NEONATAL HYPOTHERMIA AND ADHERENCE TO WORLD HEALTH ORGANIZATION THERMAL CARE GUIDELINE AMONG NEWBORNS AT MOI TEACHING AND REFERRAL HOSPITAL, KENYA.

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A RESEARCH THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTERS OF MEDICINE IN CHILD HEALTH AND PAEDIATRICS, MOI UNIVERSITY.

DECLARATION

DECLARATION BY THE CANDIDATE

This thesis is my original work and has not been presented before for any another degree in Moi University or elsewhere.

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DEDICATION

This study is dedicated to all the sick neonates who continue to teach me through their tenacity against adversity among which hypothermia takes a front row seat. Theirs is a journey that requires a great deal of fortitude. And to my late mother whose love and warmth transcends time and space.

ACKNOWLEDGEMENT

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ABSTRACT

Background: Neonatal hypothermia is a great concern with near epidemic levels globally. The prevalence in Kenya is as high as 87 %. Local data on the associated factors including adherence to warm chain guidelines as recommended by the World Health Organization (WHO) is limited.

Objective: To determine the prevalence of neonatal hypothermia, associated factors and level of adherence to the WHO thermal care guidelines among newborns admitted at Moi Teaching and Referral Hospital (MTRH).

Methods: This prospective cohort study was carried out among neonates admitted at MTRH between July and December 2016. Systematic sampling was used to recruit 372 eligible participants. Serial axillary thermometry, interview of respective mothers, observation of thermal care practices was done, and outcomes on the first day of admission determined. Means and medians described continuous variables while frequencies and corresponding percentages summarized categorical variables. Associations between the variables and neonatal hypothermia at admission were computed using the Pearson Chi-square and Fishers exact tests and the relative risks reported. Day one survival probability was assessed using the Kaplan Meier survival function with the outcome of time to event plotted on Kaplan Meier graphs. The log rank test was used to compare the survival distributions among neonates with or without hypothermia at admission.

Results: Among the 372 participants enrolled, 240 (64.5%) were born at MTRH, 177 (47.6%) were preterm while 198 (53.2%) had birth weights less than 2500grams. Admission hypothermia (AH) was noted among 73.7% (n=274) while 13% (n=49) died on day one of admission. Only 7.8% (n=29) newborns accessed optimal thermal care. Prematurity, RR=1.62 (95% CI: 1.43-1.84) and suboptimal adherence to the warm chain ($P<0.001$) significantly increased the risk of admission hypothermia specifically inappropriate thermal resuscitation appliance, RR=1.50 (95% CI: 1.34-1.67), inappropriate clothing, RR = 1.78 (95% CI: 1.54 - 2.05) and late breastfeeding, RR = 2.01 (95% CI: 1.39-2.89). There was significantly poor day one survival probability among newborns with admission hypothermia with early onset of adverse events,(mortality) compared to their none hypothermic counterparts, ($P<0.001$).

Conclusion: Three out of four neonates at the MTRH newborn unit had hypothermia at admission which was significantly associated with prematurity and adherence to warm chain. Early onset of adverse outcomes, (mortality) with poor day one survival probability was noted among the newborns presenting with hypothermia at admission.

Recommendation: Optimize adherence to the warm chain and a follow up study to determine the factors associated with the sub-optimal thermal care noted at MTRH. Priority triage and an anticipatory approach to thermal care of the preterm and lower birth weight neonate is also key.

LIST OF ABBREVIATIONS

AH	Admission hypothermia
AOR	Adjusted Odds Ratio
BFHI	Baby Friendly Hospital Initiatives
CPAP	Continuous positive Airway Pressure
IREC	Institutional Research and Ethics Committee
IUGR	Intra-uterine Growth Restriction
KDHS	Kenya Demographic and Health Survey
KMC	Kangaroo Mother Care
MDG	Millennium development goals
MTRH	Moi Teaching and Referral Hospital
NBMS	New Ballard Maturity Score
NBU	Newborn unit
NMR	Neonatal Mortality Rate
PI	Principal Investigator
RAs	Research assistants
RMBH	Riley Mother and Baby Hospital
SDG	Sustainable development goals

SSC	Skin to Skin Contact
U5MR	Under five mortality rate
WHO	World Health Organization.

OPERATIONAL DEFINITION OF TERMS

1. **Neonate:** Infant less than **28** days old.

2. **Newborn:** Neonate aged less than **24** hours.

3. **Hypothermia:** Axillary temperature less than **36.5 ^{o}c.**

4. **Normothermia:** Axillary temperatures between **36.5^{0} C** to **37.5^{o} C.**

5. **Hyperthermia:** Axillary temperatures above **37.5 ^{o} C**.

6. **Hypothermia at admission:** Hypothermia by the **1st** hour of admission

7. **Recurrent hypothermia**: More than one episode of hypothermia in the first **24** hours of admission.

8. **Hypoglycemia :** Serum glucose level **< 2.2 mmol/L**

9. **Warm chain:** The WHO **1997** thermal care protocol.

10. **Optimal adherence:** Application of at least **4** warm chain steps as listed:
    - i) **Delayed bathing:** Baths deferred to at least **after 24 hours** of age.
    - ii) **Appropriate clothing:** At least **3** layers of **dry** and **absorben**t materials as well as cap and **stockinet**.
    - iii) **Early breastfeeding:** Breast milk given within the **1st hour** of birth.

iv) **Skin to Skin Care:** Continuous or interrupted contact between mother and babies' skin during care.

v) **Rooming in:** Nursing of mother and baby together.

vi) **Appropriate warmth appliance** as per WHO guidelines as follows.

a) **Incubator care** for neonates with weights **< 1700gms**

b) **Radiant heaters /space heaters** for neonates weighing > **1700gms**

11. Outcomes:

i. Primary - Hypothermia at admission (AH)

ii. Secondary - Hypothermia recurrence and day one mortality or survival

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CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

1.1.1 Trends in the global under five (U5) and Neonatal Mortality Estimates

The neonatal population continues to post a worrying trend with a rising contribution, 47% to the overall under-five mortality despite a 53% global decline in overall U5 deaths over the same period from the 12.6 million recorded in 1990 to about 5.6 million in 2016. Internationally, the average neonatal mortality rate (NMR) stands at 18:1,000 Live Births with 7,000 neonatal deaths being recorded daily. Over a million neonates die on day one of life (Unicef 2017.Pdf, n.d.). Africa shoulders a significant burden of neonatal mortalities with most countries recording less than 50% reduction in neonatal deaths (Deribew et al., 2016). Kenya contributes greatly to neonatal mortality statistics on the continent with about 11,000 neonatal deaths yearly and a NMR of 22:1000 live births which translates to 56% of all infant mortality (KDHS, 2014; WHO, 2017). Neonatal hypothermia is a recognized threat to neonatal survival (Lunze et al., 2013).

1.2 Neonatal Hypothermia

Neonatal hypothermia is defined by the WHO as an axillary temperature below 36.5°C (97.7°F) among neonates aged less than 28 days. The WHO further sub classifies hypothermia into mild (36^oC-36.4^oC or 96.8 to 97.6°F), moderate (32^oC-35.9^oC or 89.6 to 96.7°F) and severe hypothermia of below 32^oC (WHO, 1997).

1.2.1 Risk Factors and etiology of neonatal hypothermia

Neonatal hypothermia has been associated with a number of risks largely grouped as inherent factors which includes physiological and behavioral characteristics or external factors such as the environmental conditions (Vilinsky & Sheridan, 2014). In Spain, hypothermia was associated with VLBW among infants (García-Muñoz et al., 2014). Similar results were reported earlier in Iranian NICUs (Zayeri et al., 2007). Evidence from sub-Saharan Africa cite sub-optimal thermal care practices and community level determinants like rampant poverty among the factors associated with hypothermia,(Lunze et al., 2014; Onalo, 2013).

1.2.2 The pathogenesis and pathophysiology of hypothermia among neonates

Newborns lose heat through conduction, radiation, convection or evaporation. Radiation refers to the transfer of heat from the body surface to the surrounding cooler solid surfaces through the emission of infrared electromagnetic rays. Evaporative loss on the other hand occurs due to a high rate of trans-epidermal vaporization of amniotic fluid or bath water for instance across the delicate skin especially among the ELBW infants who have a non-keratinized epidermis. Heat loss by convection occurs across the gradient to cooler air surrounding the baby and is dependent on the ambient air temperatures in the room. Newborns who are in direct contact with colder surfaces loss heat by conduction also along the temperature gradient (Beers et al., 2003).

The neonate achieves a normal temperature through non shivering thermogenesis. This involves a sympathetic neuronal discharge of hormones like norepinephrine which occurs in the brown fat tissue and mediates a metabolic response to hypothermia which results in lipolysis, oxidation or re-esterification of fatty acids hence local heat production. The rich blood supply in this tissue helps in the transfer of heat to other body organs. This metabolic involvement in heat production is the link between hypothermia and hypoglycemia among neonates. The newborn's dependence on brown fat explains the increased risk of both phenomena among preterm neonates including infants with lower than normal birth weight who have lesser brown fat stores. These metabolic processes also involve increased oxygen consumption resulting in acidosis which compounds inter-current illnesses presenting with respiratory distress but also results in increased risk of sepsis and early neonatal mortality (Berkow & Fletcher, 1992).

1.2.3 Thermometry among hospitalized Children

Axillary thermometry is recommended by the WHO due to its safety profile. The need to standardize thermometry in children for both research and clinical purposes is also highlighted in its thermal protection of the newborn protocol (WHO, 1997). Padilla et al notes that the precision of axillary measurements approximates that of core temperature taken per rectally. Even though the latter is considered gold standard, its use is limited due to its invasive nature and the potential risk of perforation of gut, cross infection among newborn as well as the unnecessary anxiety and limited acceptability among the mothers and other care givers (Padilla-Raygoza et al., 2014). The WHO further recommends that a low reading thermometer be used whenever cases of hypothermia are suspected. Sick neonates require at least 3 hourly checks while those on routine care can have spaced out evaluations at 6 hourly intervals as tailored to individual neonatal units.

1.2.4 The WHO thermal care guidelines

The WHO proposed a series of ten interconnected thermal care steps in 1997 which were aimed at curbing neonatal hypothermia (WHO, 1997). These steps enlisted below were later reviewed in 2013 (Lunze et al., 2014; WHO, 2017):

i. Warm delivery rooms with temperatures between 25O C to 28O C.
ii. Drying babies immediately using pre-warmed towels.
iii. Skin to skin contact (SSC) between mother and baby during care.
iv. Early breastfeeding (within one hour) or at least on the first day of life.
v. Delayed weighing and bathing for at least 6 hours and 24 hours respectively.
vi. Appropriate clothing and bedding.
vii. Rooming In- keeping mother and baby together for most of the time.
viii. Warm transport- use warm wrap, external heat source and SSC.
ix. Warm resuscitation- Use of appropriate thermal care appliances.
x. Continued thermal care training for parents, caretakers and health workers.

1.2.5 Factors influencing adherence to the warm chain and other thermal care and Essential newborn care guidelines

Global and continental studies have identified several factors in association to predominantly sub-optimal thermal care especially in the developing countries. Cultural beliefs and norms for example is a recurring theme in the areas where poor thermal practices have been identified (Baqui et al., 2016; You et al., 2017). Potentially harmful beliefs and norms influence the sequence of thermal care practices. On the other hand, factors cited in association with good thermal care practice include consistent antenatal clinic attendance, thermal care education and presence of skilled attendants at birth. Equally, higher maternal education and better socio-economic status were associated with better essential newborn care including thermal care (Baqui et al., 2007; Owor et al., 2016). Home delivery as a proxy to absence of skilled birth attendants was also noted to confer a likelihood of sub-optimal thermal care with deleterious practices such as delayed drying after birth being rampant (Shamba et al., 2014). A study in Uganda however disputed the link between socio-economic status and place of birth with composite newborn care practices including thermal care (Waiswa et al., 2016). Further in West Africa, younger maternal age was associated with poor practice of essential newborn care besides the influence of maternal knowledge on the same (Atiagbo, 2018). In a systematic review of studies across the African continent, Onalo et al reiterates the impact of community level determinants such as poverty on the choices made with regard to thermal care among newborns. He also cites a general parity in knowledge among care providers on the subject of what constitutes optimal thermal care to being among the drivers of the near epidemic rates of hypothermia noted across the continent,(Onalo et al,2013)

1.3 Problem Statement

Persistence in high NMRs globally has raised the contribution of neonatal deaths towards the overall U5 mortality from the 41% as recorded in 2000 to about 46% by 2016 (Danzhen et al., 2015; Lawoyin et al., 2010; You et al., 2015). This is of great concern as it puts the vision 2030 into jeopardy. Kenya features among the top ten countries with the highest NMR in Africa (Golding et al., 2017; WHO, 2017).

Monthly statistics at MTRH indicate that one in every five neonates die from illnesses closely associated with hypothermia (MTRH, 2016). Globally, rates of hypothermia as high as 92% have been reported with repeated mention in close proximity to neonatal deaths (Lunze et al., 2013) the prevalence of hypothermia, its associated factors and the appropriateness of the application of internationally accredited preventive measures such as the warm chain remains minimally explored at MTRH as is the case nationally.

1.4 Justification

There is a rising, 47% contribution of neonatal deaths to the international U5MR (WHO, 2017). Hypothermia, a closely associated phenomenon remains unabated across the globe with rates of up to 85% among hospital deliveries (Lunze et al., 2013). Epidemiological data on the prevalence of hypothermia and its related factors in Kenya remains inadequate hence need for a survey. This study offered a vital introspection opportunity for an in-depth interrogation of the congruence and efficacy of the thermal care strategies in practice. The weak links identified will enable tailored interventions at the MTRH newborn unit enabling MTRH to reduce hypothermia related mortalities hence positive strides towards vision 2030 which otherwise remains a mirage according to Unicef predictions (UNICEF, 2017). The data also forms a baseline that will inform future research direction.

1.5 Research Question

What is the prevalence of neonatal hypothermia, its associated factors and level of adherence to the WHO thermal care guidelines among newborns admitted at Moi Teaching and Referral Hospital?

1.6 Objectives

1.6.1 Broad objective

To determine the prevalence of neonatal hypothermia, its associated factors and level of adherence to the WHO thermal care guidelines among newborns admitted at Moi Teaching and Referral Hospital.

1.6.2 Specific objectives

i. To determine the prevalence of hypothermia among neonates admitted at the Moi Teaching and Referral Hospital newborn unit.

ii. To assess the adherence level to the WHO thermal care guidelines among neonates admitted at the Moi Teaching and Referral Hospital newborn unit.

iii. To determine the factors associated with neonatal hypothermia among newborns admitted at the Moi Teaching and Referral Hospital newborn unit

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Prevalence of neonatal hypothermia.

Hypothermia continues to gain significance with almost epidemic levels reported globally and even in temperate climates (Onalo, 2013). A range of 32% to 85% have been witnessed among hospital deliveries while 11% to 92% of newborns delivered at home are noted to be hypothermic at birth (Lunze et al., 2013). Rates as high as 93% have been recorded especially among preterm infants (Mank, tte van Zanten, et al., 2016). In advanced economies, hypothermia is confined to the premature infants among whom there is an estimated prevalence of 40-65%. In California for instance, prevalence of 56.2% was identified among very low birth weight neonates on admission to the neonatal intensive care unit (Miller et al., 2011a) The greatest burden of neonatal hypothermia is however seen in Asia and Africa where most of its known risk factors abound. In rare cases, incidences as low as 28% have been recorded (Shamba et al., 2014), which could be attributed to enhanced thermal care strategies.

Globally, hypothermic rates of 53.3% and 53.5% have been reported in Iran (Zayeri et al., 2007) while 64.8% and 79% was recorded in Malaysia (Boo et al., 2013). Community studies in Nepal indicate prevalence rates as high as 92% on the Asian continent (Mullany et al., 2010). Europe and USA also reported significant rates of hypothermia 53.4%,56.2% and 93% (Wilson et al., 2016) which was more notable among preterm and VLBW infants findings which were similar to those in Brazil. where rates of 32% and 51% were reported (da Mota Silveira et al., 2003; De Almeida et al., 2014). In Africa, prevalence of between 68% to 72.4% were reported in Nigeria (Ogunlesi et al., 2009). Studies from Ethiopia also posted similer results with ranges between 66.3% to 69.8% (Tasew et al., 2018).

Higher prevalence rates were noted in Zimbabwe 85% and in Uganda 83% (Byaruhanga et al., 2005) from earlier studies. On the other hand, lower rates were reported in South Africa, 46.1% and Tanzania,22.4% (Ng'eny & Velaphi, 2019).

In Kenya a report from Kenyatta national hospital revealed a rate of 27.2 among LBW infants (Simiyu, 2004) in a county referral hospital 110 (87%) of the neonates admitted to the newborn unit recorded at least one episode of hypothermia while 60% had persisted hypothermia.at MTRH 65% of preterm neonates on management for RDS were noted to be hypothermic (Nyandiko et al., 2018).

2.2 Factors associated with neonatal hypothermia

2.2.1 Etiological and risk factors

In our assessment of hypothermia, we considered the risks and etiological factors as well as the neonatal outcomes related to this phenomenon. The risk factors are broadly categorised as inherent or external. The former includes neonatal physiological and behavioural conditions such as maturity status and the development of neonatal thermoregulatory mechanisms.

External factors on the other hand encompasses health system factors including infrastructural and technological development, policy adoption and adherence to baby friendly hospital initiatives among others.it also includes maternal factors such as knowledge on thermal care, parity, socio-economic status among others.in proximity to these factors are underlying factors such as poverty levels, political factors and environmental conditions.

(a) External factors

In a study evaluating hypothermia at admission to a university hospital majority of babies born outside the hospital were noted to be hypothermic. This could be testament to the challenges faced at warm transportation to the facility among others (Ogunlesi et al., 2009) mode of delivery was also cited in association with hypothermia with caesarean delivery being closely linked to the occurrence of hypothermia (Manji & Kisenge, 2003).

A systematic in sub-Saharan Africa identifies sub optimal thermal care practices, inadequate thermal education among providers and high poverty levels to be among the proximate factors associated with neonates hypothermia (Onalo, 2013) cultural factors and practices are also contributory as seen from reports by community based studies (Mullany et al., 2010).

(b) Neonatal factors

Many studies have indicated prematurity among newborns as many factors closely associated with the occurrence of neonatal hypothermia (Demissie et al., 2018; Ogunlesi et al., 2008, 2009). Lower than normal birth weights is also mentioned (Ng'eny & Velaphi, 2019). The relationship between these factors and hypothermia resides in the limitations in thermal care inherent within the neonatal physiology.

2.2.2 Hypothermia and adverse neonatal morbidity and outcomes

Studies have demonstrated increased odds of unfavourable outcomes such as death or neurodevelopmental delays in the presence of hypothermia such as among extremely low gestational age neonates in Canada. Moderate hypothermia doubled the chances of death within the first week among European babies (Wilson et al., 2016). In Latin America it was noted that hypothermia introduced hypo dynamic and metabolic instabilities in newly born infants and was significantly associated with severe IVH (grade3/4)(OR 0.377 ,P = <0.01) and Mortality OR 0.329: P=0.012) which corroborated findings by other researchers (García-Muñoz et al., 2014). Similarly there an inverse relation between hypothermia and mortality risk observed in Iran, Nepal and the USA (Zayeri et al., 2007).

2.2.2 Adherence to the WHO thermal care guidelines

In Malaysia, none of the NICUs evaluated practiced a complete thermal care bundle (Boo et al., 2013).similar to findings in Nepal where only10.7% of the neonates in a community study got optimum care (Khanal et al., 2014) In Boo et al's report sub optimal ambient room temperatures of 20.1 0C(SD 1.6) n=30 and 22.80C SD 2.7 n 28 in obstetric theatres and delivery rooms were noted across Malaysian NICUs unlike in Iran where warm delivery rooms were seen (Delavar et al., 2014). Onalo et al in a Systematic Review also reports sub-optimal thermal care practices across the African continent (Onalo, 2013) .Use of appropriate thermal care devices for instance was not commonly noted on the continent (Karsten Lunze, Bloom, Jamison, & Hamer, 2013).

Proper application of some of the warm chain steps has been reported in foregoing studies such as immediate wiping and wrapping noted among babies in Tanzania (Shamba et al., 2014). In Karachi and Ethiopia 40% and 75% of the babies were bathed early due to the community beliefs (Ayaz & Saleem, 2010). Similar beliefs systems were also reported in west Africa (Sodemann et al., 2008) in Bangladesh (Moran et al., 2009). Delayed baths have been reported by studies done in community settings (Karsten Lunze et al., 2013).

2.3 Association between hypothermia and adverse neonatal outcomes

Studies have demonstrated increased odds of unfavorable outcomes such as death or neurodevelopmental delays in the presence of hypothermia. The severity scale as given by the WHO has inverse prognostic implications (Kumar et al., 2009; WHO, 1997). For instance, moderate hypothermia doubled the chances of death within week one of admission among European babies (Wilson et al., 2016). In Latin America, it was noted that hypothermia introduced hypo-dynamic and metabolic instabilities in newly born infants and was significantly associated with severe intra-ventricular hemorrhage (IVH) (grade3/4) (OR 0.377, $p<0.01$) and mortality OR 0.329: $p=0.012$) which corroborated findings by other researchers (García-Muñoz et al., 2014). Similarly, there was an inverse relation between hypothermia and mortality risk observed in Iran, Nepal and the USA (Miller et al., 2011b; Zayeri et al., 2007).

2.4 Conceptual framework

We adapted a model developed by Mosley and Chen in 1984 during our concept development to explain how related proximate factors operated to influence morbidity outcomes among children with hypothermia.Using this model, the factors associated with neonatal hypothermia and mortality could be broadly classified into underlying, health system or hospital factors, maternal factors and neonatal factors. Underlying factors included socio economic, political, ecological, and technological settings. Proximate to this are health system factors such as access to hospitals, referral system, thermal equipment, policies and adherence to protocols. Maternal factors could be parity, education status, mode of delivery and access to thermal care education while the neonatal factors include maturity status, birth weights and inter-current illness among others.

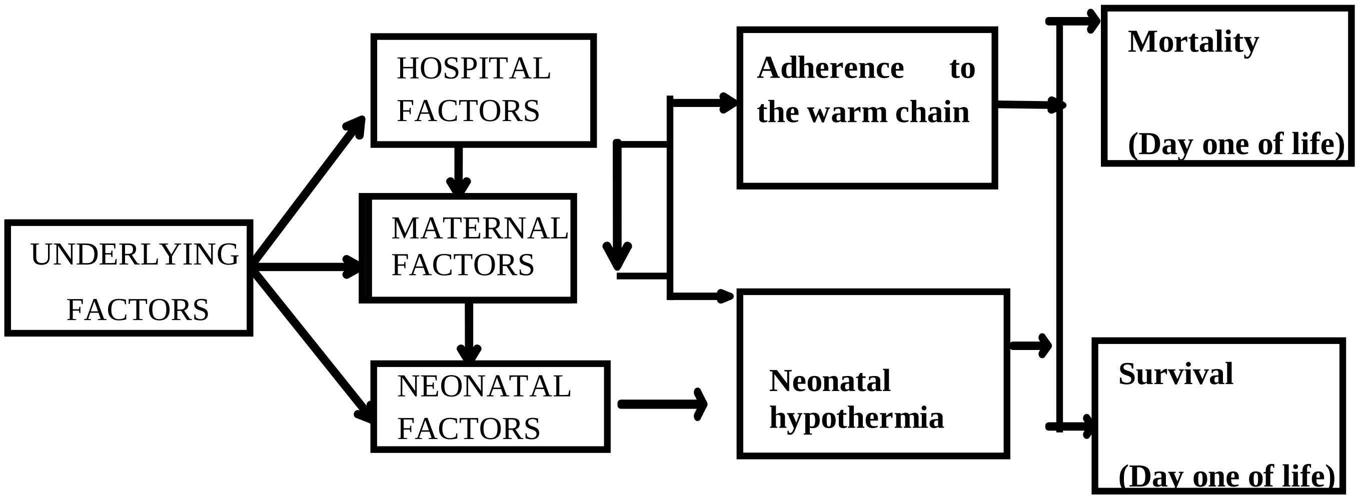

Figure 1: Conceptual framework: Neonatal hypothermia, adherence to the warm chain and day one mortality.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study Setting

The study was done at the RMBH newborn unit of Moi Teaching and Referral Hospital (MTRH) in Kenya between July and December 2016.

3.2 Study Design

This was a prospective cohort study.

3.3 Target and study populations

The target population comprised of neonates admitted at the MTRH newborn unit while the study population were the neonates admitted on their first day of life.

3.4 Eligibility Criteria

3.4.1 Inclusion criteria

We included all newborns accessed for enrolment within the first hour of admission.

3.4.2 Exclusion criteria

We excluded patients requiring urgent resuscitation at the point of initial evaluation for legibility so as not to interfere with emergency care. Patients admitted between 12 midnight and 6 a.m. were also not included due to limitations in conducting a rigorous enrolment process and interview during this time frame.

3.5 Sample Size Calculation and Sampling Procedure:

3.5.1 Sample Size Calculation:

Our objective was to estimate the prevalence of neonatal hypothermia at MTRH hence we adopted the Fishers et al formula for proportion studies. We adopted a hypothermia prevalence rate of 67. 6 % from a study by Ogunlesi et al among babies aged less than 72 hours in Nigeria for this study's proportion due to similarities in setting and design (Ogunlesi, Ogunfowora, & Ogundeyi, 2009) .The minimum sample size examinable following a normal distribution on a two sided curve at 95%

confidence level was calculated as shown below;

(α) = (0.05), Z = 1.96, Margin of error = ± 5% (0.05), P= 0.68

$$n = \frac{Z^2 p (1- p)}{e^2}$$

$$\text{Substituting } n = \frac{1.96)^2 X (0.68)(0.32)}{(0.05)^2}$$

n_0= 335

The sample size was increased by 10% (335/0.9) to cater for any non-response hence a total of 372 participants were recruited.

3.5.2. Sampling technique

Systematic sampling was adopted to recruit eligible neonates with a target of at least two participants out of an average of 6-7 neonates admitted daily. Projecting from the trends seen in previous months, 1200 babies were anticipated over the six months of study. This was divided by the sample size giving a sampling interval of 3.The first participant was picked at random at the onset of the study after which every third newborn was vetted for legibility failure of which the next baby was assessed.

3.6 Data Collection and management

3.6.1 Data collection procedure

I sought relevant approvals from IREC and MTRH and trained the research assistants (RAs) on the thermometry and study procedure. They included three clinical officers and two records officers who were recruited on account of competence and availability. Approved low reading axillary thermometers model H07-200255 able to record temperatures between 32^{o}c to 42^{o}C and ambient air thermometers were sourced from a supplier accredited by the hospital's procurement department. Eligible neonates were enrolled after completion of the admission procedure and consent obtained. A pretested questionnaire was administered to the respective mothers to elicit and the socio-demographic and thermal care related details. The neonates primary diagnosis was obtained from the initial clerkship notes by the admitting doctor as recorded in the patient's file. Assessment of the maturity status by both weight and gestational age as per the New Ballard's Maturity Score, (APPENDIX 6) were done by the principal investigator and the research assistants who had received training on the same before the commencement of the study. Calibrated weighing scales available in each cube in the MTRH newborn unit were used for the former.

Available equipment and observed aspects of thermal care practice were filled on a checklist. Ambient air temperatures in MTRH's delivery rooms, obstetric theatres as well as the various rooms within the newborn unit were measured while serial neonatal axillary temperatures were also taken at the 1st, 3rd, 6th, 12th, 18th and 24th hour by the PI and her RAs. The values obtained were recorded on the data collection tool. Significant adverse findings such as hypothermia, worrisome history and physical examination features as well as poor thermal care practice were communicated to the team in charge of care and the neonate's medical records reviewed and updated.

3.6.2 Procedure for temperature measurement

a) Neonatal axillary temperatures

The WHO recommendations on temperature measurements were adopted as follows;

i. Wash the hands as per the MTRH newborn unit protocol.
ii. Sanitize the thermometer, (APPENDIX 4) and place it high in the axilla holding it against the side the baby for 5 minutes as per the manufacturers manual or until the beeping sound is heard.
iii. Record the temperature on the patient's file and data collection tool.
iv. Notify the primary nurse of any hypothermia and other adverse findings
v. Sanitize the thermometer after use safely place and adequately cover the newborn.

b) Ambient room air temperature

Using ambient air thermometers, temperatures in various delivery rooms, obstetric theatres and in the NBU was assessed by placing the thermometers near the areas where the newborns were being attended to as sampled under **Appendix 5.** The thermometers were sanitized pre and post use as per the infection control guidelines of the hospital.

3.6.3 Data analysis

Data was checked for completeness and analyzed using SPSS version 21. Descriptive statistics such as means and median were used to present continuous variables for example age among participants while frequency listings with corresponding percentages were used for discrete variables. The Chi- square and Fishers exact tests were used to evaluate for associations between the maternal profile, neonatal characteristics, adherence to the warm chain and admission hypothermia with the relative risk ratios (RR) being reported.

For the 24 hour neonatal survival analysis, the Kaplan-Meier survival model was used to describe the survival distribution among the neonates who had hypothermia at admission and those who did not. The event of interest was death within the initial 24 hours of admission and the time to event was plotted on Kaplan Meier graphs. The follow up time was defined as time from point of admission to death or to discharge from the newborn unit or until the 24^{th} hour of admission whichever came first. At the 24^{th} hour all remaining participants were censored from the study. The Log rank test was used to compare the significance in survival distributions among hypothermic versus none hypothermic newborn.

3.6.4 Data storage

Electronic data was kept in a password protected file while the original collection tools were put in a lockable cabinet only accessible to the PI and authorized persons.

3.7 Ethical Considerations

Pre-requisite approval to carry out the study was obtained from the Institutional Research and Ethics Committee (IREC) of Moi University and the MTRH management. The nursing officers in charge of the RMBH were also notified about the study .Informed consent was sought from the participant's parents or legal representative's .Participation was voluntary with no monetary incentives or coercion and decline did not affect outlined management. Hypothermia and other adverse findings were aptly reported to the attending team for mitigation in accordance to prior permission granted at the signing of consent form. Highest level of confidentiality was upheld and all collection tools de-identified and kept safely.

CHAPTER FOUR

4.0 RESULTS

4.1 Introduction

A total of **372** mother-baby pairs were enrolled from the 1113 neonates admitted over the study period with 100% response rate.

4.2 Socio-demographic and clinical profile of participants

4.2.1 Maternal characteristics

The age range of mothers interviewed was 16- 43 years with a median of 24.0 years (IQR: 21.0, 29.0). Among them, 308 (82.8%) reported ANC attendance **(Table 1).**

Table 1: Maternal profile

Characteristics	n (%) or Median (IQR)
Age	
(Years), Median (IQR)	24 (21, 29)
Range (years) (Min. - Max.)	16 – 43
Education level	
None	
Primary	9 (2.4%)
Secondary	137 (36.8%)
Tertiary	170 (45.7%)
	56 (15.1%)
Parity	
Primiparous	
Multiparous	
Attended Antenatal Clinic	184 (49.5%)
YES	188 (50.5%)
NO	
Thermal care education	308 (82.8%)
YES	64 (17.2%)
NO	
	222(59.7%)
	150(40.3%)

4.2.2 Neonatal characteristics

The average gestational age of the participants was 35.4 weeks (SD: 3.9) with a range of 26-41 weeks. The median age (IQR) at admission was 83(34,246). Among the participants, 213 (57.3%) were males while 174 (46.8%) were preterm. A total of 274(73.7%) newborns were hypothermic while only 7.8% (29) accessed optimal thermal care by the first hour of admission. Day **1** mortality was recorded among 49 (13.2%) of the participants **(Table 2).**

Table *2*: Neonatal demographic and clinical profile

Characteristic	**n (%)**
Gender	
Male	213 (57.3)
Female	159 (42.7)
Place of birth (n %)	
MTRH	240 (64.5)
Non MTRH	132 (35.5)
Mode of Delivery	
Operative	100 (26.9)
Non-operative	272(73.1)
Maturity by NBMS	
Term	195 (52.4)
Preterm	177 (47.6)
Maturity by weight	
< 2500 grams	198(53.2)
≥ 2500 grams	174(46.8)
Diagnosis at admission	128(34.4)
Prematurity	135(36.3)
Birth Asphyxia	49(13.2)
Surgical, congenital disorders and macrosomia	60(16.2)
Neonatal Sepsis	

4.3 Prevalence of hypothermia among neonates admitted at MTRH

4.3.1 Admission hypothermia

The prevalence of neonatal hypothermia on admission at the MTRH newborn unit was 73.7% (274). Further analysis of the spectrum of temperatures at the 1st hour of admission (AH) indicated that 38 (10.2%), 172 (46.2%) and 65(17.5%) newborns had severe, moderate and mild hypothermia respectively **(Figure 2).**

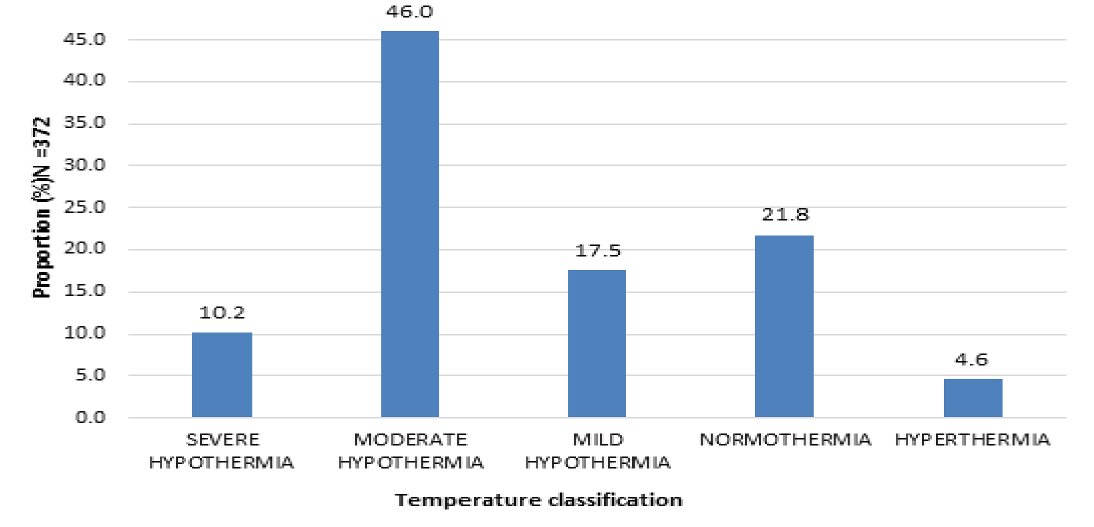

Figure 2: Spectrum of temperatures at the 1st hour of admission

4.3.2 Hypothermia trends over the initial 24 hours of admission

Recurrent episodes of hypothermia was noted among 252 (68%) of the participants on day one of admission. Nevertheless, a steady decline in the prevalence of hypothermia was noted over the initial 24 hours of admission. Serial thermometry revealed hypothermia rates of 55.6% (207), 44.9 % (167), 39.8 % (148), 34.9(130) and 87(23.4%) by the 3rd, 6th, 12th, 18th and 24th hours correspondingly. Some neonates were not assessed between the 6th and 24th hour as they had died, gone for investigations out of the unit or been released back to the mother at postnatal ward with the highest number,71 (19.1%) recorded by the 24th hour **(Figure 2).**

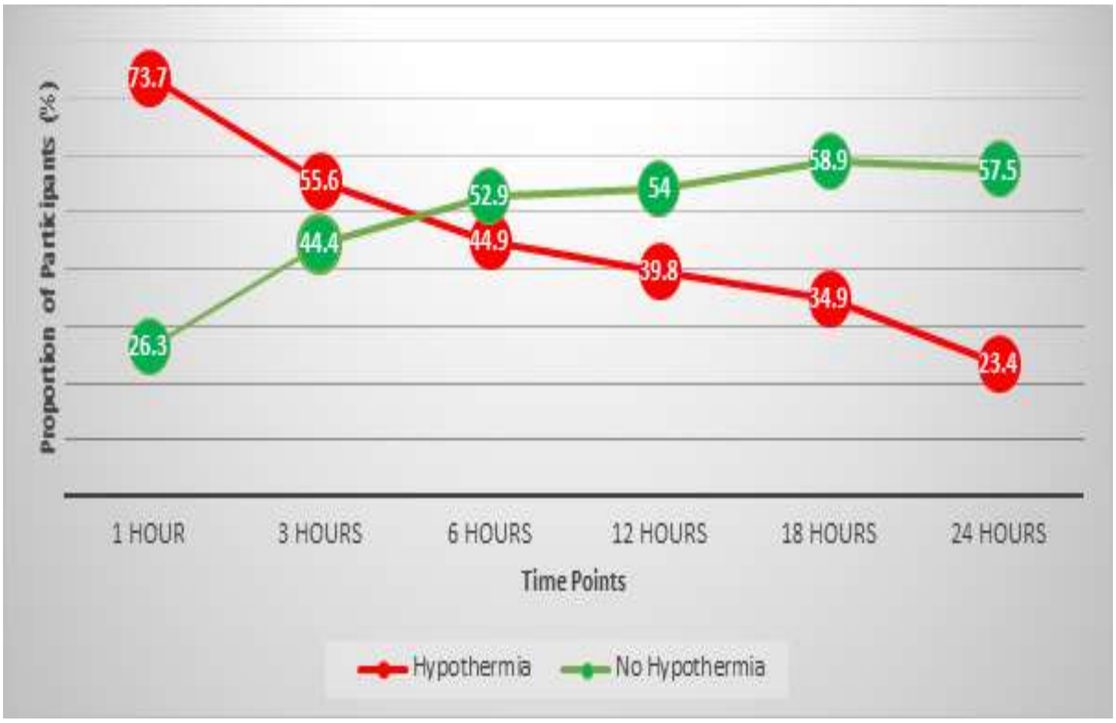

Figure 3: Neonatal hypothermia trends over the initial 24 hours of admission

4.4 Adherence to the WHO thermal care guidelines

4.4.1 Adherence to individual warm chain steps by the 1st hour of admission.

Provision of warm delivery rooms and NICUs at MTRH was also assessed over the study period with mean ambient temperatures of **24.53°C** (22°C- 27°C**)** n=38**, 20.13°C** (19°C-22°C) n=32 and **25.4°C** (24°C-28°C) n=62 being recorded at the labor rooms, operating theatres and NBU respectively. Among the mothers interviewed, 163(43.8%) indicated that they had delivered in warm rooms regardless of the place of birth while 304(81.7%) reported immediate wiping and wrapping. Warm transport was observed among 243(65.3%) neonates at admission. None of the neonates were noted to have been transported in an incubator. Warm clothing was the commonly used mode of providing warmth. The following were among the most adhered to warm chain steps correspondingly; delayed baths 73.7% (274), appropriate thermal care appliances 63.7% (237) and at least 3 layers ,81.5% (303) of warm, dry and absorbent clothing,82% (305) among the three steps under appropriate clothing. However notable absence of caps and stockings especially among the preterm babies negated the gains achieved on this step dropping the aggregate score for appropriate clothing to 48.9 % (182) since only 53 % (197) neonates wore a cap and stockings. About two fifths (150) 40.3% of the mothers had not received any thermal care education from the ante natal period to the first hour of admission of their babies in the Moi Teaching and Referral Hospital newborn unit. Rooming in, 17(4.6 %), skin to skin contact 35(9.4%) and early breastfeeding 46(12.5%) which are enshrined under kangaroo mother care were among the least adhered to steps besides the near universal weighing, 94.1% (350) noted among the participants **(Table 3).**

Table 3: Adherence to WHO thermal care guidelines at the 1st hour of admission

Warm chain step	**YES (%)**	**NO (%)**
Warm delivery rooms	163 (43.8)	209(56.2)
Immediate wiping and wrapping	304 (81.7)	68 (18.3)
Warm transport	243 (65.3)	129 (34.7)
Delayed weighing	22 (5.9)	350 (94.1)
Delayed Bathing	**274 (73.7)**	**98 (26.3)**
Appropriate clothing	**182(48.9)**	**190 (51.1)**
At least 3 layers	303(81.5)	69(18.5)
Dry, warm and absorbent	305(82.0)	67(18)
Cap /stockings	197(53.0)	175(47.0)
KMC steps ≥ 1	**65 (17.5)**	**307 (82.5)**
Early breastfeeding	46 (12.5)	326 (87.5)
Skin to skin care	35 (9.4)	337 (90.6)
Rooming	17 (4.6)	355(95.4)
Appropriate thermal resuscitation appliance	**237 (63.7)**	**135 (36.3)**
Continued thermal care education	**222 (59.7)**	**150 (40.3)**

Legend: ***Bold*** **-** *select post admission steps defining* ***'optimum adherence'***

4.4.2 Optimal adherence to the warm chain guidelines

The warm chain was optimally adhered to only among **7.8% (29)** of the participants at the first hour of admission .The steps considered in our operational definition of 'optimal adherence' included delay of baths, appropriateness of clothing and thermal resuscitation equipment as well as application of at least one among warm chain steps enshrined under KMC which included early breastfeeding, skin to skin contact and rooming in between mother-baby pairs during care **(Fig.3).** .

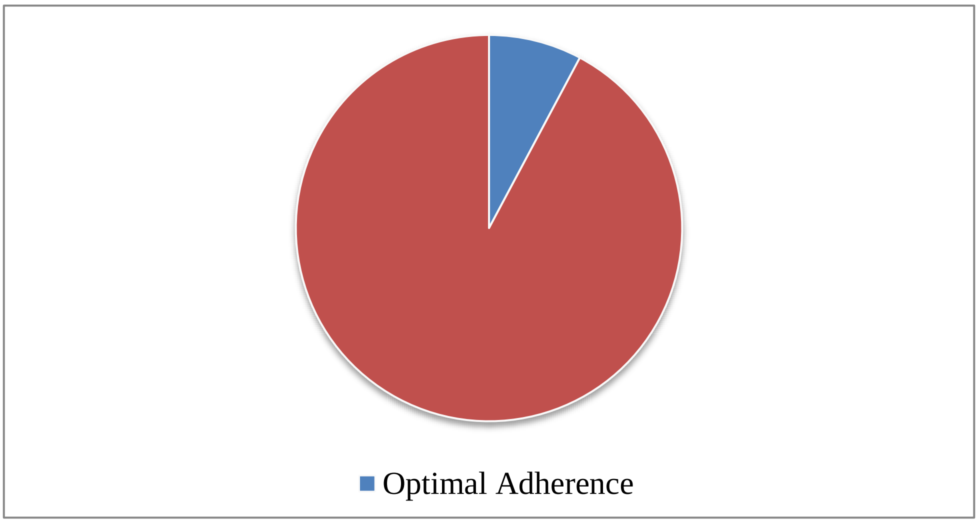

Figure 4: Optimal adherence to the WHO warm chain guidelines by the 1st hour

4.5. Factors associated with hypothermia among newborns admitted at MTRH

4.5.1Demographic and clinical factors associated with admission hypothermia

Birth weights < 2500grams (RR=1.58, 95% CI: 1.37-1.82) and gestational age <37 weeks (RR=1.62, 95% CI: 1.43- 1.84) increased the risk of hypothermia at admission by 58% and 62% respectively. Lack of continued thermal education among the mothers (RR=1.14, 95% CI: 1.01-1.28) marginally conferred a 14 % risk of admission hypothermia (p-value = 0.041) as shown on **table 4a**.

Table 4a: Analysis of demographic and clinical factors associated with admission hypothermia among newborns admitted at MTRH, Kenya, 2016[N = 372]

Variables	**Admission hypothermia**		**p-value** (p≤ 0.05)	**Relative risk** (RR) at (95% CI)
	YES: N=274(%)	**NO:** N=98(%)		
Place of birth:				
Non MTRH	94(71.2)	38(28.8)	0.427	0.95(0.83-1.08)
MTRH	180(75)	60(25)		
Mode of delivery:				
Operative	75(75)	25(25)	0.721	1.07(0.73-1.6)
Non operative	199(73.2)	73(26.8)		
Maturity by NBMS:				
Preterm	161(91.0)	16(9.0)	**<0.001**	1.62(1.43-1.84)
Term	113(57.9)	82(42.1)		
Maturity-weight:				
<2500grams	176(88.9)	22(11.1)	**<0.001**	1.58(1.37-1.82)
≥2500grams	98 (56.3)	76(47.7)		
Diagnosis				
Prematurity	119(93)	9(7)	**<0.001**	_
Birth asphyxia	94(69.6)	41(30.4)		
Congenital/Surgical	33(67.3)	16(32.7)		
Presumed sepsis	28(46.7)	32(53.3)		
Maternal parity:				
Primiparous	141(76.6)	43(23.4)	0.198	1.08(0.96-1.22)
Multiparous	133(70.7)	55(29.3)		
Thermal education:				
NO	119(79.3)	31(20.7)	**0.041**	**1.14 (1.01-1.28)**
YES	155(69.8)	67(30.2)		

4.5.2 Association between adherence to warm chain and admission hypothermia

Inappropriate appliances, RR=1.50, 95% CI: 1.34-1.67) or clothing (RR =1.78, 95% CI: 1.54-2.05), non-adherence to all the three KMC steps (RR=1.79, 95% CI: 1.36-2.36) increased the risk of AH by 50%, 78% and 79% correspondingly **(Table 4b).**

Table 4b: Association between adherence to warm chain and admission hypothermia among neonates admitted at MTRH, Kenya, 2016[N = 372]

Variables	**Admission hypothermia**		**P value** Critical $P \leq 0.05$	Relative risk (RR)(95% CI)
	YES:N=274(%)	**NO:**N=98(%)		
Delayed bathing: NO **YES**	75(76.5) 199(72.6)	23(23.5) 75(27.4)	0.452	1.05(0.92-1.20)
Appropriate appliance: NO **YES**	126(93.3) 148(62.4)	9(6.7) 89(37.6)	**<0.001**	**1.50 (1.34-1.67)**
Appropriate clothing: NO **YES**	**178(93.7)** **96(52.7)**	**12(6.3)** **86(47.3)**	**<0.001**	**1.78(1.54-2.05)**
At least 3 layers: NO YES	67(97.1) 207(68.3)	2(2.9) 96(31.7)		1.42(1.30-1.55)
Dry & absorbent NO YES	65(97) 209(68.5)	2(3) 96(31.5)		1.42(1.30-1.54)
Cap and Stockings NO YES	164(93.7) 110(55.8)	11(6.3) 87(44.2)		1.68(1.47-1.91)
At least 1 KMC step: NO **YES**	**245(79.8)** **29(44.6)**	**62(20.2)** **36(55.4)**	**<0.001**	**1.79(1.36-2.36)**
Early breastfeeding: NO YES	256(78.5) 18(39.1)	70(21.5) 28(60.9)		2.01(1.39-2.89)
Skin to skin care: NO YES	267(74.2) 7(58.3)	93(25.8) 5(41.7)		1.27(0.79-2.06)
Rooming In: NO YES	267(75.9) 7(35)	85(24.1) 13(65)		2.17(1.19-3.95)

4.5.3 Association between Hypothermia at admission (AH) and the 24 hour neonatal survival among newborns at MTRH.

a) Kaplan Meier survival distribution among newborns with or without AH

The relationship between neonatal survival and admission hypothermia (AH) was studied using time to event analysis by the Kaplan-Meier survival function. The event of interest was neonatal death and the outcome of time to mortality was assessed. The hypothermia state of the newborns categorized as presence or absence of AH was the independent variable. The results show better survival probability among neonates without AH compared to those who were hypothermic as with only one adverse event 1(1%) notable in the former group and occurring much later as opposed to the early onset of adverse events in the hypothermic group. Overall, more than 80% of the participants were censored at the end of the 24 hour follow up time thus a rank sum comparison of medians was not possible, (Figure 5).

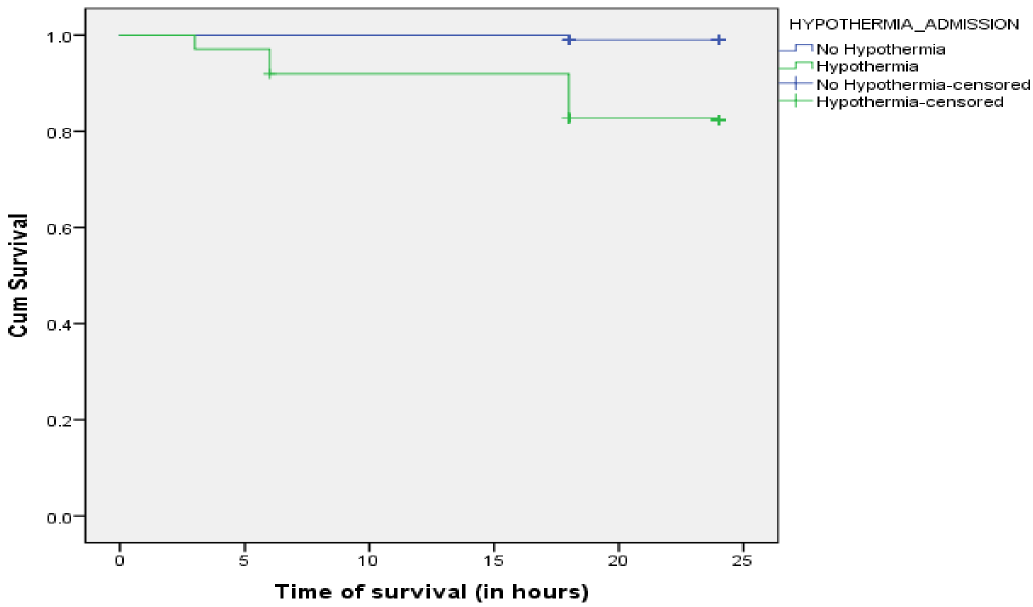

Figure 5: Twenty four hour survival distribution among newborns with or without admission hypothermia at the MTRH newborn unit, Kenya, 2016[N = 372]

b) Survival distributions comparisons among neonates with or without admission hypothermia (AH) at the MTRH newborn unit.

Comparison of the survival functions by the hypothermia state of the newborn at admission was analyzed using the Log rank test and showed a statistically significant difference in the survival distributions among the neonates disaggregated by their hypothermia categories (P-value <0.001).The neonates without admission hypothermia recorded higher average means of survival, 23.94(23.82, 24.06) compared to their hypothermic counterparts, 21.91(21.27, 22.55**, (Table 5)**

Table 5: Survival distributions comparisons among neonates with or without admission hypothermia (AH) at the MTRH newborn unit, Kenya, 2016 (N=372)

ADMISSION HYPOTHERMIA (AH)	TOTAL	NO of events (%) **(Mortality)**	**Censored N (%)**	**Mean [a] 95% CI**	Std. Error
NO	98	1(1.0)	97(99.0)	23.94 (23.82, 24.06)	0.06
YES	274	48(17.5)	226(82.5)	21.91 (21.27, 22.55)	0.33
Overall	**372**	**49(13.2)**	**323(86.8)**	**22.45 (21.97, 22.93)**	**0.25**
[a.] *Estimation is limited to the largest survival time if it is censored*					
Overall Comparisons Test of equality of survival distributions among neonates who were hypothermic and none hypothermic at admission					
	Chi- Square		Difference	Significance	
Log Rank test (Mantel-Cox)	17.05		1	< 0.001	

CHAPTER FIVE

5.0 DISCUSSION

5.1 Prevalence of Neonatal Hypothermia

Neonatal hypothermia was prevalent at MTRH with a rate of 73.7% by the first hour of admission of sick newborns to the newborn unit. The high proportion of hypothermia in our study could be attributed to the frequency of the associated factors among our participants including prematurity and suboptimal adherence to the warm chain. Akin to earlier findings at the same facility, there was significant prematurity and neonates with less than normal weights which affirms the latest Kenyan demographic report that highlights neonatal prematurity as a growing concern in Kenya. The maternal profile in our study is also in tandem with this national report (KDHS, 2014; Njuguna et al., 2014; Okwako, 2014).

The proportion of hypothermia in our study approximated results from studies done in Malaysian NICUs at 64.8% (Boo et al., 2013). Equally studies Nigeria reported similar prevalence rates among neonates aged < 24 hours at admission in a hospital at Sagamu 72.4% (Ogunlesi et al., 2008) and within < 72hrs in a University hospital, 68% respectively (Ogunlesi et al., 2009). Hospitals studies in Ethiopia posted comparable results with 69.8% ,64% 66.3% of admitted neonates being hypothermic at Gondar university hospital, NICUs in Addis Ababa as well as among public hospitals in Harar City respectively (Bayih et al., 2019; Demissie et al., 2018; Seyum & Ebrahim, 2015). The probable explanation for this could be the common hospital setting with similar challenges being expected among sick newborns admitted in public hospitals in these regions. Semblance in climatic, economic and technological limitations possibly explains parallel results seen among the African studies.

Lower prevalence rates of 32% and 51% were recorded upon admission of neonates into NICUs in Brazil where a more meticulous approach to thermal care was noted (da Mota Silveira et al., 2003; De Almeida et al., 2014). In Iran, proportions of hypothermia were also lower than our case ,53.5% and 53.3% (Nayeri & Nili, 2006; Zayeri et al., 2007). Iranian NICUs had an intentional emphasis on the application of BFHIs (Delavar et al., 2014). Lower proportions of hypothermia were also seen in other parts of Asia,52.7% (Ramani et al., 2018), in the USA,56.2%(Miller et al., 2011), in Spain 44.4% and across other European NICUs, 53.4% (Wilson et al., 2016). On the African front, studies in Tanzania 22.4% (Manji & Kisenge, 2003); South Africa 46.1% (Ng'eny & Velaphi, 2019) and Ethiopia 50.3% (Gendisha et al., 2019) also posted prevalence rates lower than our study.

Higher proportions of neonatal hypothermia were noted amongst preterm neonates in the Netherlands, 93% (Mank, van Zanten, et al., 2016), similar to findings among neonates in Nepal, 92.3% (Mullany et al., 2010), Zimbabwe 85% (Kambarami et al., 2003) and Uganda, 83% (Byaruhanga et al., 2005). The variations seen between hypothermia rates in these studies and ours could be inherent in differences in temperature measuring sites, timing of thermometry, technological, economic, cultural and ecological disparities between the study areas. The uniqueness in the demographic profiles of the study participants could also be an additional factor explaining the variance.

5.2 Adherence to the warm chain guidelines

There was sub optimal adherence to the warm chain both at the delivery rooms in MTRH and at the newborn unit. Less than a tenth of the participants in our study had the warm chain optimally adhered to by the first hour of admission. This agrees with findings in Malaysia where none of the NICUs evaluated practiced a complete thermal care bundle (Boo et al., 2013). This was also the case in Nepal where only 10.7% of the neonates in a community study got optimum care (Khanal et al., 2014).Reviews in Africa also cite negative and sub-standard thermal protection among the factors sustaining the epidemic of hypothermia in the region (Lunze et al., 2013; Onalo, 2013).

The practice to the individual warm chain steps was variable. More than half of the mothers reported lack of warmth in the delivery rooms irrespective of the place of birth. A sentinel at the MTRH delivery rooms revealed sub optimal temperatures at the labor rooms which was consistent with Boo et al's report which showed mean temperatures of 20.1 ^{0}C(SD 1.6)n=30 and 22.8^{0}C SD 2.7 n 28 in obstetric theatres and delivery rooms across Malaysian NICUs (Boo et al., 2013). The concordance can be explained by the similarities in study setting with parallel challenges expected for these hospital studies. In contrast to this, warm delivery rooms were reported in Iran as part of an intentional baby friendly hospital initiative (Delavar et al., 2014).

Good achievement of immediate wiping in this study can be attributed to the reactive nature of this step as well as the fact that there were skilled attendants for most of the births among our participants. Prioritization of the mother and the delivery of the cord were cited in Tanzania and Nepal where poor application of this step has been mentioned especially in community settings In this study, there was near universal weighing of babies which may have been so since it was a pre-requisite for the sick newborns in order for them to access appropriate dosages of feeds, fluids or medication. For the second part of this step however we found predominance in the delay of baths at the unit which contrasts community reports from Nepal (Mullany et al., 2010).

Warm clothing was the only measure taken to provide warmth during transport and there were no instances where use of incubators for transport was noted among participants at the point of admission. This is testament to the scarcity of such resources in our setting and provides an area of potential improvement. Kangaroo mother care was also not a normalized approach to transport in this study. Apprehension created by the sick state of the neonates was reported among the mothers while in some instances the mothers were still being attended to by the obstetric or anesthesiology team especially following operative delivery.

Provision of appropriate clothing was fairly achieved among our study population. This was credited to the fact that the MTRH newborn unit stocked warm absorbent linen in anticipation of the newborns requiring admissions. Unfortunately, frequent stock outs for caps and lack of appropriate sizes for the very preterm infants lowered the aggregate score for clothing. It is possible that having not anticipated preterm deliveries the mothers did not consider buying smaller sized caps. The high rate of prematurity also placed a considerable strain on the available caps and reservations were often made for the newborns on CPAP ventilation. This provides an area of potential improvement towards thermal care especially among the preterm neonates.

Antenatal education of mothers on the potential risks for preterm delivery and the need to take measures to prevent or prepare for such eventualities could be useful.

Two thirds of our participants accessed appropriate thermal care appliance. It was noted that a majority were the term newborns. Very few of the preterm infants weighing less than 1700 grams accessed incubator care as per the WHO's recommendation by the first hour of admission. There was an overall strain on the seven functional incubators available at the unit during the study period. Incubator sharing was rampant among the preterm infants and it often took at least beyond one hour for an incubator to be freed up for a newly admitted newborn. This was a major concern for the unit and efforts towards purchase of more incubators were underway at the time of this study. These limitations confirms Lunze et al's observations that use of appropriate thermal care devices is not an optimized practice in Africa (Lunze et al., 2013) but differs from the Europeans surveys which were done in a more technologically advanced economy (Wilson et al., 2016).

We grouped the following steps under KMC; Early bathing, skin to skin contact and rooming in and awarded a point for an affirmative answer for adherence to any of them by the 1st hour of admission. Even so, these were among the steps with the greatest adherence. Possibly, neonatal problems such as severe respiratory distress and obstetric complications requiring further management of the mothers made the application of these steps difficult. The average daily bed occupancy at MTRH was also as high as 85 and the limited space in the NBU presented an additional confounder for the application of steps such as rooming in.

5.3 Factors associated with admission hypothermia

We computed the association between the occurrence of hypothermia and the various demographic and clinical factors as well as the adherence to the various warm chain steps. Of the variables assessed, gestational maturity as per the NBMS was significantly associated with hypothermia with GA <37 weeks conferring a 62% higher chance of hypothermia at admission p<0.001 RR 1-621(1.427 -1.843).This concurs with findings in the Netherlands whereby near universal hypothermia, 93% was noted among neonates with gestational ages less than 32 weeks (Mank, van Zanten, et al., 2016). Similar findings were also reported in Nigeria where 82.5%, RR(1.51(1.21-1.89) and 88.9% of the hypothermic newborns were preterm (Ogunlesi et al., 2008, 2009). Increased odds of hypothermia was also noted among preterm babies in Gonder university hospital, OR 4.81(2.67-8.64); p=0.001 (Demissie et al., 2018) with tripled risks among preterm newborns within 6hrs of birth in a public hospital at Harar city in eastern Ethiopia with an adjusted odds ratio (AOR) of 3.189 (1.84-5.48) (Bayih et al., 2019). In a systematic review and meta- analysis in East Africa, there were increased odds of hypothermia among preterm neonates AOR 4.0195%CI3.02-5.00) 12 0.0% P=0.457 with complete homogeneity (Beletew et al., 2019). The risk of hypothermia conferred by prematurity is innate in the physiology of the preterm infant that limits their capacity for thermogenesis as compared to their term counterpart. The preterm has a limited amount of brown adipose tissue and a higher body surface area to volume ratio that tips the scale towards more heat loss than heat production (Beers et al., 2003).

Birth weight less than 2500 grams also significantly increased the chances of hypothermia among our participants , p<**0.001** akin to findings in Nepal, AOR 4.32 (3.13,5.00) where babies weighing less than 200g had a four-fold increased risk of hypothermia with the chances being elevated further AOR 11.13(8.10-16.70) with every 100g decrement in birth weight (Mullany et al., 2010). Obrien et al also noted high rates of hypothermia,79% among very low birth weight (VLBW) infants in Malaysia (Obrien et al ,2018) whereas in Nigerian 93.3% and 89.1% of the hypothermic babies had lower than normal weight (Ogunlesi et al., 2008, 2009). These findings are replicated in Ethiopia where less than normal weights were associated with increased odds of hypothermia in many of the studies; AOR 1.33(0.75-2.36) p=0.331 (Demissie et al., 2018), AOR=3.61 (2.10,6.18 (Ukke & Diriba, 2019), AOR=3.75 (1.29-10.88) (Seyum & Ebrahim, 2015). In Tanzania and South Africa, lower weights were equally associated with hypothermia. Ngeny et al demonstrates that weights less than 1000g conferred a double risk for hypothermia compared to normal weight. AOR 2.28(1.25-4.16) (Manji & Kisenge, 2003; Ng’eny & Velaphi, 2019). The significance in birth weight to the occurrence of hypothermia was re- affirmed by findings in systematic review of factors associated with hypothermia in sub Saharan (Onalo, 2013) and East Africa AOR 2.16 95%CI(1.03-3.29)12 3.3% P=0.005 with near homogeneity in the latter study (Beletew et al., 2019). Neonates with lower birth weights could either be premature or have intra-uterine growth restriction (IUGR) which means that they have less brown fat stores compromising thermogenesis resulting in heat production that does not match their heat loss due to additional factors such as delicate skin that allows more evaporation. Sub optimal adherence to the warm chain feasible from point of admission was found to be significantly associated with hypothermia at variable extends. Suboptimal adherence to warm chain such as inadequate clothing, are associated with hypothermia in Africa. For instance, in Ethiopia, doubled odds of hypothermia 2.10, 95% CI 1.17-3.76) were noted in the absence of cap wearing (Bayih et al., 2019; Lunze et al., 2014; Manji & Kisenge, 2003). This contrasted de Almeida's observations where lack of cap wearing did not potent any added risk OR 0.55 95% CI 0.39-0.78 possibly due to a more meticulous approach to thermal care using sophisticated technology in this setting that possibly blurred the benefits of cap wearing. Neonates without appropriate thermal resuscitation appliances as per the WHO recommendation were more likely to be hypothermic which affirms Onalo et al's observation that hypothermia in Sub-Saharan Africa was associated with lack of facilities due to rampant poverty (Onalo, 2013).

Lack of application of early breastfeeding, SSC and rooming in which are warm chain steps enshrined under KMC increased the chances of hypothermia whereas their application was beneficial which was comparable to findings in Nigeria where KMC was protective against hypothermia at admission p=0.028 (Ogunlesi et al., 2009). Mullany et al did not find any association between the practice of SSC and hypothermia in a community study in Nepal and postulated that this was practiced reactively obscuring any potential benefit. A delay in breastfeeding notably increased the risk of hypothermia in this study akin to our findings (Mullany et al., 2010). Similarly, Ethiopian studies demonstrated increased odds of hypothermia whenever there was no SSC P<0.001, AOR 2.8 95%CI (1.46-5.66) (Demissie et al., 2018; Seyum & Ebrahim, 2015) at an AOR=2.87 (1.48-5.57). Delayed breastfeeding also increased odds in neonatal hypothermia in these studies AOR 7.58 95% CI 3.61,15.91) (Seyum & Ebrahim, 2015) AOR 3.72(2.07-6.65 (Demissie et al., 2018), AOR=2.42 (1.45,4.02) (Bayih et al., 2019). When there is SSC between mother-baby pairs, heat transfer from mother to baby helps the baby to keep warm. At the point of rooming in, the mother is also able to optimize other aspects of the warm chain such as ensuring appropriate clothing in between SSC and breastfeeding sessions. Breastfeeding provides the neonate with the caloric demands of metabolism breaking the vicious cycle that exists between hypoglycemia and hypothermia. For the studies that had similar findings to ours, comparable settings and the congruence in challenges faced among hospital admissions could explain the parity.

There was less likelihood of hypothermia whenever the mothers accessed thermal education in line with the WHO's sentiments (WHO, 1997). Delaying weight measurements and baths did not express any statistical significance in this study contrary to what was expected. There was near universal weighing of participants before or immediately after admission and the near homogeneity in this population could have obscured the potential benefit of a delay in weighing. Contrary to our results, there was a doubled likelihood of hypothermia whenever early bathing was practiced in Ethiopia AOR 2.63 95% CI (1.23-5.63) (Gendisha et al., 2019) as was the case in Uganda where increased rates of hypothermia was noted whenever newborns were bathed within the first hours of birth (Byaruhanga et al., 2005).

Contrary to our expectations, births outside MTRH and operative deliveries were not associated with admission hypothermia. This differs from findings in Nigeria and Tanzania where hypothermia was noted more among outborn babies, 64.4% vs 58.3% (Ogunlesi et al., 2009) with increased incidence among babies born via caesarian section (Manji & Kisenge, 2003). It also varied from a population-based cohort in California where operative delivery was associated with hypothermia (Muller et al,2011) and a hospital study in south Africa whe re now operative birth conferred a doubled risk of hypothermia. OR 2.85(1.37-5.91). For the maternal characteristics, parity was considered and found not to be significantly associated with hypothermia consistent with findings in Uganda (Byaruhanga et al., 2005). We opted to limit our analysis scope to events occurring at MTRH hence pre-admission steps like provision of warm delivery rooms, immediate wiping and warm transport were not included in our analysis of hypothermia associated factors.

On the day one outcomes associated with hypothermia at admission, the chances of recurrent episodes was tripled p<0.001 RR=3.428(2.412-4.871). A plausible explanation could be that there was a persistence in factors initially associated with hypothermia such as prematurity and sub-optimal adherence to the warm chain among this population. Time factor is also significant in thermal care. It takes more time to achieve optimum thermal resuscitation especially when severe and moderate forms of hypothermia are encountered.

5.4 Association between hypothermia and neonatal survival

Survival analysis in this study revealed a significant difference among neonates who were hypothermic at admission compared to those who were not with more deaths among the former group in the initial 24 hours of surveillance, 17.5 %(48) vs. 1%(1,) (P <0.001) .Time to the occurrence of an adverse event, (mortality) was also shorter in the hypothermic group unlike their counterparts. Equally, many studies have highlighted an association between hypothermia and neonatal mortality. For instance, in Brazil, hypothermia at admission was associated with a 6% risk for early neonatal deaths RR 1.64(1.03-2.65 (De Almeida et al., 2014). In Nepal stratification of the neonatal temperatures into various severity scales reveals an 80% to 95% (63-100%) mortality risk for each degree decrement in temperatures with temperatures <35 degrees posing a significantly increased risk of neonatal mortality RR 6.11 95%

CI(3.98-9.38) (Mullany et al., 2010). Hypothermia has also associated with deaths among VLBW infants across European NICUs (Wilson et al., 2016). Closer home, a higher CFR is noted among hypothermic babies in Nigeria 37.6% vs. 16.7% whereas in South Africa, a quadrupled chance of death is identified among hypothermic neonates within the first week of life OR 4.79 (Ng'eny & Velaphi, 2019; Ogunlesi et al., 2008). Earlier on, the risk of mortality was tripled among hypothermic newborns in Tanzania (Manji & Kisenge, 2003). The relationship of hypothermia and death among neonates can be explained by the pathophysiology of hypothermia which involves a compromise in the biological systems of the neonate resulting in a cascade of vicious and deleterious events which are fatal.

5.5 Study limitations

This study aimed to determine the prevalence of neonatal hypothermia at MTRH's newborn unit, but logistically it was difficult to carry out the vigorous enrolment process and thermal care observation required during the first hour of admission late into the night hence neonates admitted between 12 midnight and 6 am were excluded which conferred a potential artificial decline in the prevalence rate reported. Adverse findings such as hypothermia were reported to the managing team which could translate to a decline in the associated mortalities as mitigation strategies were instituted hence limiting the scope of our conclusions. We therefore only analyzed for the factors associated with admission hypothermia and not with the temperatures obtained later after this disclosure. Our data collection tool was quantitative in design hence the information collected could not adequately address the issues around the factors associated with sub-optimal adherence to the warm chain noted at MTRH hence the need for further interrogation of this key finding.

CHAPTER SIX

6.0 CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

1. **Three quarters** of the participants had hypothermia at admission while **2/3** got a recurrent episode on day one of admission at the MTRH newborn unit.
2. Optimal adherence to warm chain was noted in **less than a 10^{th}** of the newborns admitted at MTRH.
3. **Prematurity** and **suboptimal adherence** to the warm chain were significantly associated with admission hypothermia.

6.2 Recommendations

Strategies to optimize adherence to the warm chain at MTRH with regard to the weak links in applying appropriate clothing and thermal resuscitation equipment as well as the KMC steps as identified in this study. Priority triage and an anticipatory approach to thermal care of preterm neonates should be emphasized as they are especially at risk of hypothermia. A follow up study to determine the factors associated with the sub- optimal adherence to the warm chain noted at MTRH will also be key.

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APPENDICES

APPENDIX 1: CONSENT INFORMATION FORM FOR PARENTS /GUARDIANS

SERIAL NO……………. DATE…………………

NEONATAL HYPOTHERMIA AND ADHERENCE TO WORLD HEALTH ORGANIZATION THERMAL CARE GUIDELINES AMONG NEWBORNS AT MOI TEACHING AND REFERRAL HOSPITAL, KENYA

Name of Principal Investigator: DR. LUBUYA FLORENCE

Supervisors: PROF. NYANDIKO M. WINSTONE

Dr. KIPTOON PAUL

Child health and Paediatrics,

Moi University, School of Medicine, Eldoret, Kenya.

This form has been designed for the guardians or parents of the participants of this study

This Informed Consent Form has two parts:

Information Sheet – to provide an explanation of the study and its purpose.

Certificate of Consent – to append your signature if you agree to your child's participation,

Part I: Information Sheet Introduction:

You are requested to allow your baby to be included as a participant in this study. The information given below will give you a brief summary of the study scope and its main purpose. Participation in this study is voluntary and your choice will not affect the standard of care offered to your child. You reserve the right to withdraw from the study at any time without any consequences. You will also be notified of any significant issues noted in the course of the study which affects your child.

Purpose and nature of the study:

The study aims at determining the burden of hypothermia among admitted neonates at MTRH as well as assessing the thermal care practices in place in comparison to the WHO guidelines. This is a cross sectional study where your baby will have serial three hourly temperature measurement followed by a review of their medical records. A check list will be filled by the PI or her RAs assessing the various thermal care practices. This is because there in need to assess how best thermal care is practiced at this facility with respect to available guidelines. There are no added risks to your baby while participating in this study over and above risks of routine care. There will also be no direct benefits to participation in this study except for the early detection and intervention of any thermal derangements in your child.

Contacts:

In case of any question, problems or clarifications please contact Dr. Lubuya Florence (principal investigator– 0702165151 Email ; flubuya@gmail.com)

The mail address is as follows:

DR LUBUYA FLORENCE

P.O BOX 4606-30100

ELDORET, KENYA

You may also contact the supervisors and approving authority (IREC) through 053 33471 Ext.3008.The Institutional Review Ethics Committee (IREC) which is an oversight body that approves studies and keeps surveillance on their progress to protect you as a participant.

Privacy and confidentiality of information:

Confidentiality and privacy of your protected information will be upheld with utmost respect. All identifiers will be de coupled and sharing will only be done where it is necessary to convey some of the findings to the health care providers attending your child for the benefit of the baby. Using or sharing,“ Disclosure” of such information shall be within the scope of this study as per the National privacy guidelines to which signing this consent form gives prerequisite permission.

Part II: Consent of Subject:

I have read or have had read to me the description of the research study. The investigator or his/her representative has explained the study to me to my satisfaction and answered the questions I had at this time. I have been told of the potential discomforts and adverse outcomes as well as the possible benefits (if any) of the study. I freely volunteer for my baby to take part in this study.

______________________ ______________________

parent/guardian Signature Date & Time ……

APPENDIX 2: QUESTIONNAIRE

SERIAL NO: …….

B: NEONATAL CLINICAL PROFILE

A) INITIALS……

B) PRESENTING COMPLAINTS ________________________________

C) MODE AND PLACE OF DELIVERY

MOD C/S ☐ SVD ☐

SBD ☐ OTHERS ☐

POD: MTRH ☐ OTHER FACILITY (SPECIFY) ☐ HOME ☐ OTHERS ☐

D: VITAL SIGNS

Parameter	0 -1 HRS	3 HRS	6 HRS	12 HRS	24 HRS
TEMP					
RR					
PR					
RBS					
Cap. refill					
SPO_2					

E) MATURITY:

i) New Ballard score ii) Birth Weight (grams)

d) Term ☐ Pre-Term ☐

Diagnosis

COMMENTS ________________________

D) `Any significant systemic findings during initial clerkship?

Comment ____

E) OUTCOMES:

24 HOURS: ALIVE ☐ DEAD ☐

C) MATERNAL PROFILE

i) AGE ☐ PARITY ☐

ii) LMP ☐ EDD ☐

iii) MATERNAL RESIDENCE ☐

iv)MARRITAL STATUS ☐

iii) EDUCATION LEVEL

Tertiary ☐ Secondary ☐ Primary ☐ None ☐

iv) EMPLOYMENT STATUS Employed ☐ Unemployed ☐

A .N. C ATTENDANCE Yes ☐ No ☐

a) Number of times

b) Was thermal education received on any ANC visit? Yes ☐ No ☐

D: THERMAL CARE

I) DELIVERY ROOM

a) Was delivery room warm according to the mother Yes ☐ No ☐

b) Was there any external source of heat : Yes ☐ ☐

(e.g heater, fireplace or warm blankets / sheets) Yes ☐ No ☐

II) IMMEDIATE WIPING

a) Was the baby wiped immediately? (before the delivery of the placenta)

Yes ☐ No ☐ Don't Know ☐

III) WARM WRAPPING AND BED

a) How many layers of clothing/ wrap does the baby have? ____________________

b) Is the baby's cloth / bedding dry and warm absorbent Yes ☐ No ☐

Comment____

c) Does the bay has a cup and a stockinet Yes ☐ No Comment

IV) DELAYED WEIGHING ____

V) AND BATHING

a) Was the baby weighed within 6 hours of birth Yes ☐ No ☐

b) Comment ____________________

Was the baby bathed within 24 hours of birth Yes ☐ No ☐

Comment ____________________

V) BREASTFEEDING

a) Was the baby breastfed before one hour of age Yes ☐ No ☐

b) Has the baby been exclusively breastfed since birth Yes ☐ ☐

c) If no in (b) above, comment on type and indications for alternative nutrition

____

VI) SKIN TO SKIN CARE

a) Did mother have SSC with baby before or within 1 hour of admission?

Yes N☐ ☐

b) Over the 24 hours of admission, has the mother had any skin to skin contact with the baby? Yes ☐ No ☐

If YES, specify if continuous or interrupted ____________________

c) Does the mother understand/ comfortable in offering KMC

Yes No ☐ ☐

Comment ____________________

VII) ROOMING IN

Was the baby nursed together with mother before / after admission? Yes ☐ ☐

Comment ____________________

V III) WARM TRANSPORT

a) ☐ Was an external source of heat provided during transport to the NBU? Yes
No ☐

Was KMC offered during transport to the new born unit? Yes ☐ No ☐

b) Has the child gone for any investigation outside the new born unit? Yes ☐
☐

No

If yes, comment on mode of transport ______________________________

IX) CONTINUOUS EDUCATION

a) Has the mother received any thermal care education during any of the ANC visit Yes ☐ No ☐

b) Any thermal care education from providers in the NBU since admission? Within 1ST HOUR Yes ☐ No ☐

1ST 24 HOURS Yes No ☐ ☐

c) Has the mother received any thermal care education through other modes like TV, Radio, friends and relatives? Yes ☐ ☐

X) WARM RESUSCITATION

Comment on the modalities of providing warmth during the 24 hour admission period.

Appropriate [ ] Inappropriate [ ]

Modality	0 HRS	3 HRS	6 HRS	12 HRS	24 HRS
Incubator					
Radiant Heater/ Resuscitare/bulbs					
OTHERS (specify)					
Polythene wraps					

Part 2.

DAILY RMBH THERMAL CARE EQUIPMENT AND NBU BED OCCUPANCY

PLACE	Ambient temperature	Equipment(heaters Incubators, resuscitares)	Daily bed occupancy
RMBH -Theatre			N/A
RMBH-Labour ward			N/A
RMBH- NBU			

APPENDIX 3: THE 10 STEPS OF THE WARM CHAIN

1. Delivery rooms with temperatures between $25^{O}C$ to $28^{O}C$ at the birth place

2. Immediate drying using pre-warmed towels even before delivery of the placenta.

3. Skin to skin contact (SSC) for mother and baby that is among principles of KMC.

4. Early breastfeeding (within one hour) or at least on the first day of life.

5. Delayed weighing and bathing for at least 6 hours and 24 hours respectively.

6 .Appropriate clothing and bedding (3 layers of dry and absorbent material)

7. Rooming In- keeping mother and baby together.

8. Warm transport- use of warm wrap, external heat source and SSC.

9. Warm resuscitation- Use of appropriate appliances during resuscitation

10. Continued training and raising awareness among parents, caretakers and health workers.

APPENDIX 4: TEMPERATURE MEASUREMENT

To evaluate neonatal hypothermia a low reading digital axillary thermometer was used. The thermometry procedure was as per the WHO guidelines outlined below;

Procedure of taking temperature

b) Wash the hands as per the NBU protocol and sanitize the thermometer.

c) Put the thermometer on as per the manufacturers manual and place it high in the axilla and holding against the side the baby for 5 minutes

d) Note the reading on the patients file and data collection tool and notify the primary care provider.

e) Sanitize the thermometer after use

f) Ensure the newborn is safely placed and adequately covered

APPENDIX 5: SAMPLE AMBIENT ROOM TEMPERATURES AS COLLECTED FROM RMBH LABOUR WARDS, OBSTETRIC THEATRES AND NEWBORN UNIT

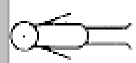
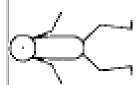
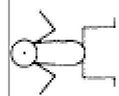
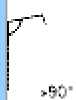
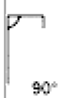
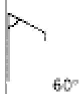
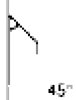
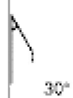
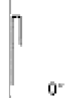
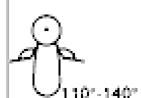
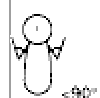
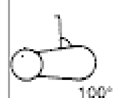
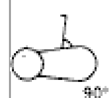
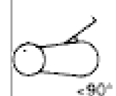
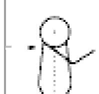
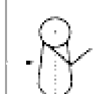
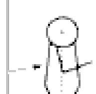
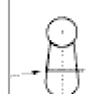
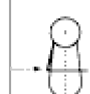
Sample ambient room temperatures as collected from RMBH labour wards, obstetric theatres and newborn unit

APPENDIX 6: NEW BALLARD SCORE FOR ASSESSMENT OF GESTATIONAL AGE

SIGN	SCORE							SIGN SCORE
	-1	0	1	2	3	4	5	
Skin	Sticky, friable, transparent	gelatinous, red, translucent	smooth pink, visible veins	superficial peeling &/or rash, few veins	cracking, pale areas, rare veins	parchment, deep cracking, no vessels	leathery, cracked, wrinkled	
Lanugo	None	Sparse	Abundant	Thinning	bald areas	mostly bald		
Plantar Surface	heel-toe 40-50mm: -1 <40mm: -2	>50 mm no crease	faint red marks	anterior transverse crease only	Creases ant. 2/3	creases over entire sole		
Breast	Imperceptible	barely perceptible	flat areola no bud	stippled areola 1-2 mm bud	raised areola 3-4 mm bud	full areola 5-10 mm bud		
Eye / Ear	lids fused loosely: -1 tightly: -2	lids open pinna flat stays folded	sl. curved pinna; soft; slow recoil	well-curved pinna; soft but ready recoil	formed & firm instant recoil	thick cartilage ear stiff		
Genitals (Male)	scrotum flat, smooth	scrotum empty, faint rugae	testes in upper canal, rare rugae	testes descending, few rugae	testes down, good rugae	testes pendulous, deep rugae		
Genitals (Female)	clitoris prominent & labia flat	prominent clitoris & small labia minora	prominent clitoris & enlarging minora	majora & minora equally prominent	majora large, minora small	majora cover clitoris & minora		
TOTAL PHYSICAL MATURITY SCORE								

PHYSICAL MATURITY

NEUROMUSCULAR MATURITY

SIGN	SCORE							SIGN SCORE
	-1	0	1	2	3	4	5	
Posture								
Square Window								
Arm Recoil								
Popliteal Angle								
Scarf Sign								
Heel To Ear								
TOTAL NEUROMUSCULAR SCORE								

Maturity Rating

Score	-10	-5	0	5	10	15	20	25	30	35	40	45	50
weeks	20	22	24	26	28	30	32	34	36	38	40	42	44

APPENDIX 7: IREC APPROVAL

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2015/170
Approval Number: 0001484

8th September, 2015

Dr. Lubuya Florence,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
08 SEP 2015
APPROVED
P.O. Box 4606-30100 ELDORET

Dear Dr. Lubuya,

RE: FORMAL APPROVAL

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

"Neonatal Hypothermia and Adherence to the World Health Organization Guidelines in Thermal Care of Newborns Admitted at Moi Teaching and Referral Hospital."

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1484*** on 8th September, 2015. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 7th September, 2016. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

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

Sincerely,

For

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

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

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
COLLEGE OF HEALHT SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

25th July, 2016

Reference IREC/2015/170
Approval Number: 0001484

Dr. Lubuya Florence,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
25 JUL 2016
APPROVED
P.O. Box 4606-30100 ELDORET

Dear Dr. Lubuya,

RE: APPROVAL OF AMENDMENT

The Institutional Research and Ethics Committee has reviewed the amendment made to your proposal titled:-

"Neonatal Hypothermia and Adherence to the World Health Organization Guidelines in Thermal Care of Newborns Admitted at Moi Teaching and Referral Hospital".

We note that you are seeking to make an amendment as follows:-

1. To make the questions more specific to thermal care and for aspects of the warm chain such as dressing and thermal care interventions to be rerecorded at each contact with study participants. Reformatting of the questionnaire has also been done.

The amendment has been approved on 25th July, 2016 according to SOP's of IREC. You are therefore permitted to continue with your research.

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

Sincerely,

For

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc:	Director	-	MTRH	Dean	-	SPH	Dean	-	SOM
	Principal	-	CHS	Dean	-	SOD	Dean	-	SON

APPENDIX 8: HOSPITAL APPROVAL

MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke
Ref: ELD/MTRH/R.6/VOL.II/2008

P. O. Box 3
ELDORET

8th September, 2015

Dr. Lubuya Florence,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"Neonatal Hypothermia and Adherence to the World Health Organization Guidelines in Thermal Care of Newborns Admitted at Moi Teaching and Referral Hospital".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

DR. JOHN KIBOSIA
DIRECTOR
MOI TEACHING AND REFERRAL HOSPITAL

CC - Deputy Director (CS)
- Chief Nurse
- HOD, HRISM