and 48% were living in cohabitation marital status. A large proportion of the mothers were casual workers (42.4%) with the majority (47.2%) having a family income of under fifty thousand Rwandan francs (approximately 65\$) per month. The study that was done by Kramer et al., (2000) showed that mortality in preterm babies is linked to low socioeconomic status disadvantage.

5.1.5 Environmental characteristics

A total of 25 (20%) mothers reported that during pregnancy, they had been exposed to factories pollution either at home or work. A study that was done by Pope et al., 2010 argues that 20% of LBW in neonates are derived from exposure to indoor air pollution throughout pregnancy.

5.1.6 Maternal characteristics

A total of 27 (21.6%) of mothers reported having undergone psychological harassment during the current pregnancy. This may have a bad impact on the obstetrical outcome as reported in a study done by Glover (2014). The author argues that stressors like depression, partner violent behavior to the pregnant mother can contribute to less likely look for health care and increase more prone to engage in smoking and alcohol consumption. In this study 58 (46.4%) reported that the current pregnancy was unplanned. This is almost similar to the finding from the study done by Singh, Sedgh, Hussain (2010) where 41% of all women report that their pregnancies were unplanned. The findings of this study show that (88.4%) did not attend pre-conception services. This may be due to non-existence of these services within the minimum package in public health centers. Furthermore, 16 (12.8%) of all pregnancy was unaccepted, and this is a predictor of mortality in a newborn (Lawn, 2013).

5.1.7 Behavioral characteristics

This study has documented that a big number of mothers (94.4%) claimed to attend ANC services whereas the majority have received immunization, deworming and folic acid. Only 16% have received long-lasting insecticide-treated nets (LLINs), and this is a big challenge for a pregnant mother to protect from malaria. In this report only (12%) of mothers had attended ANC clinic for eight weeks and receive folic

acid. A study done by Bhutta and Imdad (2012) highlights that folic acid supplementation reduces the risk of neural tube defects by 53%. An overall of mothers 52 (41.6%) claim to be exposed to second-hand smoking in the current pregnancy. This is similar to the study done by Bloch et al., 2008; Pope et al., 2010 reported that many pregnant women are a victim of nicotine from second-hand smoking, and this is associated to low birth weight.

5.1.8 Obstetrical characteristics

A total of 29 (23.2%) of the mother have been given corticosteroids during labor. This has been widely approved since 1994 by evidence gotten in more than twenty clinical trials together with extra research that corticosteroids given to the pregnant mother at high risk of preterm delivery are secure and highly effective for preventing neonatal mortality (Althabe et al., 2012; Howson et al., 2016; Mwansa-Kambafwile et al., 2010). However, this figure seems to be low comparing to the number of preterm babies born before 34 weeks (60.8%). Furthermore, there is recent study argues that antenatal corticosteroids are also effective in late preterm neonates (between 34 to 36 weeks) (Gyamfi-Bannerman et al., 2016). Studies argue that antenatal corticosteroid significantly reduces RDS, intraventricular hemorrhage, and other morbidities as well as mortality in preterm neonates. Also, this prevents baby's growth difficulties.

The report argues that even though the evidence of the usefulness of antenatal corticosteroids was recognized a long time ago, its practice stays drastically feeble, and this becomes a most significant missed opportunities over the world in decreasing morbidity and mortality in preterm neonates (WHO, 2012). The caesarean section rate was 37.6%, and this is high comparing to WHO recommendation to be between 10-15% (WHO, 2016). This is similar to studies showed that there is a relationship between moderate preterm birth and high cesarean birth rates (Shapiro-

mendoza and Lackritz, 2012). Majority of the babies who died were born by C/S (21.2%) comparing to (20.5%) born by SVD.

This statistic is supported by the study done by Werner et al (2012) that argues that C/s delivery is not associated with better neonatal outcomes in preterm babies, mode of delivery and neonatal outcomes in preterm and small-for-gestational-age newborns. The majority of mothers 53 (42.4%) have received antibiotics during labor. WHO recommends the use of antibiotic treatment for PPRM to prevent neonatal infections According to Fraser et al (2010), the use of antibiotics in PPRM have been effective in treating mothers infection, and it has shown to reduce sepsis in preterm babies. A total of 19(15.2%) mothers have been given antenatal magnesium sulphate. The recommendation from WHO says that administration of MgSO₄ to women at risk of preterm birth protects the baby's brain, and improves the quality of health in future (Katz et al., 2013). A proportion of 36 (28.8%) had preterm premature rupture of the membranes (PPROM). Studies argue that (PPROM) is strongly associated with chorioamnionitis leading to poor outcomes in preterm baby (Howson et al., 2016)

5.1.9. Relationship between factors and mortality

This study shows that APGAR score at the first minute of life was associated with mortality where those with APGAR score greater than six had a lower odds of dying compared to those with an APGAR score less than or equal to six. This is similar in the report done by Lawn et al (2013) where birth asphyxia was the major cause of mortality in babies born too soon. This study also showed that participation of mother in the care of her baby is associated with the outcome where mother's participation in the care of her baby less than every three hours has contributed to mortality. Literature argue that mothers should be involved in care of her newborn to enhance the improvement of their babies (AWHONN, 2014) therefore nurses should

encourage the mothers to be with their babies in NICU as much as possible (González and Espitia 2014)

Furthermore, this study proves that marital status is associated with neonatal mortality where babies born from parents who are in cohabitation are likely to die therefore this also similar to what Kramer (2000) argues that the low socio-economic in parents is associated to neonatal mortality

5.2 Outcomes of preterm neonates

5.2.1 Morbidities in preterm babies

The majority of babies 99 (79.2%) were affected by co-morbidities due to the immaturity of their systems. The study that was done in Texas highlights that morbidity decreases as gestational age increases (McIntire and Leveno, 2008).

Almost babies 111(88.8%) had suspect/confirmed sepsis this is similar to research done by Hoque et al., (2011) where sepsis found to be the most cause of morbidity among preterm babies. Neonatal sepsis was mostly found in babies whose mothers had UTI (92.7%) during pregnancy and in babies whose mother had PPRM (94.4%). Studies have shown an association of PPRM with neonatal sepsis (Velemínský and Tosner, 2008). A figure 78(62.4%) had Respiratory Distress Syndrome.

Studies say that this is due to lung immaturity and lack of surfactant in the alveoli, resulting in collapsing lungs that take extra pressure to inflate. Below 32 weeks gestation, the majority of babies develop RDS, although this risk can be reduced by antenatal corticosteroids to women at risk preterm birth. 27(21.6%) of babies have developed jaundice; this is quite less to the study done in Philadelphia designated that (75.4%) of the preterm neonates developed jaundice (Bastek et al., 2008). The study report that premature babies are at increased risk of jaundice because immature liver

cannot naturally metabolize bilirubin, this makes the preterm baby's brain be at higher risk of intoxication given that their blood-brain barrier is not enough developed (Lawn and Kinney 2014).

5.2.2 Length of stay in NICU

The majority of babies have stayed in NICU for one day to 7 days; this is less than the findings from other study done by Zamudio et al., 2013 where the average length of stay for a preterm newborn was 19.8 days. All deaths occurred within the first two weeks of life and were high as the length of stay was short. The deaths were 100% in babies who stayed less than 24 hours, 20% between 1day to 7 days and 17.2% from 8 days to 14 days. This is similar to the report from WHO (2012) where 80% of neonatal deaths occur in the first week of life.

5.2.3 Mortality

Among the 26(20.8%) preterm that died, 8(30.8%) died within 24 hours after birth, 13(50%) died between 1 day and seven days after birth, 5(19.2%) died within day 8 to 14.

All babies who stayed less than 24 hours have died. Those who stayed between one to seven days, (20%) of them died, those who stayed between eight days to fourteen days (17.2%) died, from fifteen days and above none died. This is similar to the global average says that most death in neonates (80%) occurs in first week (early neonatal death) (WHO, 2012) This is different from study done by Hedstrom et al(2014) where up to 50% of all neonatal deaths occurred within the first 24 hours after birth and 75% by one week of age.

In this study, the mortality was high in boys comparing to the girls, and this is similar to the study done by Kent et al (2012) where the male is associated with a higher risk

of dying when compared to girls born at a similar gestation. Mortality rates increase with decreasing gestational age, and babies who are both preterm and small for gestational age are at even higher risk (Blencowe et al., 2013). Research has documented that survival chance in preterm neonates is correlated to increase in gestation age or birth weight (Lawn et al., 2013). The findings from this study showed that the main causes of morbidity were respectively sepsis, RDS, jaundice, and asphyxia. This is about similar to the study done by Zamudio et al., 2013) where the major morbidity was RDS (52.5%), septicemia, (12.7%) and asphyxia, (9.1%). Neonatal mortality rate was 20.8% and this very high comparing to 3.5% from Iraputo (Zamudio et al., 2013)

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.0 Introduction

This chapter indicates about conclusion drawn from the whole study as well as recommendations given to all stakeholders concerned by neonatal health.

6.1 Conclusion

This study conclude that 2 factors which were associated with mortality and 2 factors associated with morbidity among neonates. Concerning mortality, were characteristics of baby (birth asphyxia, severe prematurity, ELBW) and care received by baby (inadequacy of participation in care from mothers). Concerning factors which were associated to morbidity among preterm neonates were maternal characteristic(UTI during pregnancy) and Obstetrical characteristics (PPROM). Mortality rate was 20.8%.More frequent morbidity were neonatal sepsis and RDS

6.2 Recommendations

6.2.1. Recommendations draw from factors which were associated to mortality and morbidity

Birth asphyxia should be prevented by well monitoring of labor

There is a big need to prevent, and to promptly treat UTI or vaginal infections

There is need to administer antibiotics to every woman with PPRM.

The midwives and nurses working in maternity and NICU should establish the mechanism to encourage, and remind mothers to timely participate in the care of their preterm babies in NICU.

The nurses from NICU should equally teach the parents about the care of their preterm babies as these mothers when discharged home they will also be single-handed to care their fragile babies.

6.2.2 Recommendations from outcomes

Neonatal sepsis should be prevented by treatment of infections in pregnant mothers and use of aseptic technique during delivery

Respiratory distress syndrome should be prevented by administration of corticosteroids to every woman at high risk of preterm labor

6.3 Future Research

Research should be done on assessment on mothers home care practices and outcome in preterm neonates after discharge from NICU. Other research should be focused on infection control in preterm babies admitted to these hospitals.

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APPENDICES

Appendix 1: Informed consent document in English (For babies, signed by mothers)

Introduction

Good morning/afternoon. Thank you for allowing me to talk with you. My name is ALICE MUHAYIMANA, a Master's Program student in the College of Health Sciences, School of Nursing, Department of Midwifery and Gender, at Moi University, Eldoret, Kenya. I have gotten approval from Institutional Research Review of Kenya and Rwanda. I have also received the permission from research committees of CHUK and Muhima hospital to conduct this research. I am carrying out the study to determine Factors contributing to morbidity and mortality in preterm newborns admitted to two major hospitals in Rwanda. We desire that you be free with us when you need any clarifications so that you understand what this research is all about before participation.

Objective of this research

We need your newborn baby to participate in this research concerning the determination of factors contributing to morbidity and mortality in preterm newborns admitted to this hospital. Your baby's participation will help to discover those elements and hence put in place the preventive measures.

How are you going to participate?

If you accept for your baby to participate in this research, during the session, the investigator will extract the information from his/her hospital files only, from the time of admission to the time of discharge. We will carry out the same procedure for 125 babies.

What are the risks involved?

There no risks with your baby's participation in this study.

What are the benefits?

There will be no immediate or direct benefits to you for participating in this study. However, it is hoped that your participation will help in future to decrease morbidity and mortality in preterm newborns. There will not be payments for participating.

Confidentiality

Confidentiality will be used in the whole process to provide information, to treat it, and to keep it. The name of your baby and other identities will not be written anywhere.

Right to participate or to withdraw

Taking part in this study is voluntary. You have the right to allow or refuse your baby's participation. You also have the right to withdraw your baby's participation at any time or select not to participate in the entire survey. If you withdraw your baby, you will not be asked to identify the reasons for the withdrawal, and there is no penalty for withdrawal or decision not to participate in the study.

Questions about the Research

In case of any further inquiries, you may contact the principal investigator, Alice Muhayimana @ +250788687626 or +254739573436. If there is any problem concerning the rights of your baby in participation in this study, you can contact Office of The Institutional Research and Ethical Committee of Moi University, Eldoret, Kenya +254787723677 or call CMHS Institutional Review Board, Kigali, Rwanda +250788563311.

To sign a consent to participate in this research

Do you have any questions? Have you understood the research well? Do you voluntarily agree to your baby's to participation in this study? If you agree to participate in this study, you have to sign as evidence then I will also sign.

I _____

(print name of mother/guardian)

have read and understood the above consent concerning this research. I have been given enough time to ask the questions I had and am satisfied with the responses I have been given. I voluntarily accept my baby to participate in this research study.

Signature: _____ Date: _____

I _____

(print name of investigator)

I declare that all information about the overall process, objective, risks and benefits to participate in this research study have been explained to this person

Signature: _____ Date: _____

Appendix 2: Informed consent document in Kinyarwanda

Amasezerano yo kwemera ko uruhinja rugira uruhare mu bushakashatsi asinywa na nyina

Kwibwira uwo mugiyeye kugirana ikiganiro

Mwaramutse/ mwiriwe, Murakoze kunyakira ngo tugirane iki kiganiro uyu muni. Nitwa ALICE MUHAYIMANA, nkaba ndimo kwiga mu cyiciro cya gatatu cya Kaminuza ya MOI, muri Kenya, Eldoret, muri Coleji y'ubuzima, ishuri ry'ubuforomo, ishami ry'ububyaza n'uburinganire. Nkaba naremerewe na za comite zikurikina uburenganzira bw'abakorerwaho ubushakashatsi zo muri Kenya no mu Rwanda hamwe na za comite z'ubushakashatsi mu bitaro bikuru bya Kaminuza bya Kigali hamwe n'ibitaro bya Muhima. Ubu bushakashatsi bwerekeranye no kureba impamvu zitera irwaragurika n'imfu mu mpinja zavutse zidashyitse zirwariye mu bitaro bibiri bikomeye mu Rwanda. Turifuza ko wabanza gusobanukirwa neza icyo ubushakashatsi bugamije mbere y'uko wafata icyemezo cyo kubugiramo uruhare. Turagusaba gusobanuzwa wisanzuye ikintu cyose uri bube utumvise neza.

Icyo ubushakashatsi bugamije

Turagusaba ko umwana wanyu agira uruhare muri ubu bushakashatsi bugamije kwiga ku impamvu zitera irwaragurika n'imfu mu mpinja zavutse zidashyitse zirwariye muri ibi bitaro. Amakuru azashakirwa mu ifishi y'umwana wanyu azafasha mu kumenya izo mpamvu bityo hashyirweho uburyo bwo kuzikumira bitume irwaragurika n'imfu mu mpinja bigabanuka

Uko ubushakashatsi buteye n'igihe ikiganiro kimara

Niba wemeye ko umwana wanyu agira uruhare muri ubu bushakashatsi, amakuru azashakirwa gusa mu ifishi y'umwana wawe urwariye hano kuva yakwinjira ibitaro kugeza asezerewe. Aya makuru tuzayashakira no ku bandi bana nkawe bagera muri 125.

Ingaruka zishobora kuvuka

Nta ngaruka mbi twumva zazabaho kubera gushakisha amakuru mu ifishi y'umwana wanyu

Ibyiza byo kugira uruhare muri ubu bushakashatsi

Nta nyungu y'aka kanya ku giti cye azakura muri ubu bushakashatsi, ariko ibizavamo bizafasha kugabanya irwaragurika n'imfu z'abana mu Rwanda. Nta bwishyu cyangwa igihembo dutanga ku bwo kugira uruhare muri ubu bushakashatsi

Ibanga

Ubu bushakashatsi bukorerwa mu ibanga ntabwo ndi bwandike amazina y'umwana wanyu cyangwa ayanyu bwite, aho abarizwa cyangwa ikindi cyose kimuranga. Nta makuru yerekeranye nabyo azigera ashirwa hanze.

Uburenganzira bwo kugira uruhare cyangwa kutarugira mu bushakashatsi

Mufite uburenganzira bwo kwiyemeza gutanga cyangwa se kudatanga uburenganzira ko umwana wanyu ko yagira uruhare muri ubu bushakashatsi mufite kandi uburenganzira bwo guhagarika umushakashatsi gukomeza gufata amakuru yerekeranye n'umwana wanyu igihe mubishakiye. Niba wiyemeje kudatanga ubwo burenganzira ntawe uzakubaza impamvu cyangwa ngo abiguhaniye.

Aho wabariza

Niba ufite ikibazo icyo ari cyo cyose kuri ubu bushakashatsi wahamagara

Alice Muhayimana kuri +250788687626 cyangwa +254739573436.

Niba ufite ikibazo icyo ari cyo cyose cyerekeranye n'uburenganzira bw'abakorerwaho ubushakashatsi, wahamagara muri Kenya mu biro bya IREC kuri +254787723677 cyangwa mu Rwanda i Kigali mu biro bya CMHS- IRB kuri +250788563312

Kwemeza ko wemeye kugira uruhare muri ubu bushakashatsi

Hari ibindi bisobanuro waba ukeneye? Wasobanukiwe ibyo maze kukubwira? Wemeye ko umwana wawe agira uruhare muri ubu bushakashatsi? Niba wemeye ko agira uruhare muri ubu bushakashatsi, urashyira umukono hano hepfo kuri uru rupapuro nk'ikimenyetso cyo guhamya ibyo wemeye, nanjye ndarushyiraho umukono.

.Njyewe _____

Izina ry'umubyeyi w'umwana cyangwa umurezi we

Ndemeza ko imiterere n'intego by'ubu bushakashatsi, akamaro kabwo n'izindi nkurikizi byose byose bijyanye no kwitabira ubu bushakashatsi nabisobanuriwe. Nahawe umwanya wo kubaza ibibazo byose byerekeranye n'ubu bushakashatsi kandi byasubijwe neza. Nemeje ku bushake ko umwana wanjye abugiramo uruhare.

Umukono _____ Itariki _____

Njyewe _____

Izina ry'ubaza

Ndemeza ko imiterere n'intego by'ubu bushakashatsi, akamaro kabyo n'izindi nkurikizi byose bijyanye no kwitabira ubu bushakashatsi byasobanuriwe uyu muntu

Umukono _____ Itariki _____

Appendix 3: Research toolsSNO:

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Record review checklist for the newbornFill in all questions by putting \sqrt for **Yes** and X for **No** or use code number

1. Characteristics for preterm baby

	Specify/tick
Number of babies	Single () multiple births () specify number
Gender	Male () Female()
APGAR	1min ()
Gestational age in completed weeks at birth	24-28() 29-33() 34-36()
Birth weight categories in grams	< 1000() 1001-1500 () 1501-2499() 2500-4000() >4000()
Compare BW to GA	Appropriate for gestational age () Small for gestational age (SGA) () Large for gestational age(LGA)

2. Preterm neonatal Care characteristic

Care received by the baby and the time given
Immediate resuscitation yes() No()
Vitamin K administration Tetracycline Eye ointment
Provision of warmth specify radiant warmer(a) baby crib/cot(b) Kangaroo Mother Care(c) incubator(d)
Types of feeding specify EBM (a) BM+FM (b) Artificial milk only(c) Please specify if oral (1) NGT (2)
Cord care specify with chlorhexidine 4% Done() Not done()
Immunization specify Polio 0 (a) BCG (b) given() not given()
Specific care during hospitalization in NICU (Specify)

Health education received by mother on care of her baby

How often do you come to see your baby At least every 3 hours(a) fewer than 3 hours(b) Never(c)
Have you been taught by the nurses in NICU about care of preterm neonates in this period ? yes() no() If yes tick
Hygiene(Hand washing, bathing the babies
Breastfeeding technique
Keeping baby warm
Others (specify)

BABY'S OUTCOME

3. Morbidity during NICU stay

Select one or more condition/disease by which the baby actually has during the period of hospitalization

SNO	Diagnosis
	Suspected sepsis(a) Confirmed Sepsis(b)
	Metabolic disorders specify (a) Hyperglycemia(b) Hypoglycemia (c) Others
	Respiratory Distress Syndrome
	Necrotizing enterocolitis
	Pathological Jaundice
	Anemia
	Asphyxia neonatorum
	Intraventricular Hemorrhage
	Eyes problems
	Cord complications
	Skin infections
	Congenital malformations
	Congenital syphilis
	Surgical operation
	Others- Specify

4. Mortality and other outcome

Select one or more outcome of the baby relating to the table below

a.Weight in Grams at NICU exit						
b.Length in NICU (days)	<1	1-7	8-14	14-21	22-28	>28
c.Discharge reason cured/improved(1) dead(2)						

B.QUESTIONNAIRE FOR THE MOTHER (filled by investigator)

5. Parents age

Tick the following concerning parent age

Maternal age in years	<18 (1)	18-20 (2)	21-35	>35(3)
Paternal age in years	<20 (1)	20-34 (2)	>35(3)	

6. Socio- economic characteristics

Tick the following current socio-economic status of the parents

	Choose/tick
Mother's level of education	None(1) Primary(2) Secondary(3) Technical (4) Tertiary(5)
Marital status	common-law married (1) Cohabitation (2) Single (3)separated(4)
Occupation of the mother	housewife (1) employed (2) self-employed (3) Student (4) casual (5) others (6) specify type of employment
Occupation of the father	employed (1) self-employed (2) Student (3) casual (4) others (5) specify type of employment
Income of the family per month in Rwandan francs (1 US \$=800 RWF)	> 50,000 (1) 100,000-200,000(2) 200,000-500,000 (3) 500,000- 1,000,000(4) >1,000,000 (5)

7. Environmental characteristics

Tick concerning living place / working place environment during the pregnancy of this baby

Factories around living /working yes (1) No(2)
Factories around working place yes (1) No(2)

8. Maternal characteristics

Pick maternal reproductive history and problems during this pregnancy (Tick if yes)

Gravida
Plan to get pregnancy- Planned(a) Unplanned (b) If Unplanned specify Accepted (i) and Unaccepted (ii)
If planned preconception attended yes(1) no(2)

b. Problems during Pregnancy with this Baby (tick if yes)

Problem	Tick	Problem	Tick	Problem	Tick
1. Psychological		7 Chronic Hypertension		12. Anemia	
2. Placenta abruption		8. HIV/AIDS		13. TORCH	
3. Pre-eclampsia		9. Diabetes		14. Antepartum	
4. Hyperemesis		10. Cardiac Disease		15.	
5. Malaria		11. Periodontal Infections			
6. UTIs					

9. The behavioral characteristics

Choose behavior and ANC care received during pregnancy of this baby

Have you been smoking or drinking alcohol/illicit? drug yes(1) No (2)			
Have your partner/ other people smoked close to you? yes(1) No (2)			
How many times per day have you taken your meal			
Have you had pica (craving non edible food)yes(1) No (2) specify specify chalk (a) charcoal (b) Soil (c) others(d)			
Number of ANC	Tick if yes	Bednet (LLINs)	Tick
Folic acid At what GA was given?		Pharmaceutical medications	
Update immunization with tetanus toxoid		Traditional medications	
Deworming			

10. Obstetrical characteristics

C. INFORMATION FROM RECORD REVIEW OF THE MOTHER

Tick the following concerning labor and delivery of this baby

Labor complications and intrapartum care	Tick if yes
Uterine infection or fever onset of labor	
PROM	
Fetal distress	
Mother treatment onset of labor	
Corticosteroids	
Antibiotics	
Others(specify)	
Mode of delivery 1. Vaginal delivery specify SVD (a) breech(b) 2. Instrumental delivery specify Forceps(a) Vacuum extractor (b) 3. Caesarian section	Specify
Place of birth of the baby Muhima hospital () CHUK ()	
Mother condition within 3 Post-partum period Uterine infection or fever within after 3 days delivery(1) Coma/unconsciousness after delivery(2)	

Appendix 4: Research budget

No	ITEM	UNIT	QUANT.	UNIT (Kshs.)	TOTAL
I.	STATIONERY				
1	Foolscaps	Ream	3	300.00	900.00
2	Printing papers	Ream	4	550.00	2200.00
3	Ball pens	Piece	10	25.00	250.00
5	Pencils	Piece	1	350.00	250.00
6	Erasers	Piece	5	20.00	100.00
4	Note books	Piece	10	50.00	500.00
5	Flash disks – 4GB		3	1,400.00	2,500.00
6	Spring files		10	50.00	500.00
7	Pocket files		5	100.00	500.00
9.	Airtime	Per month	300	12	3,600
10	Internet service	Per month	1000	12	12,000
SUBTOTAL					37,500
II.PRINTING SERVICES					15,000
SUBTOTAL					15,000
III.DATA COLLECTION EXPENSES					
Transport to Rwanda					40,000
In country transport					5,000
Research assistance allowance					15,000
SUBTOTAL					60,000
IV.DATA ANALYSIS EXPENSES					
Data analysis software					14,000
Biostatistician services					40,000
SUBTOTAL					54,000
V.MISCELLANEOUS					8,000
SUBTOTAL					8,000
GRAND TOTAL					174,500

Appendix 5: Timetable for MSN thesis

Time Period	Activities/Procedures
YEAR	ONE
September-Nov 2014	Introduction/orientation. General research training; introductory lectures.
Dec 1, 2014	Submit title/topic of thesis to HOD/Coordinator
Dec 15, 2014	HOD/Coordinator proposes Thesis supervisors
Dec 15, 2014	Submission of title/topic and supervisors to SONGSC
Jan 31, 2015	Approval of topic by SONGSC
Jan 15, 2015	Approval of Supervisors
Jan 10, 2015	First meeting with the first Supervisor
July 1st, 2015	Meeting with the 2 nd Supervisor
July 29, 2015	Proposal defense
August 29, 2015	Proposal submitted to IREC
YEAR	TWO
Oct – Nov 2015	Provisional approval from IREC
Dec 2015-Jan 2016	Final approval from IREC, Submission to Rwanda IRB
Feb 2016	Approval from Rwanda IRB
March 1-April, 2016	Data collection
May 30, 2016	Analyzing data, writing thesis
June 30, 2016	Draft of completed thesis to supervisor ,Thesis approved by supervisors
July 15, 2016	Submit letter of intent to defend Thesis to SONGSC and Mock Defense
August 1, 2016	Submission of thesis to the HOD
September 2016	Thesis defense

Appendix 6: IREC approval



MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471423



**MOI UNIVERSITY
SCHOOL OF MEDICINE**
P.O. BOX 4018
ELDORET

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

Reference: IREC/2015/201
Approval Number: 0001562

Ms. Alice Muhayimana,
Moi University,
School of Nursing,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Ms. Muhayimana,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Factors Contributing to Morbidity and Mortality among Preterm Neonates Admitted at Two Major Hospitals in Rwanda."

Your proposal has been granted a Formal Approval Number: **FAN: IREC 1562** on 3rd February, 2016. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 2nd February, 2017. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,



PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

3rd February, 2016

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE


03 FEB 2016

APPROVED

P.O. Box 4606-30100 ELDORET

cc Director - MTRH Dean - SOP Dean - SOM
 Principal - CHS Dean - SON Dean - SOD

Appendix 7: CMHS-IRB approval



UNIVERSITY OF RWANDA
COLLEGE OF MEDICINE AND HEALTH SCIENCES

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 23/May/2016

MUHAYIMANA Alice
College of Medicine and Health Sciences, UR

Approval Notice: No 225 /CMHS IRB/2016

Your Project title *“Factors Contributing To Morbidity And Mortality Among Preterm Neonates Admitted At Major Hospitals In Rwanda”* has been evaluated by CMHS Institutional Review Board.

Name of Members	Institute	Involved in the decision		
		Yes	Absent	No (Reason) Withdrawn from the proceeding
Prof Kato J. Njunwa	UR-CMHS	X		
Prof Jean Bosco Gahutu	UR-CMHS		X	
Dr Brenda Asimwe-Katcera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS		X	
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS		X	
Mr Kanyoni Maurice	UR-CMHS	X		
Prof Munyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gishoma Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS		X	
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS		X	
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

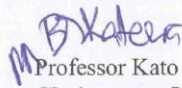
After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 23th May 2016, **Approval letter has been granted to your study.**

EMAIL: rwresearchcenter@ur.ac.rw P.O. Box: 3286, Kigali, Rwanda WEBSITE: <http://cmhs.ur.ac.rw/>

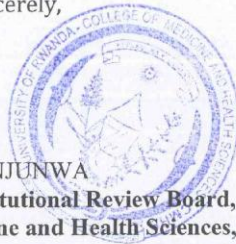
Please note that approval of the protocol and consent form is valid for **12 months**.
You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,



Professor Kato J. NJUNWA
**Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR**



Date of Approval: The 23th May 2016

Expiration date: The 23th May 2017

Cc:

- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate studies, UR

Appendix 8: Letter requesting for collecting data at CHUK

Research Committee Board
CHUK
KIGALI

Alice Muhayimana
MSc Nursing Student
Moi University,
Eldoret, Kenya

March 17th, 2016

Dear Committee,

Re: Request for permission to conduct a research

I am a staff in the school of Nursing in University of Rwanda. Am currently pursuing Masters of Science in Nursing (Maternal and Neonatal Health) in Moi University/Kenya

I am writing to request your permission for carrying out data collection activities related to my MSc. Project entitled " *Factors contributing to morbidity and mortality among preterm newborns admitted at major hospitals in Rwanda*" and this is a requirement of partial fulfillment of the degree of master of nursing. The project will be conducted during the period of 2 months, mid March-mid May 2016. During data collection information from the files of preterm neonates admitted in NICU will be extracted along with the information from their respective mothers. Kindly find attached documents giving more details about my investigation and formal approval from IREC.

Your reply and consideration will be highly appreciated

Yours Truly,

Alice Muhayimana

Appendix 9: Letter requesting for collecting data at Muhima hospital

Director of Muhima hospital
KIGALI

Alice Muhayimana
MSc Nursing Student
Moi University,
Eldoret, Kenya

March 17th, 2016

Dear Director,

Re: **Request for permission to conduct a research**

I am a staff in the school of Nursing in University of Rwanda. Am currently pursuing Masters of Science in Nursing (Maternal and Neonatal Health) in Moi University/Kenya


I am writing to request your permission for carrying out data collection activities related to my MSc. Project entitled " *Factors contributing to morbidity and mortality among preterm newborns admitted at major hospitals in Rwanda*" and this is a requirement of partial fulfillment of the degree of master of nursing. The project will be conducted during the period of 2 months, mid March-mid May 2016. During data collection information from the files of preterm neonates admitted in NICU will be extracted along with the information from their respective mothers. Kindly find attached documents giving more details about my investigation and formal approval from IREC.

Your reply and consideration will be highly appreciated

Yours Truly,

Alice Muhayimana.

Appendix 10: Permission from CHUK to conduct data collection



**CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL**

Ethics Committee / Comité d'éthique

March 21, 2016 Ref.: EC/CHUK/027/2016

Review Approval Notice

Dear Muhayimana Alice,

Your research project: "Factors contributing to morbidity and mortality among preterm newborns admitted at major hospitals in Rwanda."

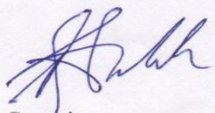
During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 21/03/2016 to evaluate your protocol of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your protocol.

You are required to present the results of your study to CHUK Ethics Committee before publication.

PS: Please note that the present approval is valid for 12 months.

Yours sincerely,

Dr. Stephen Rulisa
The President, Ethics Committee,
University Teaching Hospital of Kigali



DR. STEPHEN RULISA
HEAD - DEPARTMENT OF CLINICAL
RESEARCH
CHUK

<<University teaching hospital of Kigali Ethics committee operates according to standard operating procedures (Sops) which are updated on an annual basis and in compliance with GCP and Ethics guidelines and regulations>>.

B.P. :655 Kigali- RWANDA www.chk.rw Tél. Fax : 00 (250) 576638 E-mail : chuk.hospital@chukigali.rw

Appendix 11: Permission from Muhima hospital to conduct data collection

REPUBLICQUE DU RWANDA



VILLE DE KIGALI
DISTRICT DE NYARUGENGE
HOPITAL DE MUHIMA
B.P : 2456 KIGALI
Tél. /Fax : +252 50 37 7
E-mail : muhimahospital1@gmail.com

ETHICS COMMITTEE/ COMMITTEE D'ETHIQUE

30th March 2016 Ref: MDH/EC/...../2016

Review Approval Notice

Dear Alice MUHAYIMANA

Re: Your request for research at Muhima hospital.

During the meeting of ethic committee of Muhima District Hospital that was held on 30th March 2016 to evaluate your demand we are please to inform you that the Muhima Hospital Ethic Committee has approved your request.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the committee of any proposal change(s) or amendment(s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The committee expects to receive a final report at the end of the study.

Yours sincerely,

Dr BUTERA Yvan

Chair Person, Ethics Committee