THE EFFECT OF EARLY INTERMITTENT KANGAROO MOTHER CARE ON NEONATAL MORTALITY, MORBIDITY AND WEIGHT GAIN IN STABLE LOW BIRTH WEIGHT INFANTS

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The effect of early intermittent Kangaroo mother care on neonatal mortality, morbidity and weight gain in stable low birth weight infants

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DECLARATION

This thesis is my original work and has not been presented for a degree in any other University.

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My dear wife Priscilla

My lovely daughter Nina

My loving parents Penina and Peter

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LIST OF ABBREVIATIONS

ANC	Antenatal Clinic
aOR	Adjusted Odds Ratio
CBS	Central Bureau of Statistics
CHS	Centre for Health Solutions – Kenya
CI	Confidence Interval
CS	Caesarean section
ERC	Ethics Review Committee
JKUAT	Jomo Kenyatta University of Agriculture and Technology
KDHS	Kenya Demographic Health Survey
KES	Kenya Shilling
KMC	Kangaroo Mother Care
KNBS	Kenya National Bureau of Statistics
KNH	Kenyatta National Hospital
LBW	Low birth weight
MDGs	Millennium Development Goals
MOH	Ministry of Health
NCD	Non-Communicable Disease
OR	Odds Ratio
RCT	Randomized Controlled Trial
RDS	Respiratory Distress Syndrome
RR	Relative Risk
SDGs	Sustainable Development Goals
SGA	Small for Gestational Age
SSC	Skin to Skin Contact

UN	United Nations
UNICEF	United Nations Children's Fund
USD	United States Dollar
WHO	World Health Organization

DEFINITION OF OPERATIONAL TERMS

Conventional neonatal care

The routine care offered in the neonatal unit to Low Birth Weight (LBW) infants that mainly involved an artificial warming system (incubator).

Early intermittent Kangaroo mother care

Skin to Skin Contact (SSC) in which the LBW infant was placed vertically (prone) between the caregivers' breasts, firmly attached to the chest and below her clothes for recurrent intervals of at least one hour after each feeding cycle (Maternal and Child Health Integrated Program (MCHIP), 2012). The SSC was started within 72 hours after birth. When not on SSC, the infant was placed inside an incubator.

Stable low birth weight infant

Infants born with weight of ≤2000 grams irrespective of gestational age whose cardiovascular and respiratory functions did not require continuous support or monitoring.

Neonatal morbidity

Any disease condition, disorder and/or complication of the newborn that occurred during the first 28 days of life. Such a condition, disorder and/or complication would typically require hospitalization of the newborn in order to receive treatment.

Neonatal mortality

Death of a neonate during the first 28 days of life (WHO, 2006).

ABSTRACT

Kangaroo Mother Care (KMC) is a safe and effective alternative to conventional neonatal care of Low Birth Weight (LBW) infants. Continuous KMC can reduce neonatal morbidity and mortality in LBW infants as well as improve neonatal growth. The typical practice of KMC involves intermittent Skin to Skin Contact (SSC). There is limited data on the effectiveness of intermittent KMC in reducing neonatal mortality and morbidity and increasing weight gain in LBW infants. The aim of the study was to assess the effect of early intermittent KMC in improving the health status of stable LBW infants in terms of reduced morbidity and mortality and improved neonatal weight gain. A clustered quasi-experimental study was done with Pumwani Maternity Hospital as the intervention site and both Thika and Machakos Level 5 Hospitals as the control sites. The study composed of 171 KMC infants and 172 control infants weighing ≤2000 grams. The KMC infants received early (within 72 hours after birth) intermittent KMC for a cumulative period of eight hours a day. When not on KMC, they were placed in incubators for warmth. The infants in the control sites received the conventional neonatal care. Data was collected through baseline and exit questionnaires and by abstraction from patient files between July 2016 and June 2017. The mean birth weight among infants in the intervention group was 1555.4 (SE=20.8) grams while the mean birth weight among infants in the control group was 1430.1 (SE=20.2) grams. There were more female, 205 (59.8%) than male infants. The study outcome measures were neonatal mortality, morbidity, weight changes and duration of hospital stay. There were few neonatal deaths in the intervention group but this reduction was not statistically significant (p>0.05).The intervention reduced the risk of neonatal morbidity among stable LBW infants by 33% (RR=0.67, p<0.0001) and significantly shortened the duration of hospital stay (t (304) 14.5009, p<0.0001). It had a significantly higher mean weight gain during the neonatal period (t (302) 7.2, p<0.0001). Several factors that could be associated with neonatal mortality and morbidity were identified and controlled for through multiple logistic regression. There was a significant association between incidence of neonatal mortality with Non-Communicable Diseases (NCD) (aOR=4.7, p=0.048), birth weight (aOR=0.997, p=0.043), gestational age (aOR=0.72, p=0.005), multiple births (aOR=7.6, p=0.001) and household income (reference category was <6000 KES; 6000 to 15000, aOR=0.22; >15000, aOR=0.15, p=0.038).The regression analysis showed that there was a significant association between incidence of neonatal morbidity with intermittent KMC (aOR=0.26, p=0.001), infant sex (males, OR=2.6, p=0.003), birth complications (aOR=2.1, p=0.001), access to toilet (OR=0.53, p=0.037), place of delivery (reference category was study hospital; another hospital, OR=1.6; home, OR=0.3, p=0.009), birth weight (OR=0.997, p<0.0001), gestational age (OR=0.935, p=0.021) and NCD (OR=11.6, p=0.029). In conclusion, the intervention was effective in reducing neonatal morbidity and improving weight gain during the

neonatal period. Recommendations were made to the Ministry of Health to prepare guidance on the implementation of early intermittent KMC for LBW infants and the County health department to implement the intervention. Further research was recommended on evaluating the effect of increased duration of SSC in reducing neonatal mortality.

CHAPTER ONE

INTRODUCTION

1.1 Background information

The neonatal period, the first 28 days of life, is the most vulnerable time for a child's survival (UNICEF, 2014). There are direct causes of neonatal mortality which include neonatal morbidity, LBW and preterm births, and indirect causes like socioeconomic factors that work through proximate factors (environmental factors, maternal, neonatal and delivery factors among others) to influence neonatal survival (KDHS, 2014; Moss *et al*., 2002; UNICEF, 2018c, 2014; WHO, 2015a).

Worldwide neonatal deaths were 2.6 million in 2016 (UNICEF, 2018d). Sub-Saharan Africa (SSA) had the highest neonatal mortality rates with 32 deaths per 1,000 live births in 2012 accounting for 38 percent of global neonatal deaths (UNICEF, 2018c, 2015). Complications from preterm birth accounted for 34 percent of the neonatal deaths in 2012 and a similar proportion (35%) in 2013 (UNICEF, 2013, 2014, 2015). The neonatal mortality rate in Kenya was 22 deaths per 1,000 live births in 2014, accounting for 59 percent of all infant deaths (KDHS, 2014). This was high considering the sustainable development goals (SDGs) target of reducing the neonatal mortality rate to less than 12 deaths per 1,000 live births (UN, 2015).

The 2014 Kenya Demographic Health Survey (KDHS) showed remarkable declines in all levels of childhood mortality compared to the rates observed in the 2008 KDHS. This was however in exception of neonatal mortality rates that reduced by 33 percent. This slow decline was also reported in the 2008 KDHS when comparing data with the 2003 KDHS. The 2014 survey showed that the neonatal mortality rate in Kenya for the five years preceding the survey was 1.4 times the post-neonatal mortality rate (KDHS, 2008; KDHS, 2014).

Kangaroo Mother Care (KMC) involves care of Low Birth Weight (LBW) infants through early and prolonged Skin-to-Skin Contact (SSC) with the mother or a caregiver (Nagai *et al*., 2010; WHO, 2003). Kangaroo mother care is used as an alternative to conventional neonatal care of LBW infants (Charpak *et al.*, 1997; Nagai *et al.*, 2010) which is expensive and needs both highly skilled personnel and permanent logistic support to maintain environmental stability (thermal and humidity) (WHO, 2016a). There is evidence that KMC is a safe, effective in reducing neonatal mortality and there are no known adverse effects (Conde-Agudelo *et al.,* 2011). Besides reducing neonatal mortality, KMC has been proposed as an intervention that can reduce neonatal morbidity and improve neonatal growth in LBW infants (Conde-Agudelo *et al.,* 2011; Nagai *et al.*, 2010; WHO, 2014). Reduced neonatal morbidity and improved neonatal growth is associated with improved neonatal survival (Moss *et al*., 2002).

Many of the existing studies including those in the systematic reviews have been done in more developed countries (Conde-Agudelo *et al.,* 2011; Moore *et al.*, 2012). A trial in Ethiopia which evaluated the effectiveness of early continuous KMC before stabilization of LBW infants, was an exception (Worku and Kassie, 2005). Though the study found some benefits in reducing neonatal deaths, it has been criticized for including study group characteristics that were not controlled and unadjusted analysis (Nagai *et al*., 2010). Besides, the infants in both groups had significant morbidity and mortality (Moore *et al*., 2012) and the study did not follow infants for up to 28 days to ascertain the total outcome on neonatal mortality (Sloan *et al.,* 2011).

The typical practice of KMC involves intermittent SSC. The beneficial effect of KMC on neonatal mortality has not been demonstrated in subgroup analysis of trials that used intermittent KMC or those that used KMC in stabilized infants (Conde-Agudelo *et al*., 2011). A trial in Japan assessed the effectiveness of early continuous KMC (initiated within 24 hours) compared to late KMC in stable LBW infants (Nagai *et al*., 2010). This study found no significant differences between the two groups in health status of stable LBW infants in terms of neonatal morbidity and mortality. Many neonatal deaths occur within the first 24 hours of life and any intervention initiated later may not have the same effect. Considering that three quarters of neonatal deaths occur within the first week of life, effective interventions should be initiated as soon as possible after birth (KDHS, 2014; Lawn *et al*., 2011).

1.2 Statement of the problem

The number of neonates dying every year in Kenya is unacceptably high, with most of them occurring in urban areas and within the first few days after birth. In Nairobi, where Pumwani hospital is located, the neonatal mortality rate was 39 deaths per 1,000 live births for the 10 years preceding the 2014 survey and this was the highest in the country. Neonatal mortality rate was 24 percent higher in urban areas than rural areas KDHS, 2014) and that informed the inclusion of Machakos and Thika level 5 hospitals which serve mainly urban populations in their catchment areas. The two towns are typical of many other towns in the various counties in Kenya.

Neonatal deaths are usually a consequence of neonatal morbidity and as such there is need to explore effective strategies that could reduce the incidence of neonatal morbidity. LBW is a factor that increases the chances of neonates dying and effective strategies should be explored that would increase the weight gain during the neonatal period. There is a complex relationship between socioeconomic, maternal, neonatal, nutritional and environmental factors and incidence of neonatal morbidity and deaths that need to be explored well with relevant theories.

Many researchers think that KMC is a medical intervention that could reduce the incidence of neonatal deaths. KMC would achieve this by reducing incidence of neonatal morbidity and improving neonatal weight gain which is a measure of infant growth. These benefits of KMC are realized when continuous KMC is implemented. In practice however, many hospitals in Kenya implement intermittent KMC or no KMC at all.

In Kenya and the rest of the SSA, there is limited published data detailing how effective the intermittent KMC is in reducing neonatal mortality when compared to conventional care. This quantitative study provides health workers and policy makers with information on the effect of early intermittent KMC in reducing neonatal deaths, reducing neonatal morbidity and increasing neonatal weight gain among LBW infants (≤2000 grams).

1.3 Justification

Children are the future of the human race, and everyone should ensure that they survive, grow and live a healthy life. About one in every 26 Kenyan children die before their first birthday, most of them when they are just a few days old (KDHS, 2014). The causes of neonatal deaths are multifactorial (KDHS, 2014; Moss *et al*., 2002; UNICEF, 2018c, 2014; WHO, 2015a). The selected hospitals provide data that explore these multifactorial causes in the Kenyan context. Pumwani hospital was purposively selected as it was the largest maternity hospital in Kenya, located in Nairobi that had the highest neonatal mortality rate in Kenya. Machakos and Thika hospitals were the largest public hospitals in Machakos and Kiambu counties based on the number of deliveries (MOH, 2011). They were purposively selected to represent other hospitals in Kenya serving a similar population.

The ideal KMC is effective in reducing neonatal mortality by improving breastfeeding practices, thermal and cardiorespiratory stability and involves SSC between the LBW infant and caregiver for ≥20 hours a day (Bera *et al*., 2014; Boju *et al*., 2012; Moore *et al*., 2012; WHO, 2016b, 2003). This requires more than one caregiver for SSC and a designated KMC room equipped with beds, chairs and other supplies. Many hospitals in Kenya implement conventional neonatal care which involves use of incubators. The hospitals have inadequate incubators and many are affected by problems such as poor maintenance, frequent power outage and lack of spare parts (Maternal and Child Health Integrated Program (MCHIP), 2012). As a result, LBW infants have to share incubators and this raises the risk of nosocomial infections like pneumonia and sepsis (Conde-Agudelo *et al.,* 2011; Conde-Agudelo and Díaz-Rossello, 2016; Udani *et al,*. 2014; Lawn *et al.*, 2010). Intermittent KMC is more feasible to implement due to the lack of equipped KMC rooms and having only one caregiver in the hospital taking care of the LBW infant, but there is limited data on its effectiveness in reducing neonatal mortality or whether it can reduce neonatal morbidity and improve neonatal weight gain. The findings from this study addressed this knowledge gap.

1.4 Research questions

1. How does the incidence of neonatal mortality compare between LBW infants on early intermittent KMC and conventional neonatal care?

2. How does the incidence of neonatal morbidity compare between LBW infants on early intermittent KMC and conventional neonatal care?

3. How does the amount of weight gained during the neonatal period compare between LBW infants on early intermittent KMC and conventional neonatal care?

1.5 Objectives

1.5.1 Main objective

To determine the effect of early intermittent KMC on the incidence of neonatal mortality and morbidity and the amount of weight gain during the neonatal period.

1.5.2 Specific objectives

1. To compare the incidence of neonatal mortality among stable LBW infants on early intermittent KMC with those on conventional care

2. To compare the incidence of neonatal morbidity among stable LBW infants on early intermittent KMC with those on conventional care

3. To compare the amount of weight gained during the neonatal period among LBW infants on early intermittent KMC with LBW infants on conventional care

1.6 Research hypotheses

1. Early intermittent KMC leads to significantly decreased incidence of neonatal mortality among stable LBW infants compared to conventional care

2. Early intermittent KMC leads to significantly decreased incidence of neonatal morbidity among stable LBW infants compared to conventional care

3. Early intermittent KMC leads to significantly more weight gain during the neonatal period in stable LBW infants compared to conventional care

CHAPTER TWO

LITERATURE REVIEW

2.1 Neonatal mortality

The risk of dying is highest in the first 28 days of life everywhere in the world, with a 2016 global neonatal mortality rate (NMR) at 19 deaths per 1,000 live births. In 2016, 2.6 million neonates died, which was about 7,000 newborn deaths every day. About 1 million of the neonates died on the first day of life and almost another 1 million died in the next six days of age (UNICEF, 2014, 2018c; WHO, 2017). The annual NMR has reduced since 2000 by 2.1%, but this remains slower than the rate of mortality reduction amongst children aged 1-59 months which was 2.9% for the same period (Lawn *et al*., 2012; Newborn Survival Decade of Change Analysis core group, 2012; Rajaratnam *et al*., 2010). At this reduction rate, more than 60 countries will miss the SDG target of reducing NMR to ≤12 deaths per 1000 live births by 2030 (UN, 2015; WHO, 2017).

The 2016 high NMR of 28 deaths per 1,000 live births in SSA is evidence of the disparities in child survival across different regions. About 1 in every 36 neonates die in SSA compared to 1 in every 333 neonates in the world's high-income regions. This meant that, a neonate in SSA was 9 times more likely to die than those in high-income regions in 2016. The annual NMR reduction rate from 2000 to 2016 was 2.5% in SSA compared to a global average of 3.1%, with Eastern Asia recording 8.6% reduction (UNICEF, 2017, 2018a).

The NMR in Kenya was 22 deaths per 1,000 live births between 2009 and 2013, accounting for 59 percent of all infant deaths (KDHS, 2014). There was remarkable reduction in all levels of early childhood mortality rates between 2003 and 2014 KDHS surveys, but NMR had the lowest reduction. In Nairobi, the NMR was 39 deaths per 1,000 live births for the 5 years preceding the KDHS 2014, making it the highest in the country. Eastern and Central regions of Kenya had a NMR of 24 deaths per 1,000 live births while urban areas had 26 deaths per 1,000 live births during the same period (KDHS, 2008; KDHS, 2014; Kimani-Murage *et al*., 2014; UNICEF, 2018b).

There are multiple factors that lead to neonatal mortality. Mosely and Chen (1984) developed a theoretical model explaining the factors contributing to neonatal mortality. The model highlighted the role of socioeconomic factors (like education level and income) that work through proximate factors (like neonatal injury, delivery factors, maternal factors, environmental factors, neonatal factors and nutritional deficiency) to influence incidence of neonatal mortality (Hill, 2003; Masuy-Stroobant, 2001; Mosley and Chen, 1984). There are direct causes of neonatal mortality including complications of prematurity (35%), intrapartum complications (24%) and infections such as sepsis (15%) and pneumonia (6%). There are other causes that include congenital anomalies (11%), injuries (1%), diarrhea (1%), tetanus (1%) and other infections (7%) (Shrivastava *et al.*, 2013; UNICEF, 2018a; WHO, 2018). LBW is an underlying factor of neonatal deaths, accounting for 60-80% of all neonatal deaths (WHO, 2015a).

2.2 Low birth weight

Low birth weight has been defined by the WHO as weight at birth of less than 2500 grams (WHO, 2014). The global LBW prevalence is estimated at 15-20%, which translates to about 20 million LBW infants each year, with over 95% of them occurring in developing countries (WHO, 2015a, 2014). It is estimated that 13% of all infants in SSA are LBW, though many deliveries occur at home and 54% of infants are not weighed at birth based on 2008-2012 data (WHO, 2014).

In Kenya, a national survey in 2014 showed that 8% of all live births with documented birth weight were LBW, an increase from 6% based on a similar survey in 2008 (KDHS, 2008; KDHS, 2014). However, this figure may have been higher considering that 34 of births were not weighed (KDHS, 2014). Nairobi, where 88% of newborns had a recorded birth weight, the prevalence of LBW was 8.9%

compared to 8.4% in Eastern where 67% of births had a recorded birth weight. In Central Kenya, prevalence of LBW was 9.2% among the 96% of infants with a recorded birth weight (KDHS, 2014).

Low birth weight encompasses preterm neonates, small for gestational age neonates and the overlap between these two (WHO, 2014). Preterm birth has been shown as the largest direct cause of neonatal mortality (Shrivastava *et al.*, 2013). Further, LBW has a close association with neonatal morbidity and inhibited growth among other unfavorable health outcomes in neonates (UNICEF & WHO, 2004). This underscores the need for effective interventions for taking care of LBW infants to reduce neonatal mortality, neonatal morbidity and improve neonatal growth.

2.3 Kangaroo mother care

Kangaroo mother care is a technique for taking care of LBW infants by having SSC with the mother or a caregiver (WHO, 2016a, 2003). The WHO has endorsed the use of KMC for routine care of LBW newborns with a birth weight of ≤2000 grams, especially the clinically stable infants. This recommendation was based on the available moderate-quality evidence (WHO, 2015b). KMC works by providing warmth (thermal care) and increasing opportunities for breastfeeding irrespective of the setting, birth weight or gestational age (Maternal and Child Health Integrated Program (MCHIP), 2012).

The ideal KMC is continuous, which involves early and prolonged SSC between a LBW infant and the mother or a caregiver (Bera *et al*., 2014; Boju *et al*., 2012; Moore *et al*., 2012; WHO, 2016b, 2003). In different settings, shorter durations of KMC have been practiced and these usually range from four to six hours per day. This is referred to as intermittent KMC and is done for short periods of time either once or a few times every day for a variable duration of time depending on the setting (Boju *et al*., 2012; Charpak *et al*., 1997; Conde-Agudelo *et al*., 2011). Other variations in the practice of KMC involve exclusive or non-exclusive breastfeeding, breast or tube feeding, a completely nude or partially nude infant and early KMC

(SSC started within 24 hours post birth) or late KMC (SSC started after 24 hours post birth) (Conde-Agudelo *et al.,* 2011).

Many proponents of KMC have pointed out that the acceptance of the practice is high and its more baby and mother-friendly when compared to conventional care (Lawn *et al.,* 2010). A WHO guidance on KMC also says that it is acceptable to health workers and that presence of mothers in the ward does not bother the health workers. Many of these health workers consider KMC to be practical and would consider it for care of their own babies (WHO, 2003).

Some studies conducted on acceptability of KMC have presented findings supportive of high acceptability by various KMC stakeholders. Some have reported high acceptability by both mothers and the nursing team while others have found it acceptable in different settings including resource-limited settings (Gathwala *et al.,* 2010; Kadam *et al*., 2005; Lima *et al.,* 2000).

A study by Worku and Kassie, (2005) reported that more than 95 per cent of mothers reported that they were happy to care for their LBW babies using the KMC method. However, some have noted that in reality, there are many obstacles for the practice of KMC especially for unstable infants. Some of these obstacles have been noted to be the KMC technique, the relationship between the infant's family and health workers, as well as cultural acceptance (Nagai, *et al.,* 2010).

A study carried out in India at a tertiary hospital concluded that KMC was simple and feasible infants (Kadam *et al*., 2005). This was of particular importance in resource-limited settings where conventional neonatal care is usually expensive and may not be available to all LBW infants (Kadam *et al*., 2005). This observation was in congruence with another study done in Brazil, which reported that KMC in stabilized LBW infants was feasible and cheap in hospital set ups (Lima *et al.,* 2000).

Worku and Kassie, (2005) recommend that the feasibility of community KMC still needs to be studied further. It is important to note that despite the reported high acceptability and feasibility of KMC, only a few LBW infants in resource-limited countries have access to this intervention (Shrivastava *et al.*, 2013).

2.4 Effectiveness of Kangaroo mother care in improving neonatal health outcomes

2.4.1 Effectiveness of Kangaroo mother care in reducing neonatal mortality

The available evidence suggests that KMC is effective in reducing neonatal mortality when compared to neonatal care (Boundy *et al*., 2016; Charpak *et al*., 1997; Conde-Agudelo *et al*., 2011; Conde-Agudelo and Díaz-Rossello, 2016; Lawn *et al*., 2010; Nagai *et al*., 2010; Sloan *et al*., 2011; WHO, 2016a; Worku and Kassie, 2005). A trial in Ethiopia reported that preterm LBW infants on early KMC group had better survival rate compared to those on the conventional neonatal care (Worku and Kassie, 2005). The KMC in this trial was initiated within the first 12 hours of life.

When compared to conventional neonatal care, an updated Cochrane review in 2016 show that KMC is effective in significantly reducing the risk of neonatal mortality with a typical risk ratio of 0.6 (Conde-Agudelo and Díaz-Rossello, 2016). These results were an update of the Cochrane review in 2011 that included intermittent and continuous KMC studies. Sub group analysis in 2011 showed some disparities in mortality outcomes among the two types of KMC and the time of initiation of KMC post birth. The decreased risk of mortality was only demonstrated in the sub groups that used continuous KMC, un-stabilized infants and those that initiated KMC within 10 days post-delivery. The sub group of trials that used intermittent KMC, those that initiated KMC 10 days after birth and those that used stabilized infants found no benefit of reduced risk of neonatal mortality (Conde-Agudelo *et al.*, 2011).

A meta-analysis in 2010 of three trials found that neonates ≤2000 grams put on KMC intervention in their first week of life had lower risk of mortality compared to those on conventional care. This finding was also corroborated by the results of observational studies included in the systematic review (Lawn *et al*., 2010).

The findings from an RCT in Colombia found that there were no significant differences in mortality rates of neonates on KMC intervention compared to those on conventional care. The study concluded that neonates on KMC were not at any additional risk of dying compared to those on conventional care (Charpak *et al*., 1997).

A Japan study evaluated the effectiveness of earlier continuous KMC (intervention begun within 24 hours post birth) compared to later continuous KMC (intervention begun after 24 hours post birth). This trial reported no significant differences in mortality rates between these two groups in the neonatal period. The study called for further evaluation of early KMC and measurement of SSC duration during KMC (Nagai, *et al.*, 2010).

2.4.2 Effectiveness of Kangaroo mother care in reducing neonatal morbidity

The use of KMC in LBW infants has been proposed as a safe and feasible alternative to conventional neonatal care and has been associated with the benefit of reducing neonatal morbidity including sepsis, pneumonia and asphyxia among others (Boju *et al*., 2012; Lawn *et al*., 2010). A systematic review in 2010 on KMC concluded that KMC was associated with significant reduction in morbidity of neonates weighing less than 2000 grams (Lawn *et al*., 2010). The studies included in the systematic review classified morbidity as severe infection which included sepsis, necrotizing enterocolitis and severe pneumonia.

The 2011 Cochrane review found similar results in stabilized LBW infants, where KMC was associated with a statistically significant reduction in severe infection/sepsis (Conde-Agudelo *et al.*, 2011; Conde-Agudelo and Díaz-Rossello, 2016). Subgroup analysis in the review showed that the reduced risk of hypothermia and severe infection was only in the trials that used intermittent KMC and not continuous KMC. However, the reduced risk of nosocomial infections was evident in both groups of intermittent and continuous KMC (Conde-Agudelo *et al.,* 2011). The review found no significant differences in the risk of mild or moderate infections and readmission to hospital when neonates under KMC intervention were compared to those on the conventional neonatal care (Conde-Agudelo at al., 2011).

The duration of hospital stay is influenced by neonatal morbidity and the ability to clear hospital bills among other factors (Mwendwa *et al.*, 2012). The length of hospital stay is significantly less among infants in the KMC intervention when compared to those on conventional neonatal care in many studies (Bhavana *et al,*. 2016; Mohammadzadeh *et al*., 2011; Mwendwa *et al.*, 2012; Rangey and Sheth, 2014) .

The 2011 systematic review found that KMC decreased length of hospital stay by 2.4 days (Conde-Agudelo *et al.*, 2011). The study by Charpak *et al.*, (1997) reported an average 1.1-day savings in duration of hospital stay for KMC infants. It is important to note that KMC as a package involves early discharge from the hospital and this should be taken in to account when measuring the length of hospital stay.

An RCT in a tertiary hospital in Bangladesh reported insignificant shorter duration of hospital among KMC infants (15.6 ± 10.6 days) when compared to conventional neonatal care (18.2 ± 4.5 days). This trial used intermittent KMC with a cumulative SSC of at least 12 hours a day (Rahman *et al*., 2017).

The Japan trial that compared early versus late onset KMC in stable LBW infants reported no differences in morbidity, severe infection, hospital readmission and hypothermia. However, the length of hospital stay was shorter in the early KMC group. This trial evaluated continuous KMC compared to conventional care (Nagai *et al*., 2010).

2.4.3 Effectiveness of Kangaroo mother care on neonatal weight gain

Several studies have reported that KMC significantly increases the amount of weight gain during the neonatal period (Bhavana *et al*., 2016; Conde-Agudelo *et al.,* 2011; Conde-Agudelo and Díaz-Rossello, 2016; Mwendwa *et al.,* 2012; Rahman *et al*., 2017; Swarnkar and Vagha, 2016; Vohra *et al.,* 2015). The 2011 Cochrane review reported that KMC infants had better weight gain per day than neonates under the conventional care (Conde-Agudelo *et al.*, 2011).

A study that compared early versus late continuous KMC reported that weight loss from birth to 24 hours after birth was significantly less in infants in the earlier KMC group than the late KMC group (Nagai *et al*., 2010). This trial measured weight changes from birth to 24 hours, 48 hours, day 14 and day 28. These findings support the theory that KMC has better weight gain parameters especially when started early.

A 2002 study compared infant weight loss among intermittent KMC infants and infants on conventional care. This trial found that there was no significant difference for weight loss between the intermittent KMC group and the conventional care group on day 1, day 2, day 14 and day 28. However, the authors report high attrition of follow up on day 14 and day 28 (Miao-Ju *et al*., 2002).

Findings of non-statistically significant differences in infant body weight change from birth to day 14 between KMC infants and infants on control group have also been reported by a 2012 Cochrane review (Moore *et al*., 2012).

2.5 Theoretical framework

This study was guided by the analytical framework by Mosley and Chen, (1984) developed for analyzing social and biological variables that affect infant mortality. The model, as depicted in **figure 2.1,** proposes that the impact on neonatal mortality is influenced by socioeconomic determinants (independent variables) that operate through a certain set of proximate determinants and health interventions (intermediate variables) (Hill, 2003; Masuy-Stroobant, 2001; Mosley and Chen, 1984).

2.5.1 Socioeconomic determinants

The socioeconomic determinants that affect neonatal mortality are education level (both mother and father), household income and traditions/religious practices that influence household's economic and health-related practices (Masuy-Stroobant, 2001; Mosley and Chen, 1984). Income influences child health through food choices, water (quantity and quality), housing, clothing, hygiene and sickness care among others (Mosley and Chen, 1984).

2.5.2 Proximate determinants

The proximate determinants are maternal factors; environmental contamination; nutrient deficiency; injury and personal illness control (Hill, 2003; Masuy-Stroobant, 2001; Mosley & Chen, 1984).

Maternal factors include age, parity and birth interval while environmental contamination is measured through household crowding (persons per room), source of water supply, presence of toilettes and incidence of diarrhea (Mosley & Chen, 1984). Personal illness control affects the rate of recovery and the outcomes include complete recovery, growth faltering, disability and/or death (Mosley & Chen, 1984).

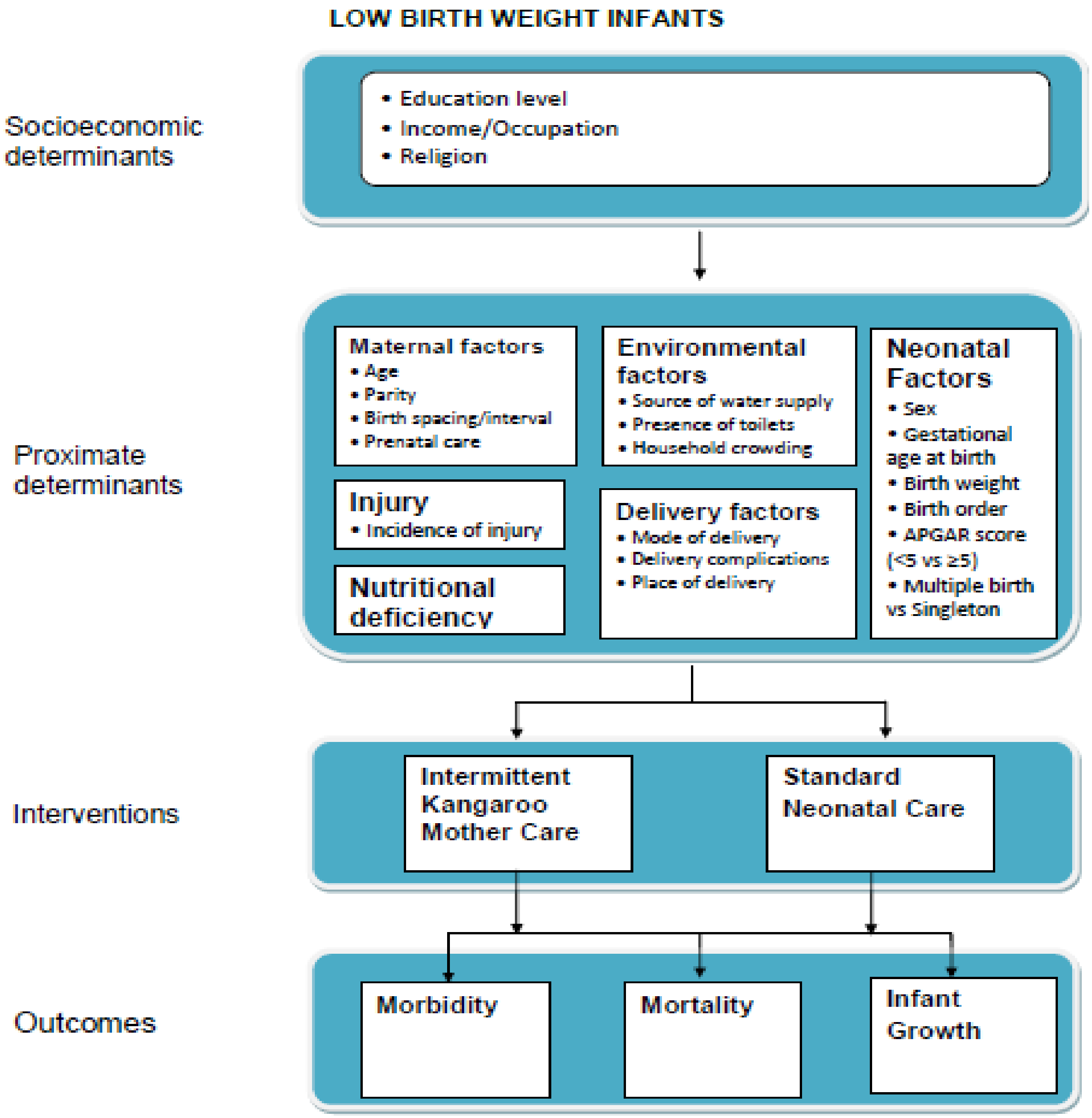

Figure 2.1: Adapted Mosley and Chen Analytical Framework (1984)

2.5.3 Previous use of the Mosley and Chen (1984) analytical framework

The analytical model developed by Mosley and Chen, (1984) has stood the test of time and has been used as a framework for many studies on child survival (Hill, 2003). The theoretical framework has been used to explain the socioeconomic determinants of under-five mortality in the three African cities (Ogada, 2014). In

Vietnam, the framework has been used to guide the study of socioeconomic and proximate determinants such as maternal factors, health system factors, neonatal factors, delivery factors and postnatal care factors influencing neonatal mortality (Målqvist, 2011). This study also explored the role of health interventions in preventing neonatal mortality. The analytical framework was adapted to identify possible predictors of neonatal mortality in Indonesia (Titaley *et al*., 2008), with community level contextual variables, socioeconomic and proximate factors as explanatory variables. The impact of household and community level environmental factors on infant and child mortality in rural Kenya has also been studied using the model (K 'oyugi, 1992).

2.6 Research gaps

Neonatal mortality rate was high in Kenya and the rest of the world (Rajaratnam *et al*., 2010; UNICEF, 2018c, 2017; WHO, 2017). There was need to implement effective interventions that could reduce the neonatal mortality rate, especially among LBW infants where it contributed to 60-80 per cent of all neonatal deaths (WHO, 2015a). From existing studies, the decreased risk of neonatal mortality had only been demonstrated among infants on continuous KMC. There was limited data on the effectiveness of early intermittent KMC on neonatal mortality. Trials that had used stable infants or initiated KMC late (10 days post birth) had not demonstrated any reduced risk of neonatal mortality. More studies are needed to determine the effectiveness of early intermittent KMC in reducing neonatal mortality.

Intermittent KMC (and not continuous KMC) had been shown to reduce the risk of severe neonatal morbidity, but not mild or moderate infections (Conde-Agudelo and Díaz-Rossello, 2016). More data is needed on the effectiveness of early intermittent KMC (recurrent one hour of SSC in every 3 hours) versus conventional neonatal care.

There is mixed evidence from the reviewed studies on the role of early intermittent KMC in increasing neonatal weight gain. A study on early continuous KMC (Nagai, *et al.*, 2010) has reported that early KMC may have better weight gain parameters than conventional neonatal care. Findings from the Conde-Agudelo *et al.*, (2011) Cochrane review showed that KMC infants had better weight gain per day, than control infants. Notable in this review is that, there was considerable heterogeneity (I^2 = 88%) among the trials reporting weight gain. Nonetheless, this contrasts findings from a 2012 Cochrane review by Moore *et al.*, (2012) that found that the infant body weight changes from birth to day 14 was not statistically different between KMC infants and control infants. More data is needed in assessing the role of early intermittent KMC in increasing weight gain during the neonatal period.

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study design

This was a clustered quasi-experimental study that had one intervention group and one control group. The intervention group consisted of LBW infants on early intermittent KMC while the control group consisted of LBW infants on the conventional neonatal care.

3.2 Study population

The study population was stable LBW infants weighing ≤2000 grams irrespective of their gestational age. These were drawn from the three hospitals during the study period.

3.3 Study area

The intervention site was Pumwani Maternity Hospital, in Nairobi City. It is one of the largest public maternity referral hospitals in Kenya with 350 beds and 150 cots (MOH, 2011). The hospital is located on the east of Nairobi City and serves mainly the low-income residents of the nearby areas.

The control sites were Thika Level 5 hospital and Machakos Level 5 hospital. Thika Level 5 hospital is one of the largest public hospitals in Kiambu County. It is located in Thika town and serves patients from rural areas around it and low-income residents of Kiandutu slums. It has 265 beds and 24 cots (MOH, 2011). Machakos Level 5 Hospital is the biggest public health facility in Machakos County with 375 beds and 57 cots. It serves residents from Machakos town including the low-income residents of *Mjini*, which is an informal settlement (MOH, 2011).

The choice of having two sites for the control group was informed by the number of deliveries in these sites that could match the number of deliveries in intervention site.

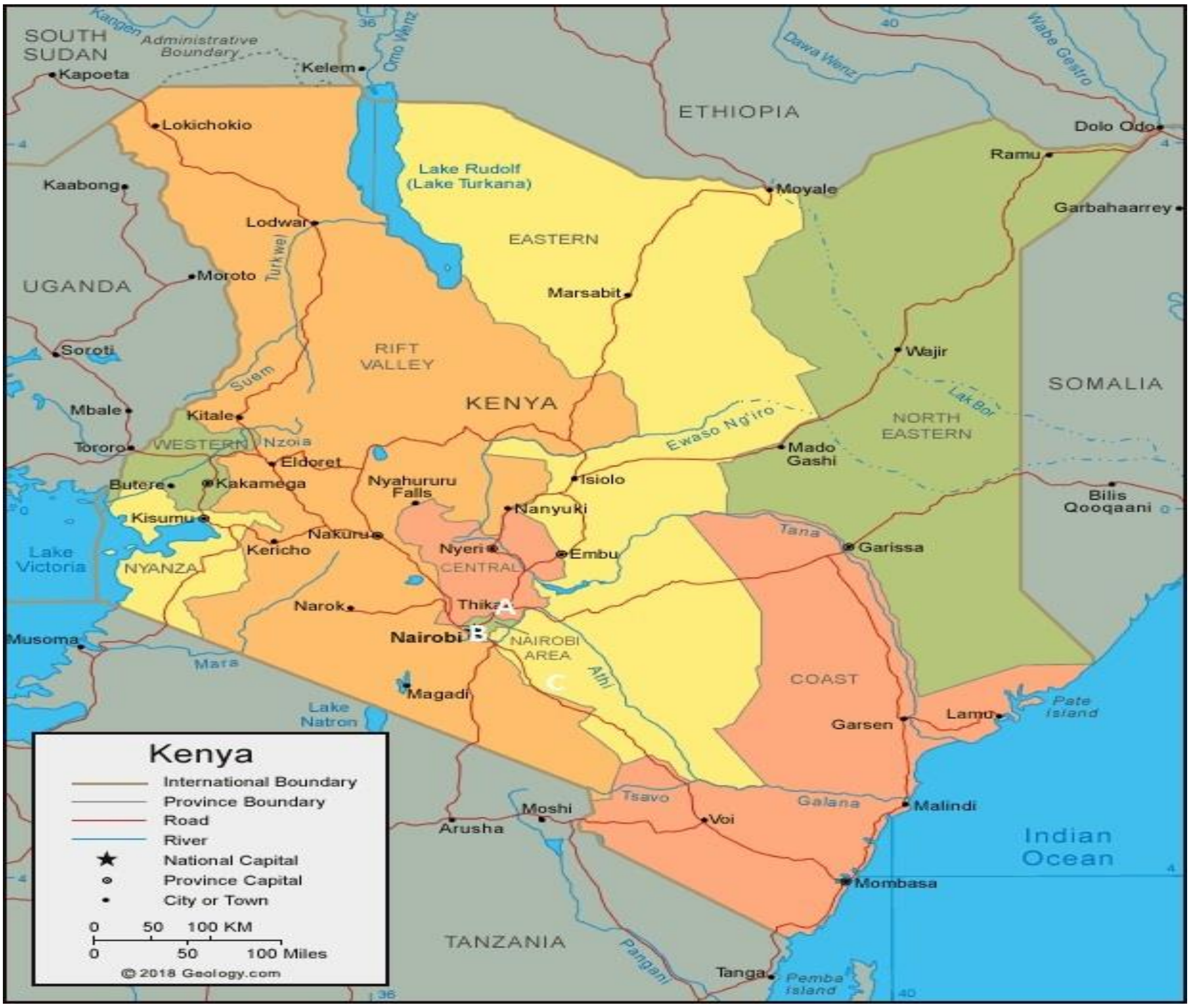

Figure 3.1: A map of Kenya showing location of the selected hospitals

KEY

A. Thika Level 5 Hospital

B. Pumwani Maternity Hospital

C. Machakos Level 5 Hospital

3.4 Inclusion criteria

All infants at the study sites who met the following criteria were included in the study; infants weighing ≤ 2000 grams irrespective of their gestational age, infants less than 72 hours of life, stable infants (whose cardiovascular and respiratory functions did not require continuous support or monitoring), mother of LBW infant willing to practice KMC and mother of LBW infant willing to give informed written consent. The criteria for the mother of LBW infant willing to practice early intermittent KMC was only applicable at the intervention site (Pumwani Maternity Hospital) as this is where the intervention was offered.

Infants at the study hospitals with major congenital malformations and severe perinatal complications were excluded from the study.

3.5 Sampling procedure

The neonatal unit admission register was used to identify infants who met the inclusion criteria for the study. The research assistants recruited all eligible infants at the study sites consecutively until a sufficient sample was attained. There was no sampling or randomization of the subjects.

3.6 Sample size determination

The sample size was computed using a formula for hypothesis tests for relative risks (Lwanga and Lemeshow, 1991) using a two-tailed test, a level of statistical significance of $p < 0.05$ and a power of 80 percent.

$$n = \frac{(Z_{\frac{\alpha}{2}} + Z_{\beta})^2 * [P_1(1-P_1) + P_2(1-P_2)]}{(P_1 - P_2)^2}$$

Where; $Z_{\frac{\alpha}{2}}$ represented the level of confidence (95%), Z_{β} represented the power of the study (80%), P_1 represented the assumed proportion with morbidity for the control group, P_2 was the assumed proportion with morbidity for the intervention group and n was the desired minimum sample size to detect a 15 percent reduction in incidence of neonatal morbidity.

Thus;

$Z_{\frac{\alpha}{2}}$ = 1.96; Z_{β} = 0.84; P_1 = 0.4; P_2 = 0.25

n = 165 LBW infants

3.7 Implementation of the study procedures

The researcher introduced and prepared Pumwani Maternity Hospital (intervention site) to offer KMC services. Through the hospital management, a specific room was identified and designated for the practice of KMC. A one-week KMC training was done at the facility targeting the Managers and health workers taking care of the LBW infants in the newborn unit. The training was done by a pediatrician and a nurse.

The LBW infants at the intervention site were started on KMC as soon as possible after birth and within 72 hours. Early intermittent KMC involved SSC contact in which the LBW infants were placed vertically (prone) between the mother's breasts, firmly attached to the chest and below her clothes for a cumulative period of at least 8 hours a day. The 8-hour period was done in 8 sessions a day with each session about one hour. During the SSC, the infants were naked and only wore a diaper, hat, and/or socks. The early intermittent KMC practice was continued in-hospital or post-discharge, until the infant attained the weight of at least 2500 grams.

At the control sites, where KMC was not being implemented, the health workers were not trained on KMC. Care of LBW infants continued to be offered by health workers as was the routine before the study (conventional neonatal care). Thermal care was generally through an artificial warming system (incubator).

At 28 days of age, discharged infants were brought back to the hospital to assess the condition of the baby and carry out an anthropometric evaluation. A short message service was sent to the mothers to remind them of the post-discharge appointment date. Those who did not show up for the appointment were called on the appointment date. During the phone call, the research assistant tried to establish the reason for failed appointment, the possibility of rescheduling the appointment and the condition of the baby. Once the baby was brought to the hospital for the appointment, the baby was weighed and assessed for any morbidity. Those who could not make it back to the facility were requested to go to the nearest health facility for weighing and report the infant weight to the research assistant.

3.8 Outcome measures of the study

The primary outcome measures of the study were; incidence of neonatal morbidity; incidence of neonatal mortality; and weight gain during the neonatal period. Neonatal mortality measured as any infant death that occurred during the neonatal period while incidence of neonatal morbidity was measured as any occurrence of neonatal complication as diagnosed by a pediatrician during the neonatal period. Weight gain was measured as the difference between weight of infants at 28 days of age and birth weight.

The secondary outcome measures of the study were; the duration of hospital stay and incidence of hospital readmission. Duration of hospital stay was measured as the difference in time (hours) from time of admission to newborn unit to time of discharge. Incidence of hospital readmission was measured as any occurrence where the LW infant had to be admitted to the hospital after discharge.

3.9 Data collection procedure

Data was collected by research assistants from mothers and infants who met the inclusion criteria. The research assistants explained to the mothers the details of the study using the information contained in the informed consent form (Appendix I). Those who consented to participate in the study were given an entry questionnaire (Appendix II).

A data abstraction tool (Appendix III) was used to abstract data from clinical records (KMC register and patients' files). An exit questionnaire (Appendix IV) was administered at the last follow up period (at 28 days of age).

3.10 Reliability and validity

The data collection tools were based on literature review, theoretical framework and tools used in other similar studies. Input on the tools was sought from the supervisors and content experts.

A pretest of the tools was done with colleagues of the researcher at a public health nongovernmental organization and two LBW infants in Pumwani hospital who were not part of the study. The questionnaires were revised to incorporate findings from the pilot study. Strategies for follow up of the subjects after discharge were put in place to reduce attrition.

3.11 Data management and analysis

3.11.1 Data entry and storage

Data was entered in a Microsoft Excel template with designed data validation rules to reduce entry errors. It was cleaned, exported to Stata Release 15 for analysis and saved in iCloud for back up.

3.11.2 Recoding of variables

During data analysis, responses that were very few were collapsed/recoded to allow for robust analysis. Responses of separated under the variable marital status were recoded as single. In level of education, none and primary levels were combined as none and primary. Monthly household income of more than 30000 and 15000-30000 was combined as one category of more than 15000. Responses on diabetes, hypertension and other chronic conditions were used to generate a composite variable called non communicable diseases (NCDs). Responses on pregnancy history was grouped in the following categories; Primigravida, No history of pregnancy loss with 1 or more live births , History of 1 or more pregnancy loss with 1 or more live births and History of 1 or more pregnancy loss with no live birth .

Apgar score at one minute was categorized as below 5 and above 5. Some variables were dropped during the analysis as they produced spurious results or were missing in many cases. These included type of floor, walls, food groups and number of rooms.

The type of care was treated as independent variable. Conventional neonatal care was coded as 0 and used as the reference category, while intermittent KMC was coded as 1.

There were five dependent variables which were the outcome measures of the study (neonatal mortality, neonatal morbidity, hospital admission, duration of hospital stay and weight changes). Neonatal mortality, neonatal morbidity, and hospital admission were coded as 0 for "no" and 1 for "yes" responses during the analysis. Weight gain during the neonatal period and duration of hospital stay were treated as a continuous variable.

3.11.3 Data analysis

Descriptive statistics were used to summarize and describe socioeconomic characteristics, proximate characteristics and outcomes measures through means, standard errors and frequencies. These background characteristics in the intervention and control sites were presented in a table. Significance tests were conducted to compare the baseline characteristics between the study arms.

Bivariate analysis using logistic regression were conducted to test the association between independent variables (baseline characteristics and type of neonatal care) and outcome measures of the study (morbidity, hospital readmission and mortality). Relative risks were computed to compare the incidence of neonatal mortality and morbidity among stable LBW infants on early intermittent KMC with those on conventional care.

Independent t-test was used to compare the mean weight gain during the neonatal period for LBW infants on early intermittent KMC and LBW infants on conventional care. Independent t-test was also used to compare the mean weight duration of hospital stay (hours) for LBW infants on early intermittent KMC and LBW infants on conventional care.

Multivariable logistic regression analysis was done to control for other variables that may influence the outcome measures of the study (mortality, morbidity and hospital admission). Multivariable linear analysis was conducted to control for other independent variables that may influence weight gain during the neonatal period and duration of hospital stay. Sub group analysis was conducted to adjust for difference in birth weight using two weight categories; ≤1500 grams and >1500 grams. P-values ≤0.05 were considered statistically significant.

3.12 Ethical considerations

The study was approved by the Kenyatta National Hospital (KNH) Ethics Review Committee (ERC), number P754/12/2015 (Appendix V). The permit to conduct the study was given by National Commission for Science, Technology and Innovation (NACOSTI), number NACOSTI/P/16/83568/10725 (Appendix VI). Institutional permission was sought from the management of the three study hospitals.

Informed written consent was obtained from mothers of infants who met the inclusion criteria. Participation in the study was voluntary and no one was coerced to participate. To ensure protection of the health records, study codes were used in place of the names of the mothers.

The researcher made provisions for any child (both in control or study group) who developed any complication during the course of the study to be managed according to the hospital protocols of the presenting complains and diagnosis. The researcher put in place a referral mechanism to counseling within the study hospitals to mitigate any emotional risk that may have arisen from participating in the study.

CHAPTER FOUR

RESULTS

4.1 Distribution of the study subjects across the study sites

A total of 343 LBW infants were recruited in the study between July 2016 and June 2017. Pumwani hospital, the intervention site, contributed 171 (49.9%) of the infants, the other 172 (50.1%) were from the control sites. The subjects were fairly distributed between the two control sites: Machakos hospital with 85 (24.8%) and Thika hospital with 87 (25.4%) infants, as shown in **figure 4.1**.

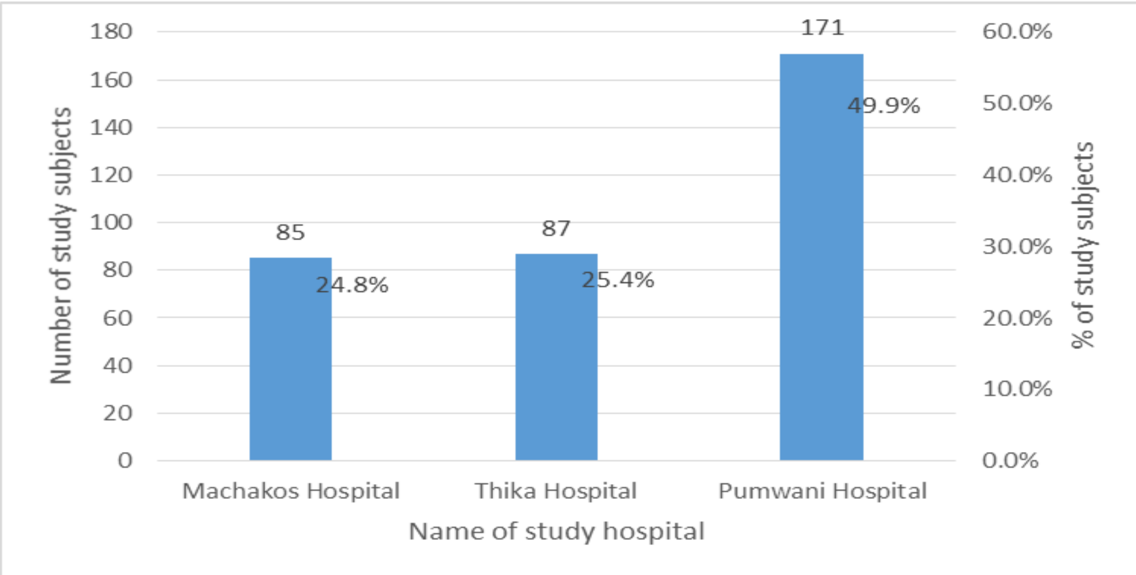

Figure 4.1: Distribution of the study subjects across the study sites

4.2 Socioeconomic characteristics of the study subjects in the intervention and control groups

A third of the respondents had household income of below 6,000 Kenya shillings per month (about 60 USD), with 268 (78.1%) renting the house they were living in. Two in every ten (22.2%) mothers of LBW infants were living in a temporary house while 82 (23.9%) had no access to a toilet. A third of the mothers (103) used kerosene as the main fuel for cooking, 19 mothers (5.5%) used river/pond as the main source of water for drinking and 37 (10.9%) mothers reported an incidence of diarrhea in the last three months before delivery.

The distribution of the socioeconomic characteristics are shown in **Table 4.1** for the intervention and control groups. Most of these characteristics were significantly different between the two groups.

Table 4.1 Socioeconomic characteristics of the study subjects in the intervention and control groups

Variables	All subjects	Intervention	Control	P value
	Frequency (%)	Frequency (%)	Frequency (%)	
Household income per month (KES)				
<6000	110 (34.4%)	64 (40.5%)	46 (28.4%)	<0.001
6000 to 15000	109 (34.1%)	65 (41.1%)	44 (27.2%)	
>15000	101 (31.6%)	29 (18.4%)	72 (44.4%)	
Type of house ownership				
Own	75 (21.9%)	12 (7%)	63 (36.6%)	<0.001
Rented	268 (78.1%)	159 (93%)	109 (63.4%)	
Type of house				
Permanent	233 (68.9%)	98 (59%)	135 (78.5%)	<0.001
Semi-permanent	30 (8.9%)	23 (13.9%)	7 (4.1%)	
Temporary	75 (22.2%)	45 (27.1%)	30 (17.4%)	
Access to toilet				
No	82 (23.9%)	32 (18.7%)	50 (29.1%)	0.025
Yes	261 (76.1%)	139 (81.3%)	122 (70.9%)	
Source of fuel for cooking				
Electricity/Gas	163 (47.7%)	77 (45.3%)	86 (50%)	<0.001
Charcoal	76 (22.2%)	16 (9.4%)	60 (34.9%)	
Kerosene	103 (30.1%)	77 (45.3%)	26 (15.1%)	
Source of drinking water				
Piped	284 (82.8%)	159 (93%)	125 (72.7%)	<0.001
River/pond	19 (5.5%)	4 (2.3%)	15 (8.7%)	
Well/borehole	40 (11.7%)	8 (4.7%)	32 (18.6%)	
Incidence of diarrhea in last 3 months among mothers of subjects				
No	302 (89.1%)	149 (88.7%)	153 (89.5%)	0.817
Yes	37 (10.9%)	19 (11.3%)	18 (10.5%)	

KES= Kenya shilling

4.3 Sociodemographic characteristics of the study subjects

4.3.1 Age characteristics of mothers in the intervention and control groups

The mean age of mothers of the LBW infants in the KMC arm was 25 years (SE=0.4) while the mean age of mothers of the LBW infants in the control arm was

25.8 years (SE=0.4). Majority of the mothers in the intervention group (33.9%) were aged between 20-25 years while majority of the mothers in the control group (40.1%) were aged 25-30 years. This difference was not statistically significant (p>0.05) as shown in **Table 4.2**.

Table 4.2: Age characteristics of mothers in the intervention and control groups

	All subjects	**Intervention**	**Control**	**P Value**
Age category (Years)	**Frequency (%)**	**Frequency (%)**	**Frequency (%)**	0.110
15-20	69 (20.1%)	40 (23.4%)	29 (16.9%)	
20-25	105 (30.6%)	58 (33.9%)	47 (27.3%)	
25-30	116 (33.8%)	47 (27.5%)	69 (40.1%)	
30-35	40 (11.7%)	21 (12.3%)	19 (11.1%)	
35-40	8 (2.3%)	4 (2.3%)	4 (2.3%)	
>45	5 (1.5%)	1 (0.6%)	4 (2.3%)	
Total	343 (100%)	171 (100%)	172 (100%)	

4.3.2 Marital status and education level characteristics in the intervention and control groups

There were 274 (79.9%) mothers of LBW infants who were married and 172 (50.2%) with secondary education. In the intervention group, 40 (28.2%) of the spouse’s level of education was none and primary compared to 11 (7.8%) in the control group. For secondary and tertiary categories, the spouse’s level of education was significantly higher in the control group than the intervention group (p<0.001). The distribution of the marital and education level characteristics were as shown in **Table 4.3** for the intervention and control groups.

Table 4.3: Marital status and education level characteristics in the intervention and control groups

Variable	All subjects	Intervention	Control	P value
	Frequency (%)	**Frequency (%)**	**Frequency (%)**	
Marital Status				
Married/cohabiting	274 (79.9%)	133 (77.8%)	141 (82%)	0.332
Single	69 (20.1%)	38 (22.2%)	31 (18%)	
Mother's level of education				
None and Primary	118 (34.4%)	65 (38%)	53 (30.8%)	0.305
Secondary	172 (50.2%)	79 (46.2%)	93 (54.1%)	
Tertiary	53 (15.5%)	27 (15.8%)	26 (15.1%)	
Spouse's level of education				
None and Primary	51 (18%)	40 (28.2%)	11 (7.8%)	<0.001
Secondary	168 (59.4%)	72 (50.7%)	96 (68.1%)	
Tertiary	64 (22.6%)	30 (21.1%)	34 (24.1%)	

4.3.3 Birth weight and gestational age characteristics in the intervention and control groups

The mean birth weight among infants in the intervention group was 1555.4 grams (SE=20.8) while the mean birth weight among infants in the control group was 1430.1 grams (20.2). The mean gestational age in the intervention group was 32.2 weeks (SE=0.2) while the mean gestational age in the control group was 28.5 weeks (SE=0.3) as shown in **Table 4.4**.

Table 4.4: Birth weight and gestational age characteristics in the intervention and control groups

Variable	Frequency	Mean	95% Confidence Interval
Birth weight			
Control group	172	1430.1	1390.2-1470.0
Intervention group	171	1555.4	1514.4-1596.4
Gestational age			
Control group	172	28.5	27.94-29.0
Intervention group	169	32.2	31.7-32.6

4.3.4 Maternal characteristics in the intervention and control groups

A birth interval of more than 36 months was reported by 92 (63.9%) of all the mothers. There were significant differences in the control and intervention group in the distribution of the birth interval (p=0.041). Antenatal clinic attendance was reported by 316 (93.2%) of all the mothers. A third of the mothers (112) were primigravida while half (169) reported having no pregnancy loss and having 1 or more live births before their most recent pregnancy.

The distribution of the maternal characteristics among the intervention and control groups was as shown in **Table 4.5**.

Table 4.5: Maternal characteristics in the intervention and control groups

Variables	**All subjects**	**Intervention**	**Control**	**P value**
	Frequency (%)	**Frequency (%)**	**Frequency (%)**	
Birth interval				
<18 months	24 (16.7%)	7 (10%)	17 (23%)	0.041
18-36 months	28 (19.4%)	18 (25.7%)	10 (13.5%)	
>36 months	92 (63.9%)	45 (64.3%)	47 (63.5%)	
ANC attendance				0.840
No	23 (6.8%)	12 (7.1%)	11 (6.5%)	
Yes	316 (93.2%)	158 (92.9%)	158 (93.5%)	
Pregnancy history				<0.001
Primigravida	112 (34%)	83 (51.9%)	29 (17.2%)	
No history of pregnancy loss with 1 or more live births	169 (51.4%)	65 (40.6%)	104 (61.5%)	
History of 1 or more pregnancy loss with 1 or more live births	38 (11.6%)	9 (5.6%)	29 (17.2%)	
History of 1 or more pregnancy loss with no live birth	10 (3%)	3 (1.9%)	7 (4.1%)	

ANC = Antenatal Clinic

4.3.5 Timing of first antenatal clinic attendance among mothers of the LBW Infants

Of the 315 mothers who attended antenatal clinic (ANC), 97 (30.8%) attended first ANC during their first trimester, 193 (61.3%) during their second trimester and 25 (7.9%) during their third trimester, as shown in **figure 4.2**. The timing of first ANC visit between the intervention and control group was significantly different (p=0.045).

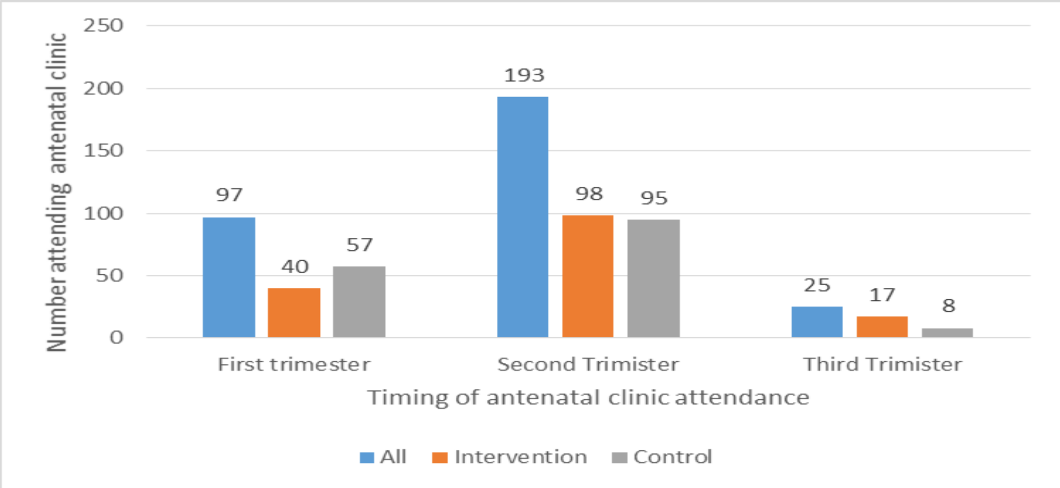

Figure 4.2: Timing of first antenatal clinic attendance among mothers of the study subjects in intervention and control groups

4.3.6 Delivery characteristics in the intervention and control groups

Most of the infants (78.4%) were born in the study hospitals. A total of 285 (83.3%) study subjects were born through spontaneous vaginal delivery (normal delivery). Delivery complications were recorded in 91 (26.6%) of the births. The distribution of the delivery characteristics among the intervention and control groups were not significantly different as shown in **Table 4.6**.

Table 4.6: Delivery characteristics in the intervention and control groups

Variables	All subjects	Intervention	Control	P value
	Frequency (%)	Frequency (%)	Frequency (%)	
Place of delivery				0.433
Study hospital	269 (78.4%)	139 (81.3%)	130 (75.6%)	
A different hospital from the study hospital	47 (13.7%)	20 (11.7%)	27 (15.7%)	
Home	27 (7.9%)	12 (7%)	15 (8.7%)	
Mode of delivery				0.629
Cesarean section	57 (16.7%)	30 (17.7%)	27 (15.7%)	
Normal	285 (83.3%)	140 (82.4%)	145 (84.3%)	
Delivery complications				0.178
No	251 (73.4%)	131 (76.6%)	120 (70.2%)	
Yes	91 (26.6%)	40 (23.4%)	51 (29.8%)	

4.3.7 Neonatal characteristics in the intervention and control groups

Most of the infants (59.8%) were female, with majority (71%) born as singleton. Majority of the subjects (81.4%) had an Apgar score of more than 5 at one minute. The distribution of the neonatal characteristics among the intervention and control groups were significantly different for infant sex and Apgar score at one minute as shown in **Table 4.7**.

Table 4.7: Neonatal characteristics in the intervention and control groups

Variables	All subjects	Intervention	Control	P value
	Frequency (%)	Frequency (%)	Frequency (%)	
Infant sex				
Female	205 (59.8%)	83 (48.5%)	122 (70.9%)	<0.001
Male	138 (40.2%)	88 (51.5%)	50 (29.1%)	
Multiple births				0.201
No	242(71%)	116 (67.8%)	126 (74.1%)	
Yes	99 (29%)	55 (32.2%)	44 (25.9%)	
Apgar score at 1 minute				0.012
Apgar score <5	56 (18.6%)	20 (13.1%)	36 (24.3%)	
Apgar Score >5	245 (81.4%)	133 (86.9%)	112 (75.7%)	

4.3.8 Nutritional characteristics in the intervention and control groups

There were more mothers (57%) having three meals a day during pregnancy than any other category. Most of the mothers, 240 (70%) reported use of micronutrients during their most recent pregnancy. The distribution of the nutritional characteristics among the intervention and control groups were significantly different as shown in **Table 4.8**.

Table 4.8: Nutritional characteristics in the intervention and control groups

Variables	All subjects	Intervention	Control	P value
	Frequency (%)	**Frequency (%)**	**Frequency (%)**	
Average number of meals per day when pregnant				<0.001
One	15 (4.4%)	8 (4.7%)	7 (4.1%)	
Two	41 (12%)	31 (18.1%)	10 (5.9%)	
Three	195 (57%)	81 (47.4%)	114 (66.7%)	
More than three	91 (26.6%)	51 (29.8%)	40 (23.4%)	
Use of micronutrient supplementation				<0.001
No	103 (30%)	72 (42.1%)	31 (18%)	
Yes	240 (70%)	99 (57.9%)	141 (82%)	

4.3.9 Diseases and substance abuse characteristics related to the subjects in the intervention and control groups

HIV infection was reported by 28 (8.5%) mothers in the study, while 45 (13.1%) had a non-communicable disease. Ten mothers (2.9%) reported alcohol use during pregnancy while 3 (0.9%) reported cigarette smoking during pregnancy. Cigarette smoking among partners was reported by 21(7.7%) of the mothers. The distribution of these characteristics among the intervention and control groups were only significantly different on alcohol use during pregnancy as shown in **Table 4.9**.

Table 4.9: Diseases and substance abuse characteristics related to the subjects in the intervention and control groups

Variables	All subjects	Intervention	Control	P value
	Frequency (%)	**Frequency (%)**	**Frequency (%)**	
HIV status				0.523
Negative	301 (91.5%)	153 (90.5%)	148 (92.5%)	
Positive	28 (8.5%)	16 (9.5%)	12 (7.5%)	
Chronic conditions (NCD)				0.082
No	298 (86.9%)	154 (90.1%)	144 (83.7%)	
Yes	45 (13.1%)	17 (9.9%)	28 (16.3%)	
Alcohol use				0.001
No	333 (97.1%)	161 (94.2%)	172 (100%)	
Yes	10 (2.9%)	10 (5.8%)	0 (0%)	
Mother cigarette smoking				0.569
No	339 (99.1%)	169 (99.4%)	170 (98.8%)	
Yes	3 (0.9%)	1 (0.6%)	2 (1.2%)	
Partner of mother smoking cigarette				0.834
No	253 (92.3%)	127 (92.1%)	126 (92.6%)	
Yes	21 (7.7%)	11 (7.9%)	10 (7.4%)	

NCD=Non-Communicable Diseases; HIV = Human Immunodeficiency Virus

4.4 Outcome measures of the study

4.4.1 Neonatal mortality, neonatal morbidity and hospital readmission among the study subjects

A total of 29 (8.5%) LBW infants died during the neonatal period. Neonatal morbidity was reported in 211 (61.5%) LBW infants while 14 LBW infants (4.5%) were readmitted to hospital after discharge. The distribution of the study outcome measures among the intervention and control group was as shown in **Table 4.10**.

Table 4.10: Incidence of neonatal mortality, morbidity and hospital readmission among subjects in the intervention and control groups

Variables	All	Intervention	Control
	Frequency (%)	Frequency (%)	Frequency (%)
Neonatal mortality			
No	311 (91.5%)	156 (92.3%)	155 (90.6%)
Yes	29 (8.5%)	13 (7.7%)	16 (9.4%)
Incidence of neonatal morbidity			
No	132 (38.5%)	87 (50.9%)	45 (26.2%)
Yes	211 (61.5%)	84 (49.1%)	127 (73.8%)
Incidence of hospital readmission			
No	300 (95.5%)	150 (97.4%)	150 (93.7%)
Yes	14 (4.5%)	4 (2.6%)	10 (6.3%)

4.4.2 Types of neonatal morbidity among the study subjects in the intervention and control groups

During the neonatal period, 185 (61.1%) LBW infants had sepsis, 79 (26.1%) had jaundice, 25 (8.3%) had Respiratory Distress Syndrome (RDS), 11 (3.6%) had diarrhea, 2 (0.7%) had bradycardia and 1 (0.3%) had low blood sugar, as shown in **figure 4.3**.

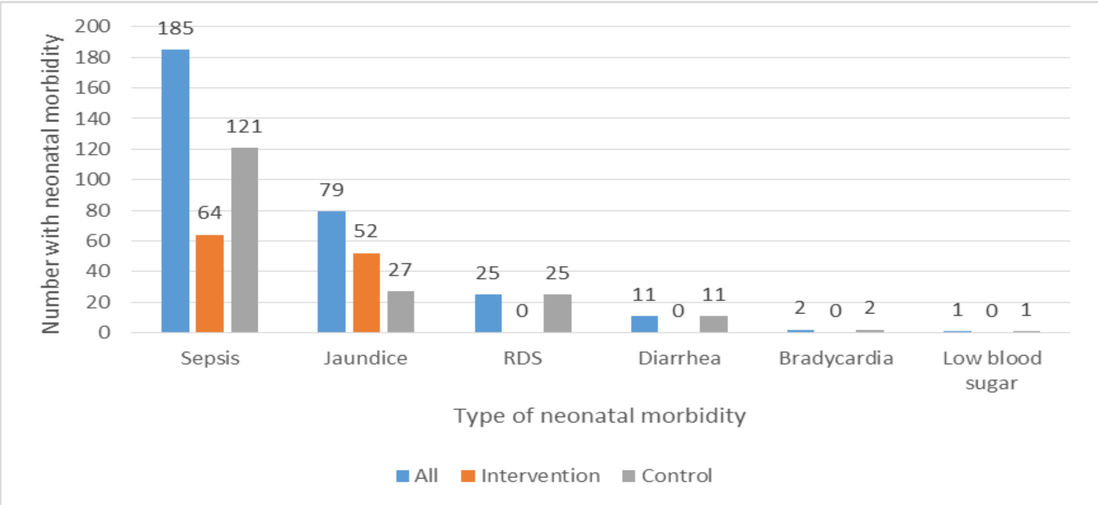

Figure 4.3: Types of neonatal morbidity among study subjects in the intervention and control groups

4.4.3 Weight gain during the neonatal period and duration of hospital stay among the study subjects in the intervention and control groups

The mean weight gain at the end of the neonatal period in the intervention group was 709.5 grams while the mean weight gain among the control group infants during the same period was 471.5 grams as shown in **Table 4.11**.

Table 4.11: Weight gain during neonatal period (grams) and duration of hospital stay (days) among the study subjects in the intervention and control groups

Variables	Frequency	Mean	95% Confidence interval
Duration of hospital stay (days)			
Control group	152	17.4	16-19
Intervention group	154	7.1	6-8
Weight gain during neonatal period (grams)			
Control group	149	471.5	440.4-502.6
Intervention group	155	709.5	653.2-765.9

4.5 Bivariate analysis of the association between baseline characteristics of the study subjects and incidence of neonatal mortality

Simple logistic regression analysis was done to examine the relationship between certain characteristics with incidence of neonatal mortality.

4.5.1 Bivariate analysis of the association between socioeconomic characteristics and neonatal mortality

Infants of mothers who had access to toilet were 80% less likely to die compared to those who did not have access to toilet [OR=0.2, 95% CI, 0.1-0.5, p<0.001]. Infants of mothers who had any incidence of diarrhea in the last three months before delivery were 2.9 times more likely to die than those of mothers who did not have diarrhea [OR=2.9, 95% CI, 1.2-7.5, p=0.023]. Infants whose mothers had a secondary level of education were 60% less likely to die when compared to those whose mothers had primary or lower level of education [OR=0.4, 95% CI, 0.2-0.9, p=0.027]. Infants whose mothers had tertiary level of education were 90% less likely to die compared to those whose mothers had primary or lower level of education [OR=0.1, 95% CI, 0.01-0.87, p=0.037].

All other socioeconomic characteristics were not significantly associated with neonatal death ($p>0.05$) as shown in **Table 4.12.**

Table 4.12: Bivariate analysis of the socioeconomic characteristics and incidence of neonatal mortality

Variable	Neonatal mortality Frequency (%)	Crude Odds Ratio	95% Confidence interval	P value
Income per month (KES)				
<6000	14 (12.8%)	Reference		
6000 to 15000	9 (8.3%)	0.6	0.27-1.47	0.274
>15000	6 (6%)	0.4	0.16-1.17	0.100
Type of house ownership				
Own	7 (9.3%)	Reference		
Rented	22 (8.3%)	0.9	0.36-2.14	0.778
Access to toilet				
No	15 (18.8%)	Reference		
Yes	14 (5.4%)	0.2	0.1-0.5	<0.0001
Source of fuel for cooking				
Electricity/Gas	13 (8.1%)	Ref.		
Charcoal	5 (6.6%)	0.8	0.3-2.3	0.676
Kerosene	11 (10.7%)	1.3	0.6-3.1	0.484
Source of drinking water				
Piped	21 (7.5%)	Ref.		
River/pond	3 (15.8%)	2.3	0.6-8.6	0.208
Well/borehole	5 (12.5%)	1.7	0.6-4.9	0.281
Maternal level of education				
None and Primary	17 (14.5%)	Reference		
Secondary	11 (6.5%)	0.4	0.2-0.9	0.027
Tertiary	1 (1.9%)	0.1	0.01-0.87	0.037
Spouses level of education				
None and Primary	4 (8.2%)	Reference		
Secondary	15 (9%)	1.1	0.4-3.5	0.859
Tertiary	7 (10.9%)	1.4	0.4-5	0.623
Incidence of diarrhea in last 3 months				
No	22 (7.3%)	Ref.		
Yes	7 (18.9%)	2.9	1.2-7.5	0.023

KES = Kenya shilling

4.5.2 Bivariate analysis of the association of maternal characteristics with neonatal mortality

Infants of mothers who took an average of two meals a day during pregnancy were 90% less likely to die during neonatal period compared to those whose mothers took an average of one meal a day [OR=0.1, 95% CI, 0.02-0.57, p=0.008]. Infants of mothers who took an average of three meals a day during pregnancy were also 90% less likely to die during neonatal period compared to those whose mothers took an average of one meal a day [OR=0.1, 95% CI, 0.03-0.32, p<0.001]. Infants of mothers who took an average of more than three meals a day during pregnancy were 86% less likely to die during neonatal period compared to those whose mothers took an average of one meal a day [OR=0.14, 95% CI, 0.04-0.5, p=0.003].

Other maternal related characteristics were not significantly associated with neonatal mortality (p>0.05) as shown in **Table 4.13.**

Table 4.13: Bivariate analysis of maternal related characteristics and neonatal mortality

Variable	Neonatal mortality Frequency (%)	Crude Odds Ratio	95% Confidence Interval	p value
Age of mother (years)		0.96	0.89-1.03	0.321
Marital status				
Married/cohabiting	26 (9.6%)	Reference		
Single	3 (4.4%)	0.4	0.12-1.5	0.185
Birth interval				
<18 months	4 (16.7%)	Reference		
18-36 months	2 (7.7%)	0.4	0.06-2.5	0.34
>36 months	6 (6.5%)	0.3	0.08-1.4	0.128
ANC attendance				
No	2 (9.1%)	Reference		
Yes	27 (8.6%)	0.9	0.2-4.2	0.937
Average number of meals per day during pregnancy				
One	6 (40%)	Reference		
Two	3 (7.3%)	0.1	0.02-0.57	0.008
Three	12 (6.2%)	0.1	0.03-0.32	<0.001
More than three	8 (9%)	0.14	0.04-0.5	0.003
HIV status				
Negative	28 (9.4%)	Reference		
Positive	1 (3.7%)	0.4	0.04-2.8	0.341
Chronic conditions (NCD)				
No	23 (7.8%)	Reference		
Yes	6 (13.3%)	1.8	0.7-4.7	0.221

ANC = Antenatal clinic; NCD = Non-Communicable Diseases

4.5.3 Bivariate analysis of the association of neonatal and other characteristics with neonatal mortality

Birth weight and gestational age were significantly associated with neonatal mortality ($p<0.05$). Infants of mothers who had delivery complications were 2.8 times more likely to die during the neonatal period than those whose mothers did not have delivery complications [OR=2.8, 95% CI, 1.3-6.1, p=0.008]. Other characteristics were not significantly associated with neonatal mortality ($p>0.05$) as shown in **Table 4.14**.

Table 4.14: Bivariate analysis of neonatal and other characteristics and neonatal mortality

Variable	Neonatal mortality Frequency (%)	Crude Odds Ratio	95% Confidence Interval	P value
Birthweight (grams)		0.997	0.996-0.999	0.002
Gestational age (weeks)		0.86	0.77 – 0.96	0.009
Infant Sex				
Female	18 (8.9%)	Reference		
Male	11 (8%)	0.9	0.4-1.9	0.761
Place of delivery				
This hospital	22 (8.2%)	Reference		
Another hospital	4 (8.7%)	1.1	0.3-3.2	0.912
Home	3 (11.5%)	1.5	0.4-5.2	0.563
Mode of delivery				
CS	3 (5.3%)	Reference		
Normal	26 (9.2%)	1.8	0.5-6.3	0.337
Multiple births				
No	12 (5%)	Reference		
Yes	17 (17.2%)	1.3	0.8-2.2	0.245
Delivery complications				
No	15 (6.1%)	Reference		
Yes	14 (15.4%)	2.8	1.3-6.1	0.008
Birth interval				
<18 months	4 (16.7%)	Reference		
18-36 months	2 (7.7%)	0.4	0.06-2.5	0.34
>36 months	6 (6.5%)	0.3	0.08-1.4	0.128
Apgar score at 1 minute				
Apgar score ≤5	6 (10.7%)	Reference		
Apgar Score >5	18 (7.4%)	0.7	0.3-1.8	0.414

CS= Caesarean Section

4.6 Bivariate analysis of the association between baseline characteristics and incidence of neonatal morbidity

Simple logistic regression analysis was done to examine the relationship between certain characteristics with incidence of neonatal morbidity.

4.6.1 Bivariate analysis of the association between socioeconomic characteristics and neonatal morbidity

Infants of mothers with a household income of 6000-15000 KES were 50% less likely to develop neonatal morbidity compared to those whose mothers had household income of less than 6000 KES per month [OR=0.5, 95% CI, 0.29-0.88, p=0.016]. Those whose mothers had an income of more than 15000 KES were 70% less likely to develop neonatal morbidity when compared to those whose mothers had a monthly household income of less than 6000 KES per month though this was not statistically significant [OR=0.5, 95% CI, 0.41-1.31, p=0.306].

Infants whose mothers had access to toilet were 50% less likely to develop neonatal morbidity than those whose mothers did not have access to toilet [OR=0.5, 95% CI, 0.27-0.8, p=0.007]. Subjects whose mothers used river/pond as the main source of water were 3.9 times more likely to develop neonatal morbidity compared to those whose main source was piped water [OR=3.9, 95% CI, 1.12-13.89, p=0.032]. Those whose main source of water was well/borehole were 3 times more likely to develop neonatal morbidity compared to those whose main source was piped water [OR=3, 95% CI, 1.3-6.7, p=0.008]. Other socioeconomic characteristics were not significantly associated with incidence of neonatal morbidity (p>0.05), as shown in **Table 4.15**.

Table 4.15: Bivariate analysis of socioeconomic characteristics and neonatal morbidity

Variable	Neonatal morbidity Frequency (%)	Crude Odds Ratio	95% Confidence Interval	P value
Maternal level of education				
None and Primary	79 (67%)	Reference		
Secondary	99 (57.6%)	0.67	0.4-1.1	0.107
Tertiary	33 (62.5%)	0.81	0.4-1.6	0.551
Spouses level of education				
None and Primary	27 (53%)	Reference		
Secondary	104 (61.9%)	1.4	0.77-2.71	0.254
Tertiary	40 (62.5%)	1.5	0.7-3.1	0.303
Household income per month (KES)				
<6000	76 (69.1%)	Reference		
6000 to 15000	58 (53.2%)	0.5	0.29-0.88	0.016
>15000	63 (62.4%)	0.7	0.41-1.31	0.305
Access to toilet				
No	61 (74.4%)	Reference		
Yes	150 (57.5%)	0.5	0.27-0.8	0.007
Source of fuel for cooking				
Electricity/Gas	99 (60.7%)	Reference		
Charcoal	55 (72.4%)	1.7	0.93-3.06	0.082
Kerosene	57 (55.3%)	0.8	0.48-1.32	0.384
Source of drinking water				
Piped	163 (57.4%)	Reference		
River/pond	16 (84.2%)	3.9	1.12-13.89	0.032
Well/borehole	32 (80%)	3	1.3-6.7	0.008
Incidence of diarrhea in last 3 months				
No	184 (60.9%)	Reference		
Yes	26 (70.3%)	1.5	0.72-3.18	0.272

KES = Kenya shilling

4.6.2 Bivariate analysis of the association of maternal characteristics with neonatal morbidity

Infants whose mothers had no pregnancy loss with ≥1 live births were 1.8 times more likely to develop neonatal morbidity compared to those whose mothers were never pregnant before (primigravida) [OR=1.8, 95% CI, 1.1-3.0, p=0.012]. Infants whose mothers had 1 or more pregnancy losses with 1 or more live births were 3.8 times more likely to develop neonatal morbidity compared to those whose mothers were never pregnant before (primigravida) [OR=3.8, 95% CI, 1.6-8.9, p=0.003].

Incidence of neonatal morbidity was 70% less likely to happen in infants with a birth interval of 18-36 months compared to those with birth interval of less than 18 months [OR=0.3, 95% CI, 0.07-0.9, p=0.034]. There was no statistically significant difference between incidence of neonatal morbidity among infants with birth interval of more than 36 months and those with birth intervals of less than 18 months (p>0.05). Other maternal characteristics were not significantly associated with incidence of neonatal morbidity (p>0.05), as shown in **Table 4.16**.

4.6.3 Bivariate analysis of the association of neonatal and other characteristics with neonatal morbidity

Infants whose mothers had delivery complications were 2 times more likely to develop neonatal morbidity than those whose mothers did not have delivery complications [OR=2, 95% CI, 1.2-3.3, p=0.012].

The other characteristics were not significantly associated with incidence of neonatal morbidity (p>0.05), as shown in **Table 4.17**.

Table 4.16: Bivariate analysis of maternal characteristics and neonatal morbidity

Variable	Neonatal morbidity Frequency (%)	Crude Odds Ratio	95% Confidence Interval	P value
Marital status				
Married/cohabiting	127 (73.8%)	Reference		
Single	84 (49.1%)	0.89	0.52-1.53	0.689
Birth interval				
<18 months	19 (79.2%)	Reference		
18-36 months	14 (50%)	0.3	0.07-0.9	0.034
>36 months	58 (63%)	0.4	0.2-1.3	0.143
Average number of meals per day when pregnant				
One	10 (66.7%)	Reference		
Two	29 (70.7%)	1.2	0.3-4.3	0.770
Three	114 (58.5%)	0.7	0.2-2.1	0.535
More than three	57 (62.6%)	0.8	0.3-2.7	0.765
ANC attendance				
No	10 (43.5%)	Reference		
Yes	198 (62.7%)	2.2	0.9-5.1	0.074
Pregnancy history				
Primigravida	56 (50%)	Reference		
No pregnancy loss with 1 or more live births	110 (65.1%)	1.8	1.1-3	0.012
1 or more pregnancy loss with 1 or more live births	30 (79%)	3.8	1.6-8.9	0.003
1 or more pregnancy loss with no live birth	6 (60%)	1	0.4-5.6	0.547
HIV status				
Negative	184 (61.1%)	Reference		
Positive	20 (71.4%)	1.6	0.7-3.7	0.286
Chronic conditions (NCD)				
No	181 (60.7%)	Reference		
Yes	30 (66.7%)	1.3	0.7-2.5	0.447

NCD = Non-Communicable Diseases; HIV = Human Immunodeficiency Virus

Table 4.17: Bivariate analysis of neonatal and other characteristics with neonatal morbidity

Variable	Neonatal morbidity Frequency (%)	Crude Odds Ratio	95% CI	P value
Birthweight (grams)		0.997	0.996-0.997	<0.001
Gestational age (weeks)		0.93	0.88 – 0.99	0.016
Infant Sex	124 (60.5%)	Reference		
Female				
Male	87 (63%)	1.1	0.7-1.7	0.633
Place of delivery				
This hospital	163 (60.6%)	Reference		
Another hospital	35 (74.5%)	1.9	0.9-3.8	0.073
Home	13 (48.2%)	0.6	0.3-1.3	0.213
Mode of delivery				
CS	31 (54.4%)	Reference		
Normal	179 (62.8%)	1.4	0.8-2.5	0.235
Multiple births				
No	145 (59.9%)	Reference		
Yes	66 (66.7%)	1.3	0.8-2.2	0.245
Delivery complications				
No	144 (57.4%)	Reference		
Yes	66 (72.5%)	2	1.2-3.3	0.012
Apgar score at 1 minute				
Apgar score ≤5	37 (66.1%)	Reference		
Apgar Score >5	151 (61.6%)	0.8	0.4-1.5	0.536

CS = Caesarean Section

4.7 Bivariate analysis of the association between baseline characteristics and incidence of hospital readmission

Infants born of mothers with non-communicable disease (NCD) were 5.7 times more likely to be readmitted to hospital compared to those born by mothers without NCD [OR=5.7, 95% CI, 1.8-17.3, p=0.002]. All other baseline characteristics were not significantly associated with incidence of hospital readmission (p>0.05) as shown in **Table 4.18**.

Table 4.18: Bivariate analysis of baseline characteristics with incidence of hospital readmission

Variable	Hospital readmission Frequency (%)	Crude Odds Ratio	95% Confidence Interval	P value
Marital status				
Married/cohabiting	9 (3.6%)	Reference		
Single	5 (7.7%)	2.2	0.7-6.8	0.166
Household income per month (KES)				
<6000	4 (4.3%)	Reference		
6000 to 15000	2 (2%)	0.5	.08-2.6	0.382
>15000	7 (7.1%)	1.7	0.5-6.1	0.394
Source of fuel for cooking				
Electricity/Gas	6 (3.9%)	Reference		
Charcoal	5 (7%)	1.9	0.5-6.3	0.321
Kerosene	3 (3.3%)	0.8	0.2-3.5	0.815
Source of drinking water				
Piped	11 (4.2%)	Reference		
River/pond	2 (12.5%)	3.3	0.7-16.2	0.146
Well/borehole	1 (2.9%)	0.7	0.08-5.4	0.710
Incidence of diarrhea in last 3 months				
No	12 (4.3%)	Reference		
Yes	1 (3.2%)	0.7	0.09-5.9	0.778
Chronic conditions (NCD)				
No	23 (7.8%)	Reference		
Yes	6 (13.3%)	5.7	1.8-17.3	0.002

KES = Kenya shilling; NCD = Non-Communicable Diseases

4.8 Association of type of neonatal care with incidence of neonatal mortality among low birth weight infants

4.8.1 Relative risk of incidence of neonatal mortality among study subjects in the intervention and control groups

The risk of neonatal mortality was reduced to 80% in the intervention group when compared to the control group. This reduction was not statistically significant (RR=0.8, 95% CI=0.4-1.7, p=0.5835).

4.8.2 Multivariable analysis of association of baseline characteristics and type of neonatal care with neonatal mortality

A multivariable logistic regression was performed to assess the effects of baseline characteristics and type of neonatal care on the likelihood of neonatal mortality. The choice of the determinants was based on their clinical significance and the results of the bivariate analysis using simple logistic regression. A backward elimination method was used in coming up with a minimum set of determinants that resulted in the optimal predictive model of neonatal mortality. The modelling begun by including all the variables in the model. It then involved removing the least significant variable (largest P value) and refitting of the model. This was continued until further removal of any other variable caused no significant decrease in R. The logistic regression model as a whole was statistically significant [likelihood ratio $\chi 2$ (14) = 55.26, $p < 0.001$].

Infants whose mothers had NCDs were 4.7 times likely to die than infants whose mothers did not have NCDs [aOR=4.7, 95% CI, 1.0-21.9, p=0.048]. Birth weight (grams) and gestational age (weeks) were significantly associated with neonatal mortality. A unit increase in birth weight (1 gram) was associated with a 0.3% reduction in the likelihood of neonatal mortality [aOR=0.997, 95% CI, 0.995-0.999, p=0.043]. Similarly, a unit increase in gestational age (1 week) was associated with a 28% reduction in likelihood of neonatal mortality [aOR=0.72, 95% CI, 0.57-0.90, p=0.005].

Infants born as multiple births were 7.6 times more likely to die than singleton infants [aOR=7.6, 95% CI, 2.3-25.4, p<0.001]. Infants born in families with a household income of 6000-15000 KES were 78% less likely to die during neonatal period compared to those born in families with a household income of less than 6000 KES per month [aOR=0.22, 95% CI, 0.05-0.96, p=0.038]. LBW infants born in families with household income of more than 15000 KES were 85% less likely to die during neonatal period than LBW infants born in families with a household income of less than 6000 KES per month [aOR=0.146, 95% CI, 0.02-0.9, p=0.038].

The intervention and other characteristics like toilet access, delivery complications and infant sex among others were not statistically associated with neonatal mortality (p>0.05) as shown in **Table 4.19**.

Table 4.19: Multivariable analysis of association of baseline characteristics and type of neonatal care with neonatal mortality

Neonatal mortality	Adjusted Odds Ratio	95% Confidence Interval	P value
Intervention group			
No	Reference		
Yes	1.8	0.4-7.4	0.406
Toilet access			
No			
Yes	0.56	0.2-1.8	0.324
Birth complication			
No			
Yes	3.01	0.95-9.6	0.061
NCD			
No			
Yes	4.7	1.0-21.9	0.048
Age of the mother (Years)	0.9	0.8-1.0	0.060
Birth weight (grams)	0.997	0.996-0.999	0.043
Gestational age (weeks)	0.7	0.6-0.9	0.005
Infant sex			
Female			
Male	1.3	0.4-3.8	0.656
Mode of delivery			
CS			
Normal	3.6	0.6-24.1	0.180
Multiple births			
No			
Yes	7.6	2.3-25.4	0.001
Partner smokes cigarettes			
No			
Yes	4.5	0.9-22.3	0.064
Monthly household income (KES)			
<6000	Ref.		
6000 to 15000	0.2	0.05-0.96	0.044
>15000	0.14	0.02-0.9	0.038
Diarrhea			
No			
Yes	0.7	0.1-3.3	0.631

NCD = Non-Communicable Diseases; CS: Caesarean Section; KES=Kenya shilling

4.9 Association of type of neonatal care with incidence of neonatal morbidity among low birth weight infants

4.9.1 Relative risk of incidence of neonatal morbidity among study subjects in the intervention and control groups

The intervention (early intermittent KMC) reduced the risk of neonatal morbidity among stable LBW infants by 33% (RR=0.67, 95% CI=0.6-0.8, p<0.001). The number needed to treat (NNT) with early intermittent KMC was 4 (95% CI=2.9-6.8) for one additional LBW infant to benefit in reduction of neonatal morbidity.

4.9.2 Multivariable analysis of association of baseline characteristics and type of neonatal care with neonatal morbidity

A multivariable logistic regression was performed to assess the effects of baseline characteristics and type of neonatal care on the likelihood of developing neonatal morbidity. The choice of the determinants was based on their clinical importance and the results of the bivariate analysis done using simple logistic regression. A backward elimination method was used in coming up with a minimum set of determinants that resulted in the optimal predictive model of neonatal morbidity. The modelling begun by including all the variables in the model. It then involved removing the least significant variable (largest p value) and refitting of the model. This was continued until further removal of any other variable caused no significant decrease in R. The final logistic regression model as a whole was statistically significant [likelihood ratio $\chi 2$ (9) = 86.22, $p < 0.0001$].

Infants in the intervention arm were 74% less likely to develop neonatal morbidity compared to the ones on the control arm [aOR=0.26, 95% CI, 0.13-0.57, p=0.001]. The infants' birth weight (grams) was significantly associated with incidence of neonatal morbidity. Every unit increase in birth weight (1 gram) was associated with a 1% reduction of incidence of neonatal morbidity [aOR=0.99, 95% CI, 0.995-0.998, p<0.001]. LBW male infants were 2.6 times more likely to develop neonatal morbidity compared to LBW female infants [aOR=2.63, 95% CI, 1.4-4.9, p=0.003]. Those with birth complications were 2.1 times more likely to develop neonatal morbidity compared to LBW infants who did not experience delivery complications [aOR=2.1, 95% CI, 0.9-14.7, p=0.041].

The other characteristics were not statistically significant predictors of incidence of neonatal morbidity (p>0.05) as shown in **Table 4.20**.

Table 4.20: Multiple logistic regression analysis of association of baseline characteristics and type of neonatal care with neonatal morbidity

Neonatal morbidity	Adjusted Odds Ratio	95% Confidence Interval	P value
Intervention group			
No	Reference		
Yes	0.27	0.1-0.6	0.001
HIV status			
Negative	Reference		
Positive	1.9	0.6-6.3	0.268
Birth weight (grams)	0.996	0.995-0.998	0.000
Gestational age (weeks)	1.08	0.98-1.2	0.103
Infant sex			
Female	Reference		
Male	2.6	1.4-4.9	0.003
Maternal level of education			
None and Primary	Reference		
Secondary	0.53	0.3-1.0	0.064
Tertiary	0.5	0.2-1.4	0.18
Birth complication			
No	Reference		
Yes	2.1	1.0-4.3	0.041
Partner smokes			
No	Reference		
Yes	3.7	0.9-14.7	0.068

HIV = Human Immunodeficiency Virus

4.10 Association of type of neonatal care with incidence of neonatal hospital readmission among low birth weight infants

4.10.1 Relative risk of incidence of hospital readmission among subjects on the intervention and control groups

The risk of hospital readmission was reduced to 40%in the intervention group when compared to conventional neonatal care infants, though the reduction was not statistically significant (RR=0.4, 95% CI=0.1-1.3, p=0.1305).

4.10.2 Multivariable analysis of association of baseline characteristics and type of neonatal care with incidence of hospital readmission during the neonatal period

A multivariable logistic regression was performed to assess the effects of baseline characteristics and type of neonatal care on the likelihood of hospital readmission. The choice of the determinants was based on their clinical significance and the results of the bivariate analysis. A backward elimination method was used in coming up with a minimum set of determinants that resulted in the optimal predictive model of hospital readmission. The modelling begun by including all the variables in the model. It then involved removing the least significant variable (largest p value) and refitting of the model. This was continued until further removal of any other variable caused no significant decrease in R. The final logistic regression model as a whole was statistically significant [likelihood ratio $\chi2$ (8) = 42.44, $p < 0.0001$].

Infants whose mothers had NCD were 11.6 times more likely to be readmitted during the neonatal period compared to LBW infants whose mothers did not have NCDs [aOR=11.6, 95% CI, 1.3 -104.2, p=0.029]. A unit increase in birth weight (1 gram) was associated with a 1.2% reduction in likelihood of neonatal hospital readmission [aOR=0.988, 95% CI, 0.98-0.99, p=0.007].

Characteristics like household income and incidence of diarrhea among others were not significantly associated with hospital readmission (p>0.05) as shown in **Table 4.21**.

Table 4.21: Multivariable logistic regression analysis of association of baseline characteristics and type of neonatal care with incidence of neonatal hospital readmission

Hospital readmission	Adjusted Odds Ratio	95% Confidence Interval	P Value
Non communicable disease			
No	Reference		
Yes	11.6	1.3-104.2	0.029
Age of the mother (Years)	0.8	0.6 – 1.1	0.195
Birth weight (grams)	0.99	0.98-0.997	0.007
Incidence of diarrhea in last 3 months			
No	Reference		
Yes	7.2	0.2-223.9	0.26
Partner smokes cigarettes			
No	Reference		
Yes	6.1	0.2-167.7	0.282
Monthly household income (KES)			
<6000	Reference		
6000 to 15000	0.1	0.002-5.15	0.261
>15000	2.7	0.2-39.7	0.468

KES = Kenya shilling

4.11 Association of type of neonatal care with duration of hospital stay (days)

Independent samples t-tests were conducted to compare the duration of hospital stay (in days) among infants in intervention and control groups. Infants in the intervention arm spent a significantly shorter duration (Mean=7.1, 95% CI=6.3-7.9) than those on the control arm (Mean=17.4, 95% CI=16.2 -18.6), [t (304) 14.5009, p<0.0001].

4.11.1 Association of type of neonatal care with duration of hospital stay (days) for infants with birth weight ≤ 1500 grams

An independent t-test was conducted to compare duration of hospital stay (days) among intervention infants (birth weight ≤ 1500 grams) and control infants (birth weight ≤ 1500 grams).

Intervention infants spent a significantly shorter duration (Mean=7.7, 95% CI=6.5-8.9) than control infants (Mean=17.5, 95% CI=16.1 -18.9), [t (182) 10.3, P<0.0001].

4.11.2 Association of type of neonatal care with duration of hospital stay (days) for infants with birth weight >1500 grams

An independent t-test was conducted to compare duration of hospital stay (days) among intervention infants (birth weight >1500 grams) and control infants (birth weight >1500 grams). Intervention infants spent a significantly shorter duration (Mean=6.4, 95% CI=5.4-7.4) than control infants (Mean=17.3, 95% CI=15.1 – 19.5), [t (120) 9.99, p<0.0001] for both groups with a birth weight > 1500 grams.

4.12 Linear analysis of the association of type of neonatal care with duration of hospital stay (days)

4.12.1 Simple linear analysis of association of type of neonatal care with duration of hospital stay

A linear regression analysis established that the intervention could significantly predict the duration of hospital stay (days) [F (1, 304) = 210.27, p<0.0001]. The intervention accounted for 40.7% of the explained variability in duration of hospital stay. The regression equation was: predicted duration of hospital stays = 17.4 - 10.3 x (intervention), where ‘control’ = 0 and ‘intervention’ = 1.

The predicted value for duration of hospital stay in control infants was 17.4 days and the predicted value for duration of hospital stay in intervention infants was 7.1 days. The slope of the line is negative since the coefficient for intervention was negative (-10.3). Therefore, the intervention reduced the duration of hospital stay by a mean of 10.3 days.

4.12.2 Multivariable linear analysis of association of baseline characteristics and type of neonatal care with duration of hospital stay (days)

A multiple regression analysis established that the intervention, age of the mother, birth weight, Apgar score at one minute, household income, place of delivery, mode of delivery, multiple births, birth complication, ANC attendance and gestational age (weeks) could significantly predict the duration of hospital stay (days) [F (13, 226) = 15.77, p<.0001]. The R-squared was 0.4757, which meant that about 48% of the variability of duration of hospital stay (days) was accounted for by the variables in the model. The adjusted R-squared indicated that about 45% of the variability of duration of hospital stay was accounted for by the model, even after taking into account the number of predictor variables in the model.

The linear regression model, as shown in **Table 4.22**, showed the significant predictors of the duration of hospital stay (days). The coefficients for each of the variables indicated the amount of change to expect in duration of hospital stay (days) given a one-unit change in the value of that variable, given that all other variables in the model were held constant. We would expect a decrease of 11.7 days in the duration of hospital stay for practicing early intermittent KMC, assuming that all other variables in the model were held constant. We would also expect a decrease of 0.003 days in the duration of hospital stay for every one-unit increase in birth weight (grams), assuming that all other variables in the model were held constant. The model predicted a decrease of 3.3 days in the duration of hospital stay for every unit increase of household income of more than 15000 shillings, assuming that all other variables in the model were held constant. The model also predicted that being born in another hospital increased the duration of hospital stay by 2.5 days, assuming that all other variables in the model were held constant, as shown in **Table 4.22**.

Table 4.22: Multivariable linear analysis of association of selected determinants with duration of hospital stay (days)

Duration of hospital stay (days)	Coefficient	95% Confidence Interval	t	P value
Intervention (Yes)	-11.7	-13.7 – (-9.7)	-11.69	0.000
Age of the mother (Years)	0.02	-0.13 – (-0.2)	0.29	0.771
Birth weight (grams)	-0.003	-0.007 – (-0.0006)	-2.34	0.02
Apgar score (>5 at 1 minute)	0.6	-1.4 – 2.7	0.58	0.561
Household income (Kenya shilling)	*Reference category is <6000			
6000 to 15000	-0.4	-2.4 – 1.6	-0.42	0.675
>15000	-3.3	-5.4 – (-1.2)	-3.14	0.002
Place delivered	* Reference category is Study hospital			
A different hospital	2.5	-0.002 – 5.0	1.97	0.05
Home	0.6	-3.6 – 4.7	0.27	0.791
Mode of delivery	* Reference category is Caesarean section			
Normal	-1.65	-3.8 – 0.5	-1.48	0.139
Multiple births (Yes)	-0.47	-2.2 – 1.2	-0.54	0.59
Birth complication (Yes)	-1.15	-3.1 – 0.8	-1.16	0.246
ANC attendance (Yes)	0.08	-3.7 – 3.8	0.04	0.966
Gestational age (weeks)	0.11	-0.2 – 0.4	0.8	0.426

ANC = Antenatal Clinic

4.13 Association of type of care with weight gain during neonatal period among low birth weight infants

An independent samples t-test was conducted to compare weight gain during the neonatal period among intervention infants and control infants. Intervention infants had a significantly higher mean weight gain (Mean=709.5, 95% CI=653.2-765.9) during the neonatal period than control infants (Mean=471.5, 95% CI=440.4-502.6), [t (302) 7.2, p< 0.0001].

4.13.1 Association of type of care with weight gain during the neonatal period among infants with birth weight ≤ 1500 grams

An independent t-test was conducted to compare weight gain during neonatal period in the intervention group (birth weight ≤ 1500 grams) and the control group (birth weight ≤ 1500 grams). The mean weight gain during the neonatal period among the intervention infants was significantly higher (Mean=686.8, 95% CI=611.4-762.2) than the control infants (Mean=528.1, 95% CI=495.7 – 560.6), [t (171) 4.2524, p<0.0001] for both cohorts with a birth weight ≤ 1500 grams.

4.13.2 Association of type of care with weight gain during neonatal period for infants with birth weight >1500 grams

An independent t-test was conducted to compare weight gain during neonatal period in the intervention group (birth weight >1500 grams) and control group (birth weight >1500 grams). The mean weight gain during the neonatal period among intervention infants was significantly higher (Mean=729.3, 95% CI=645.5 – 813.0) than control infants (Mean=352.3, 95% CI=296.2 – 408.4), [t (129) 6.3532, p<0.0001] for both cohorts with a birth weight >1500grams.

4.14 Linear analysis of association of type of neonatal care with neonatal weight gain

4.14.1 Simple linear analysis of association of type of neonatal care with neonatal weight gain

A linear regression analysis established that the intervention could significantly predict weight gain during neonatal period [F (1, 302) = 52.23, p<0.0001]. The intervention accounted for 14.5% of the explained variability in the weight gain during the neonatal period. The regression equation was: predicted neonatal weight gain = 471.5 + 238.1 x (intervention), where 'control' = 0 and 'intervention' = 1. Therefore, the intervention increased the mean weight gain by 238.1 grams during the neonatal period.

The predicted value for weight gain among control infants was 471.5 grams and the predicted value for weight gain among intervention infants was 709.6 grams. The slope of the line was positive since the coefficient for the intervention was positive (238.1).

4.14.2 Multivariable linear analysis of association of baseline characteristics and type of neonatal care with weight gain during the neonatal period

A multivariable regression analysis established that the intervention, infant sex, age of the mother, birth weight, Apgar score at one minute and household income could significantly predict the weight gain during the neonatal period [F (7, 239) = 9.78, p<0.0001]. The R-squared was 0.2226, meaning that approximately 22% of the variability of net weight gain was accounted for by the variables in the model. The adjusted R-squared indicated that about 20% of the variability of net weight gain was accounted for by the model, even after taking into account the number of predictor variables in the model.

Table 4.23 shows the linear regression model for mean neonatal weight gain (grams). The coefficients for each of the variables indicated the amount of change to expect in the neonatal weight gain given a one-unit change in the value of that variable, assuming that all other variables in the model were held constant. Based on the model, we would expect an increase of 293.7 grams in the neonatal weight gain for practicing early intermittent KMC, assuming that all other variables in the model were held constant. We would also expect a decrease of 0.25 grams in the net weight gain for every one-unit increase in birth weight (grams), assuming that all other variables in the model were held constant. An increase of 95.8 grams in the net weight gain was expected if the Apgar score at one minute was more than 5, assuming that all other variables in the model were held constant.

Table 4.23: Multivariable linear analysis of association of selected determinants with net weight gain

Infant weight gain (grams)	Coefficient	95% Confidence Interval	t	P Value
Intervention (Yes)	293.7	211.9 – 375.4	7.07	<0.0001
Infant sex (Male)	59.1	-18 – 136.3	1.51	0.133
Age of the mother (Years)	1.95	-5.4 – 9.3	0.52	0.602
Birth weight (grams)	-0.25	-0.4 – (-0.1)	-3.5	0.001
Apgar score >5 at 1 minute	95.8	1.6 – 190.0	2	0.046
Monthly household income (Kenya shilling)	*Reference category is <6000			
6000 to 15000	-16.8	-108.2 – 74.5	-0.36	0.717
>15000	70.8	-26.8 – 168.4	1.43	0.154

CHAPTER FIVE

DISCUSSION

5.1 Incidence of neonatal mortality

The neonatal mortality in this study was 8.5% among the stable LBW infants weighing ≤2000 grams. Simiyu, (2004) reported a neonatal mortality rate of 57.4% among LBW infants at Kenyatta National Hospital. The Worku and Kassie, (2005) trial reported an overall 30.4% neonatal mortality in unstable and stable LBW infants. Nagai, *et al.,* (2010) reported a neonatal mortality rate of 4.1% in stable LBW infants. This trial was putting both study groups on either early or late KMC.

5.2 Incidence of neonatal morbidity

Findings from this study indicate that neonatal morbidity was very high. The common forms of neonatal morbidity in this study were neonatal sepsis (61.1%), jaundice (26.1%), RDS (8.3%) and diarrhea (3.6%). Literature has shown that LBW is associated with high incidence of neonatal morbidity (Su *et al*., 2016). The study population was LBW infants of up to 2000grams birth weight. This may contribute to the high incidence of morbidity seen in the study.

Very LBW infants (below 1500grams birth weight) have a higher incidence of neonatal morbidity compared to other categories of LBW with a higher birth weight. Su *et al.,* (2016) in their retrospective cohort study found morbidity incidences of between 78.7% - 88.5% in very low birth weight infants (<1500grams birth weight). Subgroup analysis of this study found an incidence of 76.7% morbidity for infants with birth weight of ≤1500 grams. A study done in south west Cameroon reported high morbidity among LBW infants. This study reported incidence of neonatal asphyxia of 47.2% (Njim *et al*., 2015).

Literature has showed that the leading cause of neonatal morbidity is neonatal sepsis (Titaley *et al*., 2008; UN, 2015; UNICEF, 2017, 2018c). A study looking at morbidity in LBW infants at Kenyatta National Hospital reported that 37% of the LBW infants had a diagnosis of suspected sepsis (Simiyu, 2004). AlFaleh, (2010) reported 41% septicemia in very LBW infants at a tertiary hospital in Saudi Arabia. Su *et al.,* (2016) reported incidence of sepsis of 27.6% in very LBW infants in Taiwan.

5.3 Factors associated with neonatal mortality

The researcher found that maternal level of education, access to toilet and incidence of diarrhea in the last three months before delivery were the socioeconomic determinants that were significantly associated with neonatal mortality ($p<0.005$). Neonatal mortality, as theorized by Mosley and Chen, (1984), is influenced by socioeconomic determinants that work through proximate determinants. A study in Ghana found that dwelling in low socioeconomic neighborhoods was associated with incidence of high neonatal mortality (Kayode *et al*., 2014). Olayinka *et al.,* (2012) also identified maternal level of education to have a significant relationship with neonatal survival. Increasing household income increases the buying power and improves quality of living. This would result in better access to quality water and reduced incidence of diarrhea. The overall effect is expected to be improvement in neonatal survival.

This study identified some proximate determinants that significantly affected neonatal mortality. These were delivery complications and average number of meals per day during pregnancy ($p<0.05$). Mosley and Chen, (1984) identified delivery complications and nutrient deficiency as having adverse effects on neonatal survival. Nutrient deficiency of the mother would deprive the fetus of essential nutrients and that would mean that LBW infants whose mothers were taking one meal a day had a higher risk of neonatal death.

An observational study in Ghana identified multi-gestation as a significant contributor of neonatal mortality (Kayode *et al.,* 2014). Multiple births are typically associated with

LBW and this may contribute to poor neonatal survival. Non-communicable diseases affect household income due to the high cost of medical care, frequent transport cost to and from health services and lost productivity (WHO, 2011). The study by Kayode *et al.,* (2014) reported inadequate birth spacing, ANC utilization, grand parity and place of delivery as significant factors of neonatal survival. Olayinka *et al.,* (2012) in their Ghana study found that the place of delivery had a significant relationship with neonatal mortality. The findings from this study showed a non-significant relationship between these determinants and neonatal mortality ($p>0.05$).

Several other proximate determinants in this study including infant sex, mode of delivery, use of micronutrients, HIV status and Apgar score at one minute did not influence neonatal survival ($p>0.05$) as envisioned in the Mosley and Chen, (1984) analytical framework. Janaswamy *et al.,* (2016) reported a non-significant relationship between infant sex and mode of delivery with neonatal mortality. In our study, this may be due to the small proportion of neonatal deaths that may partly be attributed to the eligibility criteria of including stable LBW infants.

Birth weight and gestational age had a significant relationship with neonatal mortality ($p<0.05$). There is evidence that LBW infants have a lower chance of surviving during the neonatal period (Janaswamy *et al.,* 2016, Kayode *et al.,* 2014) and that LBW is responsible for 60-80% of neonatal deaths in many developing countries (Njim *et al*., 2015; WHO, 2015a).

5.4 Factors Associated with Neonatal Morbidity

This study found that there was a significant relationship between access to toilet, source of drinking water, monthly household income, delivery complications, birth interval and pregnancy history with incidence of neonatal morbidity ($p<0.05$). The analytical framework used in the study which was developed by Mosley and Chen, (1984) proposes that certain socioeconomic determinants influence neonatal morbidity through proximate determinants. The model considers these socioeconomic determinants as household level factors that affect child health. Access to toilet and source of drinking water are influenced directly by household income.

This study investigated other socioeconomic characteristics including marital status of the mother, her level of education and incidence of diarrhea in the last three months before delivery as proposed in the analytical model. These characteristics did not have a significant relationship with neonatal morbidity ($p>0.05$). A study in Nigeria found a significant relationship between level of education of mothers and neonatal morbidity (Olayinka *et al.,* 2012). Level of education was expected to influence the household income as a higher level of education would be associated with getting a better job and that would increase the household income. After adjusting for other factors including the type of neonatal care, the researcher found out that male infants were at a higher risk of developing neonatal morbidity ($p<0.05$). In a study of LBW infants, the researchers found that sex of the infant was not a significant predictor of neonatal morbidity (Janaswamy *et al.,* 2016).

Mosley and Chen, (1984) propose that proximate determinants directly influence the risk of morbidity. In line with this theoretical framework, delivery complications, birth interval and pregnancy history were identified by the study to be significantly associated with neonatal morbidity ($p<0.05$). Olayinka *et al.,* (2012) found place of delivery to be significantly associated with neonatal morbidity. All other proximate factors investigated in this study including mode of delivery, multiple births, average number of meals ate per day during pregnancy and Apgar score at one minute were not significantly associated with neonatal morbidity during the neonatal period ($p>0.05$).

Having NCDs as a mother of a LBW infant was significantly associated with incidence of hospital readmission during the neonatal period ($p<0.05$), which is an indicator of neonatal morbidity. There are some studies that have found mothers having NCDs to be associated with neonatal morbidity. Njim *et al.,* (2015) found that NCDs (hypertensive disorders) and HIV infection were significantly associated with neonatal morbidity. Njim *et al.,* (2015) found maternal age >36 years contributing significantly to neonatal morbidity. This study found no significant relationship between neonatal morbidity with maternal age ($p>0.05$). The mothers of LBW infants in this study were all relatively young which could explain lack of any significant differences in incidence of neonatal morbidity across the mothers' age groups. After adjusting for other factors in the study, this study found out that being HIV infected as a mother of LBW infant increased the risk of developing neonatal morbidity ($p<0.05$). Though significant, the wide confidence interval may necessitate further evaluation of the relationship in different settings.

Birth weight and gestational age had a significant relationship with incidence of neonatal morbidity ($p<0.05$), with incidence reducing with increase of birth weight (grams) and gestational age (weeks). This aligns well to the postulation of the Mosley and Chen, (1984) analytical framework. A study in India on LBW ≤2000 grams (Janaswamy *et al.,* 2016) also found a correlation between birth weight and neonatal morbidity. Birth order however was not a significant factor in incidence of neonatal morbidity ($p>0.05$) in this study as postulated in the Mosley and Chen, (1984) analytical framework.

5.5 Effect of early intermittent Kangaroo mother care in reducing neonatal mortality

The researcher did not find any statistically significant benefit of practicing early intermittent KMC in reducing neonatal mortality ($p>0.05$). Early intermittent KMC in this study involved skin to skin contact between the mother and the low birth weight infant every three hours, for a cumulative period of 8 hours. The KMC was started as soon as possible after birth but within 72 hours of life.

Literature has shown that LBW infants cared on continuous KMC have less neonatal mortality than those on the conventional care (Conde-Agudelo *et al*., 2011; Conde-Agudelo and Díaz-Rossello, 2016). There is no consensus on reduced neonatal mortality among LBW infants on intermittent KMC when compared to conventional neonatal care(Conde-Agudelo *et al*., 2011; Conde-Agudelo and Díaz-Rossello, 2016).

Worku and Kassie, (2005) reported that LBW infants on early KMC group (within 12 hours) had better survival rate compared to those on the conventional neonatal care but Charpak *et al.,* (1997) found no significant differences in mortality rates of neonates on KMC intervention compared to those on conventional care. Conde-Agudelo *et al.,* (2011) concluded that evidence was sufficient to confirm that KMC significantly reduces mortality in LBW infants. The decreased risk of neonatal mortality was only demonstrated in the subgroups that used continuous KMC. Lawn *et al.,* (2010) after meta-analysis of three trials concluded that LBW infants (≤2000 grams) put on KMC intervention in their first week of life had lower risk of neonatal mortality compared to those on conventional care.

5.6 Effect of early intermittent Kangaroo mother care in reducing neonatal morbidity

The practice of early intermittent KMC for a cumulative period of 8 hours a day was significantly associated with a reduction of neonatal morbidity when compared to the conventional neonatal care ($p>0.05$). This reduction was evident even after controlling for confounding variables like infant sex, Apgar score, birth weight and gestational age among others. A study on short term spell of KMC in LBW infants concluded that KMC was a safe and feasible alternative to conventional neonatal care, and reduced neonatal morbidity (Boju *et al*., 2012).

Lawn *et al.,* (2010) also concluded in their systematic review that KMC was associated with significant reduction in morbidity of neonates weighing less than 2000 grams. Another review by Cochrane had similar findings (Conde-Agudelo *et al*., 2011) for infants on intermittent KMC and not continuous KMC.

The researcher found that the practice of early intermittent KMC was not significantly associated with a reduction of incidence of hospital readmission ($p>0.05$). The

Cochrane review of 2011 also reported no difference in readmission to hospital when neonates under KMC intervention were compared to those on the conventional neonatal care (Conde-Agudelo *et al*., 2011).

The findings show a significant lower duration of hospital stay (days) among early intermittent KMC infants when compared to LBW infants on conventional neonatal care. This can be attributed to the reduced neonatal morbidity which usually lengthen the duration of hospital stay. Conde-Agudelo *et al.,* (2011) reported a considerably less duration of hospital stay among infants in the KMC intervention. Charpak *et al.,* (1997) reported an average 1.1-day savings in hospital stay for KMC infants. Nagai *et al.,* (2010) who evaluated early versus late continuous KMC also found a shorter duration of hospital stay among early KMC group.

5.7 Effect of early intermittent Kangaroo mother care on improving neonatal weight gain

The mean weight gain during the neonatal period among early intermittent KMC infants was significantly higher than that of infants on conventional neonatal care ($p<0.05$). This advantage in weight gain during the neonatal period was evident irrespective of the birth weight category (≤1500 and >1500 grams), gestational age, infant sex, Apgar score (≤5 and >5) or any baseline characteristic.

Conde-Agudelo *et al.,* (2011) concluded that KMC infants had better weight gain per day compared to neonates under the conventional care. They also reported improved growth parameters including length gain that can be associated with neonatal weight gain. Nagai *et al.,* (2010) found that when KMC was started early, KMC infants had less weight loss within the first few hours of life and had better overall net weight gain by the end of the neonatal period. Miao-Ju *et al.,* (2002) reported no significant weight changes in their study that compared intermittent KMC infants and the conventional care infants. Moore *et al.,* (2012) also reported non-significant weight changes during the neonatal period by 14 days of life.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

1. There were fewer deaths among low birth weight infants (≤2000 grams) on early intermittent Kangaroo mother care compared to those on conventional neonatal care, though not statistically significant ($p>0.05$). This reduction was clinically important considering that every death is a tragedy to a family.
2. Early intermittent Kangaroo mother care was effective in reducing neonatal morbidity in low birth weight infants (≤2000 grams) compared to conventional neonatal care ($p<0.05$). Infants on the intervention arm also had shorter duration of hospital stay and a significantly less incidence of hospital readmission.
3. Low birth weight infants (≤2000 grams) on early intermittent Kangaroo mother care had a significantly higher weight gain during the neonatal period compared to those on conventional neonatal care ($p<0.05$). The effect of early intermittent Kangaroo mother care on increasing weight gain during the neonatal period was present in both birth weight categories of ≤1500 grams and >1500 grams.

6.2 Recommendations

1. The Maternal, Neonatal and Child Health Department in the Ministry of Health in Kenya should develop a policy for implementation of early intermittent Kangaroo mother care for stable low birth weight infants across its health facilities. This would standardize the practice of early intermittent KMC and reduce neonatal morbidity and increase weight gain during the neonatal period.
2. The County Director of Health should implement early intermittent Kangaroo mother care for stable low birth weight infants in health facilities. This would target facilities that do not have adequate resources for the practice of continuous kangaroo mother care or the facilities implementing conventional neonatal care.
3. Further research is recommended to evaluate the effect of early intermittent Kangaroo mother care with a skin to skin contact duration of more than 8 hours a day and/or other settings on reducing neonatal mortality. This research showed that cumulative skin to skin contact duration of 8 hours a day reduced the number of neonatal deaths but this reduction was not statistically significant.

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APPENDICES

Appendix I: INFORMED CONSENT FORM

Consent Form for Participation in a Research

TITLE: THE EFFECTIVENESS OF EARLY INTERMITTENT KANGAROO MOTHER CARE (KMC) ON THE HEALTH STATUS OF STABLE LOW-BIRTH-WEIGHT (LBW) INFANTS: A QUASI EXPERIMENTAL STUDY

Dear Respondent,

You are invited to participate in a research study conducted by Joseph Kennedy Muthoka. I am a PhD (Public Health) student at JKUAT. This research project is funded by me as part of my PhD program. The purpose of this research is to determine the factors associated with neonatal survival and the effectiveness of early intermittent KMC and conventional neonatal care on stable LBW infants.

You will be randomly allocated to either the intervention group or the control group and fill in a questionnaire. If allocated to the intervention group, your participation will involve practicing skin-to-skin contact (SSC) in which your pre-term or LBW infant will be placed vertically (prone) between your breasts. The infant will be firmly attached to the chest and below your clothes for a cumulative period of at least 8 hours every day. You will also be given information on breastfeeding. This 8 hour period may be done in several sessions a day but any session should not be less than 1 hour. The SSC will be continued until the infant attains the weight of 2000 grams or reaches the gestational age of 40 weeks. When not practicing the SSC, the infant will be placed inside the incubator or the available artificial warming system. You will be expected to bring the baby to the hospital at 28 days of age to assess the condition of the baby, weigh the baby and ask you questions relating to the condition of the baby.

If allocated to the control group, your infant will be given routine care offered in the neonatal unit to pre-term or LBW infants. This generally includes an artificial warming system (incubator). You will also be given information on breastfeeding. You will be expected to bring the baby to the hospital at 28 days of age to assess the condition of the baby, weigh the baby and ask you questions relating to the condition of the baby.

The risks of this study are minimal. Some aspects in the study that relate to pregnancy loss or infant death may be uncomfortable to some respondents. You may decline to answer any or all the questions and you may terminate your involvement at any time if you choose to. There will be no direct benefit to you for your participation in this study. You will be reimbursed any study related costs that you will incur. Knowledge gained through this study may enable health authorities to make informed decisions about the best strategy to care for stable LBW infants in order to improve neonatal survival.

If you consent to participate in the study, I will have access to your information on the health records. I will use study codes instead of your name to maintain confidentiality. Please do not write your name on the questionnaire. I promise to do everything I can to ensure that any information obtained from you or your file is confidential. Your identity will not be revealed in any publication resulting from this study.

Your choice to participate in the study is voluntary. Without the help of people like you, research on the effect of KMC in LBW infants cannot be conducted. You may choose not to participate and may withdraw your participation consent at any time. There is no penalty if you do not participate.

If you have any questions or concerns about participating in this study, or if any problems arise, please contact me at +254 720 262659 or ken.muthoka@gmail.com. In case you have any questions or concerns about your rights as a research participant, please contact the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee, Telephone (+254-020) 2726300-9 Ext 44355, E-mail: uonknh_erc@uonbi.ac.ke.

Consent

I have read this consent form and have been given the opportunity to ask questions. I give my consent to participate in this study.

Participant's signature________________________________ Date: __________________

Researcher's signature________________________________ Date: __________________

Sincerely,

Kennedy Muthoka,
PhD in Public Health Student
Jomo Kenyatta University of Agriculture and Technology (JKUAT)

Appendix II: ENTRY QUESTIONNAIRE

TITLE: THE EFFECTIVENESS OF EARLY INTERMITTENT KANGAROO MOTHER CARE (KMC) ON THE HEALTH STATUS OF STABLE LOW-BIRTH-WEIGHT (LBW) INFANTS: A QUASI EXPERIMENTAL STUDY

SUBJECT CODE: ________ TODAY'S DATE (Day /Month/Year): ______________

Instructions:

- **This data will be collected from the mother through a face to face interview conducted by the research assistant**
- **Interviews will be conducted between 12 and 24 hours post-delivery at a time convenient for the mother**

AREA OF RESIDENCE: ________________

AGE (Years): ______________________ SEX: □ Female □ Male

SECTION A: SOCIOECONOMIC DETERMINANTS

1. What is your marital status?

   □ Single □ Married/Cohabiting □ Separated/Divorced □ Widowed

2. What is your religious affiliation?

   □ None □ Christian □ Hindu □ Muslim □Other (Specify) ___________

3. Does your religious belief discourage you from utilizing modern healthcare services?

   □ Yes □ No

4. What is your highest level of formal education?

☐ None ☐ Primary ☐ Secondary ☐ Tertiary

5. If married/cohabiting, what is your spouse's level of formal education attained?

☐ None ☐ Primary ☐ Secondary ☐ Tertiary

6. What is your current employment status?

☐ Unemployed ☐ Employed

   a. If you are unemployed, what is your main source of income?

   ____

   b. If you are employed, what kind of job do you do?

☐ Casual ☐ Formal ☐ Self-employed

7. If married/cohabiting, what is your spouse's employment status?

☐ Unemployed ☐ Employed

   a. If your spouse is unemployed, what is his main source of income?

   ____
   ______

   b. If your spouse is employed, what kind of job does he do?

☐ Casual ☐ Formal ☐ Self-employed

8. What is your total household income per month (Kenya shillings)?

☐ Less than 6,000 ☐ 6,000 to 15,000 ☐ 15,001 to 30,000 ☐ 30,001 to 50,000

☐ More than 50,000

9. What is the number of persons living together with you in the house you live in?

____

10. Regarding the house you currently live in;

    a. What type of house is it?

    ☐ Temporary ☐ Semi-permanent ☐ Permanent

b. How many rooms does the house have? ___________

c. What type of ownership do you have for the house?

 Rented Own

d. The house has what type of walls?

 Iron sheets Concrete Carton/Paper

 Other (Specify) ______________________________

e. Do you have access to toilet (latrine) in the house you live in?

 Yes No

f. If yes to 10 (e) above, does the house you live in have an inbuilt toilet?

 Yes No

g. The house has what type of floor?

 Mud Cemented/tiled

 Other (Specify) ______________________________

h. Do you own the following items in your house?

No.	**Item**	**Ownership**
1.	Fridge	Yes No
2.	Television	Yes No
3.	Computer	Yes No

11. What is the main source of fuel for cooking in your house?

 Kerosene Gas Charcoal Electricity

12. What is the main source of fuel for lighting in your house?

 Kerosene Electricity Other (specify) ________________

13. What is the source of your drinking water for use in your house

 Pond

☐ Well/borehole

☐ Piped

☐ River

☐ Other (please specify) ________________________

14. Have you had any incidence of diarrhea in the last three months?

☐ Yes ☐ No

SECTION B: PROXIMATE DETERMINANTS

The following questions relate to your most recent pregnancy

15. What is the sex of the infant?

☐ Female ☐ Male

16. What was the birth weight (in grams)? __________________

17. Where did the delivery take place?

☐ In this hospital ☐ At home ☐ In another hospital

18. What was the gestational age (in weeks) (the number of weeks before your last menstrual cycle/The time between conception and birth)? _______________

19. What was the mode of delivery?

☐ Normal (Spontaneous Vaginal Delivery) ☐Assisted delivery ☐ Caesarean Section

20. How many babies did your most recent pregnancy have?

☐ Singleton ☐ Multiple births

If Multiple births,

a. How many babies did the pregnancy have? ______________

b. What was the birth weight (in grams) of the other babies? ____________

c. What is the status of the other babies?

☐ Alive ☐ Dead

21. Were there any complications (problems) during delivery of this most recent baby?

☐ Yes ☐ No

If Yes, please tick which problem (complication) you experienced

☐ Fetal distress (the baby was in some kind of danger when the heart rate was slow)

☐ Breech Position or “malpresentation.” (The baby is positioned in the uterus head up, bottom down; sideways; or feet first

☐ Placenta previa (The placenta was covering the cervix)

☐ Meconium aspiration (Meconium (a black, tarry substance in the baby’s intestines) is present in amniotic fluid the baby has inhaled)

☐ Nuchal Cord (The umbilical cord is wrapped around the baby’s neck)

☐ Cephalopelvic Disproportion (CPD) - The baby’s head is too big to pass through the mother’s pelvis, resulting in “failure to progress.”

☐ Other delivery problems (complications), please specify___________________________

22. Have you been pregnant before this most recent pregnancy?

☐ Yes ☐ No

If Yes,

a. How many times have you been pregnant before this most recent pregnancy? _______

b. What is the number of times you have given birth prior to this most recent pregnancy? __________

c. What is the birth date of the child before this most recent pregnancy? (Day /Month/Year) _________________________

23. During this most recent pregnancy, did you attend the prenatal clinic?

☐ Yes ☐ No

If Yes,

a. Which month of the pregnancy did you first attend the prenatal clinic. Please circle one

☐ First trimester (1– 3 months)

☐ Second trimester (4 – 6 months)

☐ Third trimester (7– 9 months)

b. How many times in total, during this most recent pregnancy, did you attend the prenatal clinic? ________

24. During the pregnancy period, on average, how many meals did you have in a day?

☐ One ☐ Two ☐ Three ☐ Four or more

25. Please tick the foods (meals and snacks) from the list below that you ate or drank on average when you were pregnant.

☐ Breakfast ☐ Snack ☐ Lunch ☐ Snack ☐ Dinner ☐ Snack

☐ Any other food (Please specify) ______________________

26. Please indicate the food groups from the list below that you ate or drank on average when you were pregnant

No.	**Food Group**	**Examples**	**Your response**
a.	Carbohydrates	Maize, rice, wheat, sorghum, millet, or any other grains or foods made from these (e.g. *ugali*, bread, noodles, spaghetti (pasta), porridge or chapatti)	☐ Yes ☐ No
		White roots and tubers- examples: potatoes, yam, cassava, or other foods made from	☐ Yes

		roots like *mukimo*	☐ No
		SWEETS- sugar, honey, soda or sweetened juice drinks, chocolates, candies, cookies and cakes	☐ Yes ☐ No
b.	Proteins	ORGAN MEAT- liver, kidney, heart	☐ Yes ☐ No
		FLESH MEAT- beef, pork, lamb, goat, rabbit, game, chicken, duck, other birds, insects	☐ Yes ☐ No
		EGGS	☐ Yes ☐ No
		FISH AND SEAFOOD	☐ Yes ☐ No
		MILK AND MILK PRODUCTS - milk, cheese, yogurt	☐ Yes ☐ No
		LEGUMES, NUTS AND SEEDS - beans, peas, lentils, nuts	☐ Yes ☐ No
c.	Vitamins	Pumpkin, carrot or sweet potato	☐ Yes ☐ No
		Kale (sukuma wiki), spinach, managu,	☐ Yes

		mchicha, Cowpeas(kunde) + other locally available vegetables	☐ No
		Mango, oranges, peach, custard apple, passion fruit and 100% fruit juice made from these + other locally available fruits	☐ Yes ☐ No
d.	Fats	Oil, fats or butter added to food or used for cooking Nuts	☐ Yes ☐ No

27. During your most recent pregnancy, did you use any micronutrients supplements (like folic acid, iron, multivitamins or calcium)?

☐ Yes ☐ No

28. During your most recent pregnancy, did you consume any alcoholic beverages?

☐ Yes ☐ No

29. During your most recent pregnancy, did you smoke cigarettes?

☐ Yes ☐ No

30. If you are living with a spouse or cohabiting, does your partner smoke?

☐ Yes ☐ No ☐ Not Applicable

31. Please indicate below which chronic condition(s) you have:

☐ Diabetes ☐ Yes ☐ No

☐ Hypertension (High Blood Pressure) ☐ Yes ☐ No

☐ Heart disease ☐ Yes ☐ No

☐ Other Chronic Condition, please specify

____

Appendix III: DATA ABSTRACTION TOOL

Subjects study code: __________________

Instructions:

- **This data will be collected directly from the patient file and the KMC register by the research assistant**

SECTION A: MOTHER

Collect information about the mother from the source documents on the following aspects;

1. Age: ______________ (Years)
2. Pre-pregnancy weight__________ (kilograms)
3. Weight at birth ___________ (kilograms)
4. Weight gain during pregnancy ___________ (kilograms)
5. Gravida ___________
6. Parity ___________
7. Place of delivery

   ☐ In this hospital ☐ At home ☐ In another hospital
8. Type of delivery

   ☐ Normal (Spontaneous Vaginal Delivery) ☐ Caesarean Section
9. Please indicate the HIV status of the mother

   ☐ Positive ☐ Negative ☐ Unknown
10. Any complications during the pregnancy___________

    ☐ Yes ☐ No
11. If yes to question 10 above, please specify the complication(s)

    ____
    ____

    ____

12. Birth status of the most recent pregnancy;

☐ Singleton ☐ Multiple

13. Does the mother suffer from any of the following chronic condition(s)?

☐ Diabetes	☐ Yes	☐ No
☐ Hypertension (High Blood Pressure)	☐ Yes	☐ No
☐ Heart disease	☐ Yes	☐ No

☐ Other Chronic Condition (please specify)

____

SECTION B: INFANT

Collect information about the infant from the source documents on the following aspects;

1. Infant's gestational age at birth in weeks; __________________
2. Infant's birth weight (grams) __________________
3. Infant's weight (grams) in 24 hours __________________
4. Infant's weight (grams) in 48 hours __________________
5. Infant's sex:

   ☐ Male ☐ Female
6. Apgar score at 1 minute; __________________
7. Infant's weight (grams) at admission to KMC unit__________________
8. Infant's weight (grams) at discharge from KMC unit__________________
9. Infant's weight gain (grams) at KMC unit__________________
10. Infant's weight (grams) at last follow up period (28 days) __________________
11. Infant's weight (grams) gain at last follow up period (28 days)

    ____
12. Infants age at enrolment to KMC unit (hours) __________________
13. Number of days spent in KMC unit__________________
14. Average time spent practicing KMC/KMC dosage (actual time spent doing skin to skin contact per day) __________________

15. Duration of hospital stay (hours) __________________

16. Any infant's complication during neonatal period

    ☐ Yes ☐ No

17. If yes to question 13 above, please specify the complication

    ____

18. Baby's health status on discharge;

    ☐ Healthy ☐ Not Healthy

19. Incidence of neonatal sepsis during the hospital stay (any infection that was characterized by body temperature changes, breathing related problems, diarrhea, low blood sugar, reduced neonatal movements, reduced sucking, seizures, bradycardia, swollen belly area, vomiting, and/or jaundice)

    ☐ Yes ☐ No

20. Baby's condition on discharge;

    ☐ Alive ☐ Dead

21. If dead, please indicate cause of death _______

    - ☐ Sudden infant death (unexplained death, mostly during sleep)
    - ☐ Injury
    - ☐ Pneumonia
    - ☐ Diarrhea
    - ☐ Malaria
    - ☐ Measles
    - ☐ Malnutrition
    - ☐ Other (please specify) ___________________

Appendix IV: EXIT QUESTIONNAIRE

TITLE: THE EFFECTIVENESS OF EARLY INTERMITTENT KANGAROO MOTHER CARE (KMC) ON THE HEALTH STATUS OF STABLE LOW-BIRTH-WEIGHT (LBW) INFANTS: A QUASI EXPERIMENTAL STUDY

SUBJECT CODE: ________ TODAY'S DATE (Day /Month/Year): ________________

Instructions:

- **This data will be collected from the mother through a face to face interview conducted by the research assistant**
- **Interviews will be conducted at the study hospital on the 28 day of life for the infant**

AREA OF RESIDENCE: ________________ AGE (Years): ______________

SEX: ☐ Female

1. Did you practice skin to skin contact (Kangaroo care) at home after discharge from the hospital

   ☐ Yes ☐ No

   If yes, how many hours per day on average did you practice the skin to skin contact (Kangaroo care)? _____________ (hours)

2. What is the current status of your baby after discharge from the hospital?

   ☐ Alive ☐ Dead

   If dead, what was the cause of the death?

   ☐ Sudden infant death (unexplained death, mostly during sleep)
   ☐ Injury
   ☐ Pneumonia
   ☐ Diarrhea
   ☐ Malaria
   ☐ Measles

☐ Malnutrition

☐ Other, please specify ____

3. What is the current weight (grams) of your most recent baby?

   ____

4. Has the baby had any injury (accident) since birth?

   ☐ Yes ☐ No

   If yes, what type of injury did the baby have?

   ☐ Falls ☐ Intentional ☐ Burns ☐ Poisoning

   ☐ Other, please specify____

5. Has your baby been admitted to any hospital since being discharged from the Pumwani Maternity Hospital?

   ☐ Yes ☐ No

6. Regarding the house you stay in after delivery

   a. How many rooms does the house have? ____________________
   b. How many people stay with you in the same house ____________________

7. What is the source of drinking water in the house you currently live in?

   ☐ Pond

   ☐ Well/borehole

   ☐ Piped

   ☐ River

   ☐ Other (please specify) ________________________

8. Have you had any incidence of diarrhea in the last one month?

   ☐ Yes ☐ No

   a. If yes, how many incidences of diarrhea did you have in the last one month? ______

9. Has the baby had any incidence of diarrhea in the last one month?

☐ Yes ☐ No

a. If yes, how many incidences of diarrhea did the baby have in the last one month? ______

10. Do you have access to toilet (latrine) in the house you live in?

☐ Yes ☐ No

a. If yes, does the house you live in have an inbuilt toilet?

☐ Yes ☐ No

11. After delivery, on average, how many meals do you have in a day?

☐ One ☐ Two ☐ Three ☐ Four or more

12. Please tick the foods (meals and snacks) from the list below that you ate or drank yesterday

☐ Breakfast ☐ Snack ☐ Lunch ☐ Snack ☐ Dinner ☐ Snack

☐ Any other food (Please specify) ____________________

13. Please tick the food groups from the list below that you ate or drank yesterday

No.	**Food Group**	**Examples**	**Tick Yes or No**
a.	Carbohydrates	Maize, rice, wheat, sorghum, millet, or any other grains or foods made from these (e.g. *ugali*, bread, noodles, spaghetti (pasta), porridge or chapatti)	☐ Yes ☐ No

		White roots and tubers- examples: potatoes, yam, cassava, or other foods made from roots like *mukimo*	☐ Yes ☐ No
		SWEETS- sugar, honey, soda or sweetened juice drinks, chocolates, candies, cookies and cakes	☐ Yes ☐ No
b.	Proteins	ORGAN MEAT- liver, kidney, heart	☐ Yes ☐ No
		FLESH MEAT- beef, pork, lamb, goat, rabbit, game, chicken, duck, other birds, insects	☐ Yes ☐ No
		EGGS	☐ Yes ☐ No
		FISH AND SEAFOOD	☐ Yes ☐ No
		MILK AND MILK PRODUCTS - milk, cheese, yogurt	☐ Yes ☐ No
		LEGUMES, NUTS AND SEEDS - dried beans, dried peas, lentils, nuts	☐ Yes ☐ No
c.	Vitamins	Pumpkin, carrot or sweet potato	☐ Yes

			☐ No
		Kale (sukuma wiki), spinach, managu, mchicha, Cowpeas(kunde) + other locally available vegetables	☐ Yes ☐ No
		Mango, oranges, peach, custard apple, passion fruit and 100% fruit juice made from these + other locally available fruits	☐ Yes ☐ No
d.	Fats	Oil, fats or butter added to food or used for cooking Nuts	☐ Yes ☐ No

☐ Yes ☐ No

14. After discharge from the hospital, has the child had any incidence of neonatal sepsis (any infection that was characterized by body temperature changes, breathing related problems, diarrhea, low blood sugar, reduced neonatal movements, reduced sucking, seizures, bradycardia, swollen belly area, vomiting, and/or jaundice)?

    ☐ Yes ☐ No

15. After birth of your most recent child, did you consume any alcoholic beverages?

    ☐ Yes ☐ No

16. After birth of your most recent child, did you smoke any cigarettes?

    ☐ Yes ☐ No

17. If you are living with a spouse or cohabiting, does your partner smoke?

    ☐ Yes ☐ No ☐ Not Applicable

Appendix V: KNH ETHICAL REVIEW APPROVAL

KENYATTA NATIONAL HOSPITAL APPROVED 09 FEB 2016 KNH/UoN-ERC P.O. Box 20723-00202 NRB.

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Ref: KNH-ERC/A/93

9th March, 2016

Joseph Kennedy Muthoka
TM 410-2918/2014
Principal Investigator
JKUAT

Dear Joseph

Revised research proposal: The effect of Early Intermittent Kangaroo Mother Care (KMC) on the Health status of stable low-birth –weight(LBW) infants: A randomized controlled trial (P754/ 12/2015)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and **approved** your above proposal. The approval period is from 9th March 2016 – 8th March 2017.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

"Protect to discover"

Yours sincerely,

PROF. M.L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director, CS, KNH
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Ref: KNH-ERC/ Mod&SAE/326

19th October 2016

Kennedy Muthoka
TM 410-2918-2014
P o Box 15167, 00100
NAIROBI

Dear Kennedy

Re: Approval of modifications – study titled "The effect of early intermittent Kangaroo Mother Care (KMC) on the health status of stable low-birth weight(LBW) infants: A Quasi-Experimental Design (P754/12/2015)

Refer to your communication dated August 22, 2016.

Upon review of the requested modifications, the KNH-UoN ERC has **approved** the following:

1. Change of eligibility criteria by birth weight from 1300 – 1600g to a birth weight below 2000g.
2. Include other health facilities – Thika Level 5 Hospital and Machakos level 5 hospitals to be control sites.
3. Change of study design from Randomized controlled trial to a Quasi-Experimental design
4. The revised study title is also approved.

The documents are hereby endorsed and stamped for use.

Yours sincerely,

PROF. M.L. CHINDIA
SECRETARY, KNH-UON ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director, CS, KNH
The Chair, KNH- UoN ERC
The Dean, School of Medicine,UoN

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Appendix VI: PERMISSION TO CONDUCT THE STUDY FROM NACOSTI

NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY AND INNOVATION

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Ref. No. **NACOSTI/P/16/83568/10725**

Date: **14th November, 2016**

Joseph Kennedy Muthoka
Jomo Kenyatta University of Agriculture
And Technology
P.O. Box 62000-00200
NAIROBI.

RE: RESEARCH AUTHORIZATION

Following your application for authority to carry out research on ***"The effectiveness of early intermittent Kangaroo Mother Care (KMC) on the health status of stable low-birth-weight (LBW) infants: A randomized controlled trial,"*** I am pleased to inform you that you have been authorized to undertake research in **Nairobi, Kiambu and Machakos Counties** for the period ending **29th April, 2017.**

You are advised to report to **the County Commissioners, the County Directors of Education and the County Directors of Health Services, Nairobi, Kiambu and Machakos Counties** before embarking on the research project.

On completion of the research, you are expected to submit **two hard copies and one soft copy in pdf** of the research report/thesis to our office.

DR. M. K. RUGUTT, PhD, HSC.
DIRECTOR-GENERAL/CEO

Copy to:

The County Commissioners
Selected Counties.

National Commission for Science, Technology and Innovation is ISO 9001:2008 Certified

Appendix VII: PUBLICATIONS

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Burden and factors responsible for neonatal morbidity among Low-Birth-Weight infants in Kenya

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ABSTRACT

Kenya, like the rest of Sub-Saharan Africa and many other developing countries in the world, has made progress in improving newborn health, but did not meet the millennium development goal four for child health. Neonatal morbidity and mortality remains unacceptably high. The objectives of this study were to estimate the burden on neonatal morbidity and determine the socioeconomic and proximate factors responsible for neonatal morbidity in Kenya. A cohort study was carried out at Pumwani maternity hospital, Thika Level 5 hospital and Machakos Level 5 hospital with a sample of 343 stable LBW (≤2000g) infants. Informed by the concepts of Mosley and Chen (1984) analytical framework, several socioeconomic and proximate factors of neonatal morbidity and mortality were examined. Cross tabulations and multiple logistic regression analyses were done to determine the relationships between these factors and neonatal morbidity. The burden of neonatal morbidity was high, 61.5% (N=343) of the low-birth-weight infants. Micronutrient use, lower birth weight, pregnancy history, infant sex being male, birth complications and source of water as rivers, well and ponds were factors responsible for neonatal morbidity. Stakeholders should develop programs that address these factors to improve newborn health among birth-weight infants.

Keywords: Neonatal health; Neonatal morbidity; socioeconomic determinants; proximate determinants; low-birth weight-infants; newborn health

I. INTRODUCTION

Goal 3 of the United Nations Sustainable Development Goals (SDGs) is to ensure healthy lives and promote well-being for all at all ages [1]. Neonatal morbidity is the main cause of neonatal mortality [2]. Globally, it is estimated that neonatal sepsis accounts for 26%-32% of neonatal deaths while asphyxia account for 23%-29% of all neonatal deaths [2,3,4]. A review of exiting community studies showed that neonatal morbidity could be responsible for 42%-50% of neonatal deaths in the first week of life [2,5]. Other causes of neonatal deaths include low-birth-weight (less than 2500 g) which also has a causal relationship with neonatal morbidity [6,7,8,9,10].

The burden of neonatal morbidity is evidently very high. This has been demonstrated in several studies in developing countries [11,12,13]. Kenya, like the rest of Sub-Saharan Africa, has made notable progress in improving neonatal health outcomes. Despite the progress, Kenya did not achieve the Millennium Development Goals for child health [14]. The neonatal mortality in Kenya is 22 deaths per 1,000 live births [15,16]. Most of these neonatal deaths (30%), are caused by severe neonatal infections [34]. Addressing neonatal morbidity is therefore a health priority, to enable Kenya achieve the vision 2030 and goal 3 of the SDGs [1,17].

Currently, most neonatal infections in many developing countries stem from a failure to identify and address socioeconomic and other pertinent factors associated with the incidence of neonatal morbidity [2]. Mosley and Chen (1984) [31] developed an analytical framework for analyzing determinants of child health. According to the model, impact on morbidity and mortality is influenced by socioeconomic determinants (independent variables) that operate through a certain set of proximate determinants (intermediate variables). Socioeconomic determinants include variables that relate to productivity of mothers and fathers. Education level of parents influences their occupation and buying power of the household. Income influences neonatal survival through food choices, water (quantity and quality), housing, clothing, hygiene and sickness care among others [18,19]. Higher education levels are associated with better neonatal outcomes [20] High education, especially maternal, improves the status of women and access to information and health services. Mother's time is necessary for a healthy baby as she requires time for prenatal visits and breastfeeding among others. Traditions, norms and attitudes include factors that affect the economic and health related practices. These may include factors like power relationships within the household, value of children and belief about disease causation among others [21,22,23,24].

The proximate determinants that directly influence the risk of neonatal morbidity and mortality has been identified as maternal factors; environmental contamination; nutrient deficiency; injury; and personal illness control. Factors that affect maternal health has impact on neonal survival. These factors may include age, parity and birth interval. Synergism between these factors may also ocur and this differentially affect child health and survival especially when two or more such unfavorable factors occur together [21]. Household crowding, source of water supply, food handling practices, incidence of diarrhea and/or presence of latrines or toilettes are physical indices associated with environmental contamination. The contamination is directly associated with neonatal morbidity. Nutrient deficiency influence child survival based on the nutrients available to the neonate and the mother [18,21]. Nutrient deficiency during lactation can affect the quality of breastmilk. On the other hand, injuries reflect environmental risks that differ in socioeconomic and environmental contexts. Incidence of injuries whether intentional or accidental affect neonatal survival [18,21]. Personal illness control influences the rate of developing neonatal illness. Personal illeness control entail medical interventions like curative mesures of existing and diagnosed diseases. Timely access to quality medical interventions may be associated with favorable neonatal outcomes [1,25,26].

This study addresses one of the major areas of research needed to advance newborn health by investigating the risk factors of neonatal morbidity in low income countries. This knowledge is useful in tailoring interventions to curb the high neonatal mortality, especially among LBW infants which is an overriding factor contributing to the majority of neonatal deaths.

II. METHODS AND MATERIAL

A. Study Design and Setting

A cohort study was carried out at Pumwani Maternity hospital, Thika Level 5 hospital and Machakos Level 5 hospital. This study was done as part of a larger study on the effectiveness of early intermittent Kangaroo Mother Care; A quasi-experimental study. The facilities were roughly similar in patient population characteristics and the health care system. Pumwani hospital, located in Nairobi, is one of the largest public maternity referral hospitals in Kenya with 350 beds and 150 cots [21]. Thika Level 5 hospital is one of the largest public hospitals in Kiambu County with 265 beds and 24 cots while Machakos Level 5 hospital is the biggest public health facility in Machakos County with 375 beds and 57 cots [27]. The study population was all stable LBW infants weighing ≤2000 grams irrespective of their gestational age who were admitted at the three hospitals during the study period.

The sample size was 343 drawn from the three facilities by consecutively enrolling eligible LBW infants into the study. The inclusion criteria for the study was infants weighing ≤2000 grams irrespective of their gestational age, infants less than 72 hours of life, stable infants (not on oxygen or phototherapy, on full feeds and retaining, Oxygen saturation of >95%, Heart rate of >100 beats per minute, capillary refill <3 seconds) and willingness to give written consent. LBW infants with major congenital malformations or severe perinatal complications and cases where the caregiver was unwilling to give written consent were excluded from the study. The follow up period was the neonatal period (28 days).

B. Data Collection and Procedures

Data was collected between June 2016 to June 2017 using structured tools which were guided by the concepts of the Mosley and Chen (1984) analytical framework [21] and from literature review (Fig. 1).

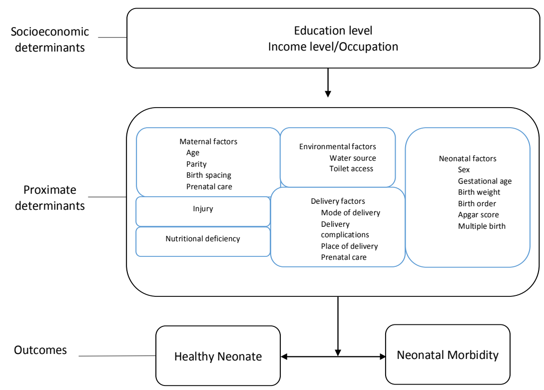

Figure 1: Adopted Mosley and Chen Analytical Framework (1984) [21]

Tools were pre-tested before onset of the study. Data was collected by two research assistants in each hospital from mothers and infants who met the eligibility criteria. The research assistants were trained on questionnaire administration and their roles were to distribute, administer, collect the questionnaires and clarify instructions if necessary. An entry questionnaire was adminstered within 72 hours post delivery through face to face interviews in the postnatal ward, at a time that was convenient to the mother. An exit questionnaire was administered at the last follow up (at 28 days of age) asking details about incidence of injury, nutritional factors and environmental factors. Data was also abstracted from the patient files.

C. Variables

The dependent variable was incidence of neonatal morbidity which was coded as: No incidence of morbidity=0 and incidence of morbidity=1. Independent variables were socioeconomic variables (education level of husband/spouse and mother, income level, and occupation) and proximate variables like maternal factors (age, parity, birth spacing and prenatal care), delivery factors (mode of delivery, delivery complications and place of delivery), injury, nutritional deficiency, environmental factors (water supply and presence of toilets) and neonatal factors (sex, gestational age at birth, birth weight, birth order, Apgar score and multiple birth).

D. Data Management and Analysis

Microsoft Excel was used for data entry and storage. Data analysis was done using Stata Statistical Software: Release 14 [28]. An alpha of 0.05 was used for statistical significance. Initially, basic descriptive statistics were used to describe the respondents‟ socioeconomic characteristics. Cross tabulations were done to determine the relationships between independent and dependent variables (neonatal morbidity). Multiple logistic regression analysis was conducted to determine the predictors of neonatal morbidity. The variables included in the regression model were based on their clinical significance. A backward stepwise method was used in coming up with a minimum set of determinants that resulted in the optimal predictive model of the final outcomes. Subgroup analysis was also done for neonatal sepsis and incidence of hospital readmission.

E. Ethical Considerations

Ethical clearance for the study was given by the Kenyatta National Hospital Ethics Review Committee after reviewing the study protocol. Institutional permission was sought from the respective County authorities and Medical Superintendents of the study hospitals. Permit to conduct the study was given by National Comission for Science, Technology and Innovation (NACOSTI). An informed consent was obtained and confidentiality was ensured by coding the questionnaires.

III. RESULTS AND DISCUSSION

A. Results

i. Socioeconomic characteristics,

A total of 343 LBW infants were recruited in the study between July 2016 to June 2017. The mean age of the mothers was 25.4 (SD=5.3), range 15-45 years. Majority of the mothers, 79.9% (N=343) were married/cohabiting, with half of them (50.2%, N=343) having secondary education. More than half of their spouses (59.4%, n=283) had secondary education. A third of the mothers had household income of below 6,000 Kenya shillings per month (about 60 USD), with majority 78.1% (N=343) renting the house they were living in. Two in every ten (22.2%, n=338) of the mothers were living in a temporary house with a similar number (23.9%, N=343) having no access to a toilet. A third of the mothers used kerosene as the main fuel for cooking. A small fraction of mothers, 5.5% (N=343) used river/pond as the source of water for drinking. A few of the respondents, 10.9% (n=339) had an incidence of diarrhea in the last three months before delivery. The distribution socioeconomic characteristics was as shown in Table 1.

ii. Proximate characteristics,

The average birth weight was 1492.6 grams (SD=275.3), range 700-2000 grams. The average gestational age among the mothers was 30.3 weeks (3.8), 20-40 weeks. More than half (59.8%, n=343) of the infants were female, and majority (78.4%, N=343) were born in the study hospital. Most of the infants (83.3%, n=342) were born through spontaneous vagina delivery and only a third (29%, n=341) were multiple births. Delivery complications were recorded in 26.6% (n=342) of the births. About two thirds (63.9%, n=144) of the infants had a birth interval of more than 36 months. A few of the mothers (4.4%, n=342) reported taking only one meal on average during their most recent pregnancy. Most (93.2%, n=339) of the mothers attended antenatal clinic while pregnant. About half (51.4%, n=329) of the mothers reported having no pregnancy loss and having 1 or more live births prior to their most recent pregnancy. Nearly a third (30%, N=343) of the mothers had not used micronutrient supplementation during their most recent pregnancy. HIV prevalence was 8.5% (n=329) among the mothers while prevalence of non communicable diseases was 13.1% (N=343) among the mothers. A few (2.9%, N=343) of the mothers reported use of alcohol during pregnancy while 0.9% (n=342) smoked cigarette during pregnancy. Some 7.7% (n=274) of the mothers reported that their spouses smoked cigarettes during the pregnancy period. Majority (81.4%, n=301) of the infants had an Apgar score at 1 minute of more than 5.

iii. Incidence of neonatal morbidity,

TABLE 1. ASSOCIATION BETWEEN SELECTED SOCIOECONOMIC CHARACTERISTICS AND NEONATAL MORBIDITY

Variable		**Infant complication (Yes)**	**P Value**
		n (%)	
Marital status	Married	170 (62%)	0.689
	Single	41 (59.4%)	
Maternal level of education	Primary & below	79 (67%)	0.27
	Secondary	99 (57.6%)	
	Tertiary	33 (62.5%)	
Spouses level of education	Primary & below	27 (53%)	0.481
	Secondary	104 (61.9%)	
	Tertiary	40 (62.5%)	
Household income per month	<6000	76 (69.1%)	0.053
	6000 to 15000	58 (53.2%)	
	>15000	63 (62.4%)	
Type of house ownership	Own	51 (68%)	0.192
	Rented	160 (59.7%)	
Access to toilet	No	61 (74.4%)	0.006*
	Yes	150 (57.5%)	
Source of fuel for cooking	Electricity/Gas	99 (60.7%)	0.0064*
	Charcoal	55 (72.4%)	
	Kerosene	57 (55.3%)	
Source of drinking water	Piped	163 (57.4%)	0.003*
	River/pond	16 (84.2%)	
	Well/borehole	32 (80%)	
Incidence of diarrhea in last 3 months	No	184 (60.9%)	0.269
	Yes	26 (70.3%)	

*. The Chi-square statistic is significant at the 0.05 level

Almost two thirds (61.5%, N=343) of the LBW infants had an incidence of neonatal morbidity and more than half (53.9%, N=343) of the LBW infants had an incidence of neonatal sepsis. Neonatal sepsis was the most common form of neonatal morbidity, accounting for 87.7% (n=211) of the neonatal morbidity. A total of 14 (4.5%, n=314) neonates were readmitted to hospital after discharge.

iv. Association between selected socioeconomic characteristics and neonatal morbidity,

The relation between access to toilet, source of fuel for cooking and source of drinking water were significantly associated with incidence of neonatal morbidity ($p<0.05$). There was no significant relationship between the other socioeconomic characteristics and incidence of neonatal morbidity ($p>0.05$).

v. Association between selected proximate characteristics and neonatal morbidity,

Among the proximate characteristics, delivery complications, pregnancy history and use of micronutrients were significantly associated with neonatal morbidity ($p<0.05$). The other proximate characteristics including infant sex, place of delivery, mode of delivery, multiple births, birth interval, average number of meals per day during pregnancy, ANC attendance, HIV status, NCDs and Apgar score at one minute were not significantly associated with infant complications ($p>0.05$).

TABLE 2. ASSOCIATION BETWEEN SELECTED PROXIMATE CHARACTERISTICS AND NEONATAL MORBIDITY

Variable		**Neonatal morbidity (Yes)**	**P Value**
		n (%)	
Infant Sex	Female	124 (60.5%)	0.633
	Male	87 (63%)	
Place of delivery	This hospital	163 (60.6%)	0.065
	Another hospital	35 (74.5%)	
	Home	13 (48.2%)	
Mode of delivery	CS	31 (54.4%)	0.233
	Normal	179 (62.8%)	
Multiple births	No	145 (59.9%)	0.244
	Yes	66 (66.7%)	
Delivery complications	No	144 (57.4%)	0.011*
	Yes	66 (72.5%)	
Birth interval	<18 months	19 (79.2%)	0.094
	18-36 months	14 (50%)	
	>36 months	58 (63%)	
Average number of meals per day when pregnant	One	10 (66.7%)	0.484
	Two	29 (70.7%)	
	Three	114 (58.5%)	
	More than three	57 (62.6%)	
ANC attendance	No	10 (43.5%)	0.068
	Yes	198 (62.7%)	
Pregnancy history	Never pregnant	56 (50%)	0.007*
	No pregnancy loss with 1 or more live births	110 (65.1%)	
	1 or more pregnancy loss with 1 or more live births	30 (79%)	
	1 or more pregnancy loss with no live birth	6 (60%)	
Use of micronutrient supplementation	No	48 (46.6%)	0.000*
	Yes	163 (67.9%)	
HIV status	Negative	184 (61.1%)	0.283
	Positive	20 (71.4%)	
Chronic conditions (NCDs)	No	181 (60.7%)	0.446
	Yes	30 (66.7%)	
Apgar score at 1 minute	Apgar score 1-5	37 (66.1%)	0.536
	Apgar Score 6-10	151 (61.6%)	

*. The Chi-square statistic is significant at the 0.05 level

The gestational age, birth weight, age of the mother and birth order were not statistically associated with the incidence of neonatal morbidity ($p>0.05$).

vi. Multiple analysis of association of selected determinants with neonatal morbidity,

A multiple logistic regression analysis was performed to ascertain the effects of socioeconomic characteristics and proximate characteristics on the likelihood of developing neonatal morbidity. Eight successive iterations were performed using backward and forward stepwise method retaining only ten determinants in the final model. The logistic regression model as a whole was statistically significant [likelihood ratio $\chi2$ (13) = 86.33, $p < 0.000$].

Use of micronutrients was significantly associated with incidence of neonatal morbidity. LBW infants whose mothers used micronutrients were 4.3 times [95% CI, 2.1-8.7, p=0.000] more likely to develop neonatal morbidity than infants whose mothers did not use micronutrients during pregnancy.

The infants birth weight (grams) was significantly associated with incidence of neonatal morbidity. Every unit increase in birth weight (1 gram) was associated with a 1% reduction of incidence of neonatal morbidity [OR=0.99, 95% CI, 0.995-0.997, p=0.000].

Infant sex was significantly associated with incidence of neonatal morbidity. LBW male infants were 2.5 times more likely to develop neonatal morbidity compared to LBW female infants [OR=2.5, 95% CI, 1.3-4.8, p=0.005]. Complications during delivery were significantly associated with incidence of neonatal morbidity. Those with birth complications were 2.9 times [95% CI, 1.4-5.9, p=0.004] more likely to develop neonatal morbidity compared to LBW infants whose mothers did not experience delivery complications.

There was a significant association between water source and and incidence of neonatal morbidity. The incidence of morbidity was 11.5 times higher among those who used water from rivers/ponds compared to those who used piped water [OR=11.5, 95% CI, 1.8-73.8, p=0.01]. The incidence of morbidity was 4.4 times higher among those who used water from a well or borehole [OR=4.4, 95% CI, 1.3-14.5, p=0.014].

The other socioeconomic and proximate characteristics were not statistically significant predictors of incidence of neonatal morbidity (p>0.05).

TABLE 3. ASSOCIATION OF SELECTED DETERMINANTS WITH NEONATAL MORBIDITY

Neonatal morbidity	Adjusted Odds Ratio	P value	[95% Conf. Interval]	
			Lower	Upper
Micronutrient use	4.309736	0.000	2.146884	8.651527
HIV status	2.304508	0.164	0.7110904	7.468468
Birth weight	0.9960246	0.000	0.9945579	0.9974936
Gestational age	1.038182	0.407	0.9502162	1.134291
Infant sex	2.525618	0.005	1.327304	4.805794
Maternal Education level				
Primary and below	Reference category			
Secondary	0.7624738	0.447	0.3787448	1.534981
Tertiary	0.6281353	0.414	0.2060756	1.914608
Birth complication	2.888588	0.004	1.391976	5.994313
Partner smoking status	2.937215	0.115	0.7693452	11.21374
Water source				
Piped	Reference category			
River/pond	11.45693	0.01	1.778629	73.79913
well/borehole	4.425524	0.014	1.34663	14.54391
Household income				
<6000 (about 60 USD)	Reference category			
6000 to 15000	0.751173	0.481	0.3391824	1.663591
>15000	1.071953	0.872	0.4606837	2.494299
_cons	6.244379	0.248	0.278662	139.9268

B. Discussion

This study found that neonatal morbidity was very high, with about two thirds of the LBW infants having an incidence of neonatal morbidity. There are other studies that have shown similar high incidences of morbidity, with a particular one in India reporting incidences of 72.2% [11].

Our study found that there was a significant relationship between source of drinking water with incidence of neonatal morbidity. This is in line with the analytical framework used in the study [21]. Socioeconomic determinants influence neonatal morbidity through proximate determinants. The model considers these socioeconomic determinants as household level factors that affect child health. Source of drinking water is influenced directly by household income, though as a variable was not significantly associated with incidence of morbidity in our study. Maternal and spouse‟s level of education would influence the household income as a higher level of education would be associated with getting a better job and that increase the household income, but these too were not statistically significant.

This study investigated other socioeconomic characteristics including marital status of the mother and incidence of diarrhea in the last three months before delivery. These characteristics did not have a significant relationship with neonatal morbidity. A study done in Nigeria found a significant relationship between level of education of mothers and neonatal morbidity [31]. They however did not investigate other socioeconomic characteristics.

The analytical framework (Fig. 1) identifies the proximate determinants that directly influence the risk of neonatal morbidity. Our study found that micronutrient use, birth weight, infant sex, delivery complications and water source were significantly associated with incidence of neonatal morbidity among LBW infants. The proportion of LBW infants with morbidity was higher among the mothers who used micronutrients supplements. This is contrary to existing literature where routine iron supplementation during pregnancy has a significant benefit in reducing incidence of anemia in mothers and improved perinatal outcomes including reduced low birth weight delivery [29]. Contrary to our findings, Olayinka, Abimbola and Adeleke (2012) [30] found place of delivery to be significantly associated with neonatal morbidity. Other studies have reported contrary findings. Njim et al. (2015) [31] found that NCDs (hypertensive diasorders) and HIV infection were significantly associated with neonatal morbidity. Njim et al. (2015) [31] also found maternal age >36 years contributing signifantly to neonatal morbidity. Our study found no significant relationship between neonatal morbidity with maternal age, though most of the mothers in our study were much younger.

A study in India on LBW ≤2000 grams [32] also found a correlation between birth weight and neonatal morbidity, just as we did in our study. Birth order however was not a significant factor in neonatal morbidity in our study as outlined in the Mosley and Chen (1984) [21] analytical framework. We found that LBW male infants had a significantly higher risk of developing neonatal sepsis and/or morbidity. In a similar weight category study of LBW infants, Janaswamy et al. (2016) [32] found that sex of the infant was not a significant predictor of neonatal morbidity.

IV.CONCLUSION

This study investigated the risk factors of neonatal morbidity in Kenya, which is applicable in other developing countries. We identified that neonatal morbidity was high among certain respondent characteristics like micronutrient use, lower birth weight, infant sex being male, birth complications, and source of water as rivers, well and ponds. This knowledge is useful in tailoring interventions to improve newborn health, and ultimately reduce neonatal mortality. There is need to investigate the relationship between micronutrient use and increased incidence of neonatal morbidity.

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Why are Neonates Dying? Socioeconomic and Proximate Determinants of Neonatal Mortality among Stable Low-Birth-Weight (LBW) Infants in Kenya

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Abstract

Background: Neonatal mortality rates are very high in Kenya, like the rest of Sub-Saharan Africa. The sustainable development goals aim to reduce the current 21 neonatal deaths per 1,000 live births to below 12 deaths per 1,000 live births. The rate of decline in Neonatal mortality in many countries is very slow compared to other childhood mortality rates. The objective of this study was to determine the socioeconomic and proximate determinants of neonatal mortality in Kenya. **Methodology:** A cohort study was carried out at Pumwani Maternity hospital, Thika Level 5 hospital and Machakos Level 5 hospital in Kenya with a sample of 343 stable LBW infants (≤2000g). Informed by the concepts of the Mosley and Chen (1984) analytical framework, several socioeconomic and proximate characteristics were included in the study. Cross tabulations and multiple logistic regression analyses were done to determine the relationships between the determinants and neonatal mortality. **Results:** The mean birth weight was 1492.6 g (SD=275.3) and mean gestational age was 30.3 weeks. Most infants (59.8%, N=343) were female. Incidence of neonatal mortality was 8.5% (n=340). Household income, birth complications, birth weight, gestational age and multiple births were significant determinants of neonatal mortality among the LBW infants weighing £2000 grams. **Conclusion and recommendations:** The findings affirm the Mosley and Chen (1984) analytical framework on determinants of neonatal survival. The study provides useful information on determinants of neonatal mortality that is relevant to the Kenyan context and applicable to other low income countries.

Keywords: neonatal survival; neonatal mortality; socioeconomic determinants; proximate determinants; low-birth-weight infants

1. INTRODUCTION

The neonatal period is only the first 28 days of life and yet is the most vulnerable time for a child's survival [1,2,3,4]. Goal 3 of the United Nations Sustainable Development Goals call for an end to preventable deaths of newborns and children by 2030. All countries should aim at reducing neonatal mortality to below 12 per 1,000 live births [5]. Neonatal mortality has been declining globally, falling from 33 deaths per 1,000 live births in 1990 to 21 deaths per 1,000 live births in 2012. However, this represents a slow decline of 37 percent compared to the 47 percent in the under-five mortality rate. Pre-term birth has been shown as the largest direct cause of neonatal mortality [6]. Low-birth-weight (less than 2500 g) has a causal relationship with neonatal mortality. Globally, LBW contributes to 60% - 80% of all neonatal deaths [3,4,7,8,9].

In Kenya, all childhood mortality rates have declined between 2003 and 2014. Neonatal mortality however has shown the slowest decline rate of only 33 percent. The neonatal mortality was 22 deaths per 1,000 live births between 2009 and 2014 [10,11]. This was 1.4 times higher than the post neonatal rate. The neonatal mortality rate has distribution disparities with neonatal mortality being 24 percent higher in urban areas than in rural areas. Nairobi, the capital city of Kenya, has the highest neonatal mortality (39 deaths per 1,000 live births). Data from Kenya show that wealthier families experience highest neonatal mortality rates compared to poorer families [10,11].

Mosley and Chen (1984) [12] developed an analytical framework for analyzing determinants of child survival in developing countries. According to the model, impact on mortality is influenced by socioeconomic determinants (independent variables) that operate through a certain set of proximate determinants (intermediate variables). Socioeconomic determinants include variables that relate to the productivity of mothers and fathers. Education level of parents influences their occupation and buying power of the household. Income influences neonatal survival through food choices, water (quantity and quality), housing, clothing, hygiene and sickness care among others [13,14]. Higher education levels are associated with better neonatal outcomes [15] High education, especially maternal, improves the status of women and access to information and health services. Mother's time is necessary for a healthy baby as she requires time for prenatal visits and breastfeeding among others. Traditions, norms and attitudes include factors that affect the economic and health related practices. These may include factors like power relationships within the household, value of children and belief about disease causation among others [12,16,17,18].

The proximate determinants that directly influence the risk of neonatal mortality have been identified as maternal factors; environmental contamination; nutrient deficiency; injury; and personal illness control (which include health interventions). Factors that affect maternal health have impact on neonatal survival. These factors may include maternal age, parity and birth interval. Synergism between these factors may also occur and this differentially affect child survival especially when two or more such unfavorable factors occur together [12]. Household crowding, source of water supply, food handling practices, incidence of diarrhea and/or presence of latrines or toilettes are physical indices associated with environmental contamination. The contamination is directly associated with neonatal morbidity. Nutrient deficiency influence child survival based on the nutrients available to the neonate and the mother [12,13]. Nutrient deficiency during lactation can affect the quality of breast milk. On the other hand, injuries reflect environmental risks that differ in socioeconomic and environmental contexts. Incidence of injuries whether intentional or accidental affect neonatal survival [12,13,19,20].

It is clear that neonatal mortality rates are high in Kenya and that the causes of these are multifactorial. Understanding the specific socioeconomic and proximate determinants of neonatal survival in Kenya can help develop and implement effective interventions that can reduce the neonatal mortality rate, especially among LBW infants which contributes to the majority of neonatal deaths.

2. METHODS AND MATERIAL

2.1 Study Design and Setting

This was a cohort study carried out at Pumwani Maternity hospital, Thika Level 5 hospital and Machakos Level 5 hospital. The sites were selected as part of a larger study on the effectiveness of early intermittent Kangaroo Mother Care; A quasi-experimental study. It is assumed that the facilities share similarities in patient population characteristics and also the health system. Pumwani hospital, located in Nairobi, is one of the largest public maternity referral hospitals in Kenya with 350 beds and 150 cots [21]. Thika Level 5 hospital is one of the largest public hospitals in Kiambu County with 265 beds and 24 cots while Machakos Level 5 hospital is the biggest public health facility in Machakos County with 375 beds and 57 cots [22]. The study population was all stable LBW infants weighing ≤2000 grams irrespective of their gestational age who were admitted at the three hospitals during the study period.

The sample size was 343 drawn from the three facilities by consecutively enrolling eligible LBW infants into the study. The inclusion criteria for the study was infants weighing ≤2000 grams irrespective of their gestational age, infants less than 72 hours of life, stable infants (not on oxygen or phototherapy, on full feeds and retaining, Oxygen saturation of >95%, Heart rate of >100 beats per minute, capillary refill < 3 seconds) and willingness to give written consent. Infants with major congenital malformations or severe perinatal complications and cases where the caregiver was unwilling to give written consent were excluded from the study. The follow up period was the neonatal period (28 days).

2.2 Data Collection and Procedures

Data was collected between June 2016 to June 2017 using structured tools which were guided by the concepts of the Mosley and Chen (1984) analytical framework [12] and from literature review (Fig. 1).

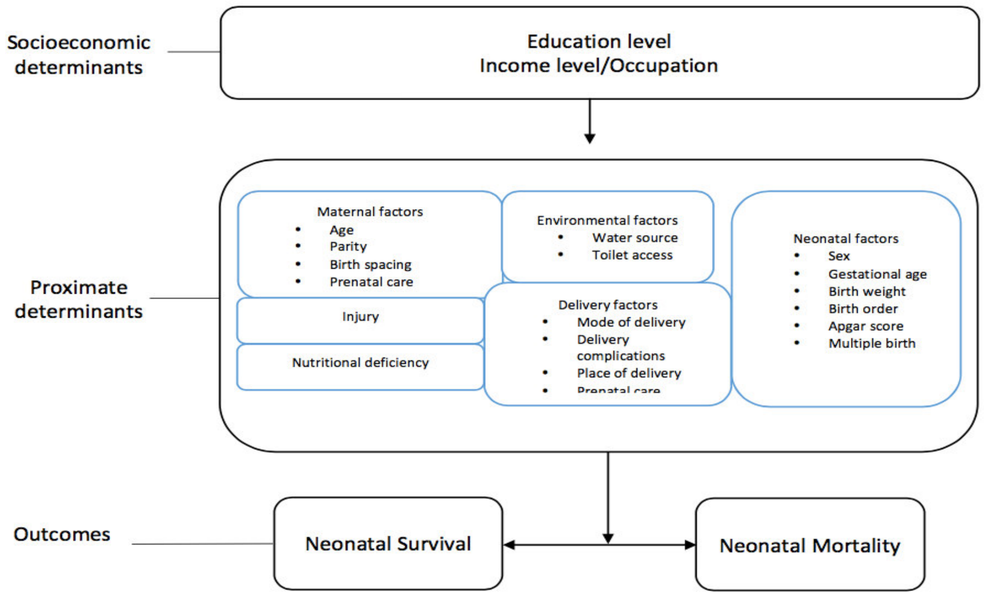

Figure 1: Adopted Mosley and Chen Analytical Framework (1984) [12]

The data collection tools were pre-tested before onset of the study. An entry questionnaire was administered within 72 hours post-delivery through face to face interviews in the neonatal unit, at a time that was convenient to the mother. An exit questionnaire was administered at the last follow up (at 28 days of age) asking details about incidence of injury, nutritional factors and environmental factors. A data abstraction tool was used to obtain information from the patient files.

2.3 Data Management and Analysis

Microsoft Excel was used for data entry and storage. Data analysis was done using Stata Statistical Software [23]. An alpha of 0.05 was used for statistical significance. Initially, basic descriptive statistics were used to describe the respondents' socioeconomic characteristics. Cross tabulations were done to determine the relationships between independent and dependent variables. Multiple logistic regression analysis was conducted to determine the predictors of neonatal morbidity and mortality. The variables included in the regression model were based on their clinical significance. A backward stepwise method was used in coming up with a minimum set of determinants that resulted in the optimal predictive model of the final outcomes.

2.4 Ethical Considerations

Ethical clearance for the study was given by the Kenyatta National Hospital Ethics Review Committee after reviewing the study protocol. Institutional permission was sought from the respective County authorities and Medical Superintendents of the study hospitals. Permit to conduct the study was given by National Commission for Science, Technology and Innovation (NACOSTI). An informed consent was obtained and confidentiality was ensured by coding the questionnaires.

3. RESULTS

3.1 Socioeconomic characteristics

A total of 343 LBW infants were recruited in the study between July 2016 to June 2017. The mean age of the mothers was 25.4 (SD=5.3), range 15-45 years. Majority of the mothers, 79.9% (N=343) were married/cohabiting, with half of them (50.2%, N=343) having secondary education. More than half of the spouses (59.4%, n=283) had secondary education. A third of the mothers had household income of below 6,000 Kenya shillings per month (about 60 USD), with majority 78.1% (N=343) renting the house they were living in. Two in every ten (22.2%, n=338) of the mothers were living in a temporary house with a similar number (23.9%, N=343) having no access to a toilet. A third of the mothers used kerosene as the main fuel for cooking. A small fraction of mothers, 5.5% (N=343) used river/pond as the source of water for drinking. A few of the mothers, 10.9% (n=339) had an incidence of diarrhea in the last three months before delivery.

3.2 Proximate characteristics

The average birth weight was 1492.6 grams (SD=275.3), range 700-2000 grams. The average gestational age among the mothers was 30.3 weeks (3.8), 20-40 weeks. More than half (59.8%, n=343) of the infants were female, and majority (78.4%, N=343) were born in the study hospital. Most of the infants (83.3%, n=342) were born through spontaneous vaginal delivery and only a third (29%, n=341) were multiple births. Delivery complications were recorded in 26.6% (n=342) of the births. About two thirds (63.9%, n=144) of the infants had a birth interval of more than 36 months. A few of the mothers (4.4%, n=342) reported taking only one meal on average during their most recent pregnancy. Most (93.2%, n=339) of the mothers attended antenatal clinic while pregnant. About half (51.4%, n=329) of the mothers reported having no pregnancy loss and having 1 or more live births prior to their most recent pregnancy. Nearly a third (30%, N=343) of the mothers had not used micronutrient supplementation during their most recent pregnancy. HIV prevalence was 8.5% (n=329) among the mothers while prevalence of non communicable diseases was 13.1% (N=343) among the mothers. Few (2.9%, N=343) mothers reported use of alcohol and 0.9% (n=342) reported cigarette smoking during pregnancy. Cigarette smoking among partners were reported in 7.7% (n=274) of the mothers. Majority (81.4%, n=301) of the infants had an Apgar score at 1 minute of more than 5.

3.3 Incidence of neonatal mortality

A total of 29 (8.5%, n=340) LBW infants died during the neonatal period in the three hospitals.

3.4 Association between selected socioeconomic characteristics and neonatal mortality

Maternal level of education, access to toilet and incidence of diarrhea in the last 3 months before delivery was significantly associated with neonatal mortality (p<0.05) as shown in Table 1 below. All the other socioeconomic characteristics were not significantly associated with neonatal death (p>0.05).

Table 1. Association between selected socioeconomic characteristics and neonatal mortality

Variable		Mortality (Yes)	P Value
		n (%)	
Marital status	Married	26 (9.6%)	0.174
	Single	3 (4.4%)	
Maternal level of education	Primary & below	17 (14.5%)	0.011*
	Secondary	11 (6.5%)	(Fishers Exact)
	Tertiary	1 (1.9%)	
Spouses level of education	Primary & below	4 (8.2%)	0.861
	Secondary	15 (9%)	
	Tertiary	7 (10.9%)	
Income per month	<6000	14 (12.8%)	0.213
	6000 to 15000	9 (8.3%)	
	>15000	6 (6%)	
Type of house ownership	Own	7 (9.3%)	0.778
	Rented	22 (8.3%)	
Access to toilet	No	15 (18.8%)	0.000*
	Yes	14 (5.4%)	
Source of fuel for cooking	Electricity/Gas	13 (8.1%)	0.603
	Charcoal	5 (6.6%)	
	Kerosene	11 (10.7%)	
Source of drinking water	piped	21 (7.5%)	0.196
	river/pond	3 (15.8%)	
	well/borehole	5 (12.5%)	
Incidence of diarrhea in last 3 months	No	22 (7.3%)	0.018*
	Yes	7 (18.9%)	

*. The Chi-square statistic (Fishers Exact) is significant at the 0.05 level

3.4 Association between selected proximate characteristics and neonatal mortality

The proximate characteristics significantly associated with neonatal mortality were multiple births, delivery complications and average number of meals per day during pregnancy (p<0.05). Table 2 shows the association of proximate characteristics and neonatal mortality including those that were not statistically significant (p>0.05).

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Table 2. Association between selected socioeconomic characteristics and neonatal mortality

Variable		Mortality (Yes) n (%)	P Value
Infant Sex	Female	18 (8.9%)	0.761
	Male	11 (8%)	
Place of delivery	This hospital	22 (8.2%)	0.774
	Another hospital	4 (8.7%)	
	Home	3 (11.5%)	
Mode of delivery	CS	3 (5.3%)	0.441
	Normal	26 (9.2%)	
Multiple births	No	12 (5%)	0.000*
	Yes	17 (17.2%)	
Delivery complications	No	15 (6.1%)	0.006*
	Yes	14 (15.4%)	
Birth interval	<18 months	4 (16.7%)	0.328
	18-36 months	2 (7.7%)	
	>36 months	6 (6.5%)	
Average number of meals per day when pregnant	One	6 (40%)	0.002*
	Two	3 (7.3%)	
	Three	12 (6.2%)	
	More than three	8 (9%)	
ANC attendance	No	2 (9.1%)	0.937
	Yes	27 (8.6%)	
Pregnancy history	Never pregnant	9 (8.2%)	0.918
	No pregnancy loss with 1 or more live births	14 (8.3%)	
	1 or more pregnancy loss with 1 or more live births	4 (10.5%)	
	1 or more pregnancy loss with no live birth	0 (0%)	
Use of micronutrient supplementation	No	7 (7%)	0.515
	Yes	22 (9.2%)	
HIV status	Negative	28 (9.4%)	0.49
	Positive	1 (3.7%)	
Chronic conditions (NCDs)	No	23 (7.8%)	0.215
	Yes	6 (13.3%)	
Apgar score at 1 minute	Apgar score 1-5	6 (10.7%)	0.412
	Apgar Score 6-10	18 (7.4%)	

*. The Chi-square statistic (Fishers Exact) is significant at the 0.05 level

Birth weight and gestational age were significantly associated with incidence of neonatal mortality. A unit increase in birth weight (1 gram) was associated with a 0.3% reduction in likelihood of neonatal mortality [OR=0.997, 95% CI, 0.996-0.999, p=0.0002]. Similarly, a unit increase in gestational age (1 week) was associated with a 14% reduction in likelihood of neonatal mortality [OR=0.86, 95% CI, 0.77-0.96, p=0.009]. The age of the mother and birth order were not statistically associated with the incidence of neonatal mortality [p>0.05].

Table 3. Association between birth weight, gestational age, birth order and age of the mother with neonatal mortality

Neonatal Mortality	Unadjusted odds ratio	95% CI	P value
Birth weight (grams)	0.997	0.996-0.999	0.002
Gestational age (weeks)	0.86	0.77-0.96	0.009
Birth order	1.3	0.8-2.1	0.328
Age mother (Years)	0.96	0.9-1.0	0.321

3.5 Multiple analysis of association of selected determinants with neonatal mortality

A multiple logistic regression analysis was performed to ascertain the effects of socioeconomic characteristics and proximate characteristics on the likelihood of neonatal mortality. Twelve successive iterations were performed using forward and backward stepwise method retaining eight determinants in the final model. The logistic regression model as a whole was statistically significant [likelihood ratio χ2 (9) =48.8, p<0.000].

Household income per month was significantly associated with neonatal mortality. Infants born in families with a household income of 6,000-15000 (60 – 150 USD) were 60% less likely to die during neonatal period compared to those born in families with a household income of less than 6000 (60 USD) per month [OR=0.4, 95% CI, 0.1-1.1, p=0.004]. LBW infants born in families with household income of more than 15000 (>150 USD) per month were 84% less likely to die during neonatal period than LBW infants born in families with a household income of less than 6000 (60 USD) per month [OR=0.16, 95% CI, 0.04-0.56, p=0.004].

Birth complications were significantly associated with incidence of neonatal mortality. LBW infants of mothers who had birth complications were 4.1 times more likely to die [OR=4.1, 95% CI, 1.6 -10.8, p=0.004] compared to those of mothers who did not have birth complications.

Birth weight (grams)and gestational age (weeks) were significantly associated with neonatal mortality. A unit increase in birth weight (1 gram) was associated with a 0.3% reduction in likelihood of neonatal mortality [OR=0.997, 95% CI, 0.995-0.999, p=0.032]. Similarly, a unit increase in gestational age (1 week) was associated with a 21% reduction in likelihood of neonatal mortality [OR=0.79, 95% CI, 0.68-0.92, p=0.002].

Multiple birth was significantly associated with neonatal mortality. Infants born as multiple births were 6.6 times more likely to die than singleton infants [OR=6.6, 95% CI, 2.5-17.4, p<0.001]. Infant sex and mode of delivery were not statistically associated with a reduction of neonatal mortality (p>0.05) as shown in Table 4.

Table 4. Multiple analysis of association of selected determinants with neonatal mortality

Neonatal mortality	Adjusted Odds Ratio	95% CI	P value
Household income (KES)	Ref cat <6000 KES (60 USD)		
6000 to 15000	0.400223	0.1-1.1	0.078
>15000	0.1599596	0.04-0.56	0.004
Birth complication	4.109571	1.6-10.8	0.004
NCDs	2.802114	0.8-9.2	0.091
Birth weight	0.9978971	0.996-0.999	0.032
Gestational age	0.7920633	0.68-0.91	0.002
Infant sex	1.561453	0.6-4.0	0.357
Mode of delivery (Normal)	2.880042	0.6-12.9	0.168
Multiple birth	6.62262	2.5-17.4	0.000

4. DISCUSSION

The neonatal mortality in this study was 8.5% (n=340) among the LBW infants weighing £2000 grams. This was considerably lower than neonatal mortality rates reported in other studies. Simiyu (2004) reported a neonatal mortality rate of 57.4% (n=533) among LBW infants at Kenyatta National Hospital, Kenya [24]. The difference can be explained by the difference in eligibility criteria where our study enrolled only stable LBW infants. A KMC trial in 2005 reported an overall 30.4% (n=125) neonatal mortality which was much higher than in this study [25]. It is notable that the clinical trial also included unstable LBW infants, which may explain the higher neonatal mortality rate. Nagai, et al., (2010) reported a neonatal mortality rate of 4.1% (n=73) which was much lower than that reported in our study. This trial was putting both study groups on either early or late KMC and this may have had an overall effect on the overall low neonatal mortality rate [26].

Our study found that household income was the only the socioeconomic determinant that was significantly associated with neonatal mortality. Mosley & Chen (1984) analytical framework have identified several socioeconomic determinants that work through proximate determinants to influence neonatal mortality [12]. Most of these socioeconomic factors are associated with household income and would agree with findings of another study in Ghana that found dwelling in low socioeconomic neighbourhoods being associated with high neonatal mortality [27]. Olayinka et al. (2012) identified maternal level of education to have a significant relationship with neonatal survival [28]. Increasing household income increases the buying power and improved quality of living. This would result in better access to quality water and reduced incidence of diarrhoea. The overall effect is improvement of neonatal survival.

We identified some proximate determinants that significantly affected neonatal mortality. These included multiple births and delivery complications. Mosley & Chen (1984) identify the same as having adverse effects on neonatal survival [12]. An observational study in Ghana also identified multi-gestation as a significant contributor of neonatal mortality [27]. Multiple births are typically associated with LBW and this may contribute to poor neonatal survival. The study in Ghana reported inadequate birth spacing, ANC utilization, grand parity and place of delivery as significant factors of neonatal survival [27]. Olayinka et al. (2012) in their study found that the place of delivery had a significant relationship with neonatal mortality [28]. These findings were contrary to our cohort study findings that showed a non significant relationship between these determinants and neonatal mortality.

Several other proximate determinants in our study including maternal and/or paternal level of education, infant sex, toilet access, mode of delivery, use of micronutrients, HIV status and Apgar score at one minute did not influence neonatal survival as envision in the Mosley and Chen (1984) analytical framework [12]. Janaswamy et al. (2016) did not also find a significant relationship between infant sex and mode of delivery with neonatal mortality [29]. In our study, this may be due to the small proportion of neonatal deaths that may partly be attributed to the eligibility criteria of stable infants.

Birth weight and gestational age had a significant relationship with neonatal mortality, which was in agreement with the Mosley & Chen (1984) analytical framework [12]. Many other studies agree that lower birth weight infants have a lower chance of surviving during the neonatal period [27,29] and that LBW is responsible for 60-80% of neonatal deaths in many developing countries [7,30].

5. CONCLUSIONS

The study confirmed that there are certain socioeconomic and proximate determinants that affect neonatal mortality as proposed by the Mosley and Chen (1984) analytical framework. This study identified household income, birth complications, birth weight, gestational age, and multiple births as significant predictors of neonatal mortality. The study provides useful information on determinants of neonatal mortality that is relevant to the Kenyan context and applicable to other low income countries. This knowledge is useful in designing interventions and policies that can reduce neonatal mortality.

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