

**UMBILICAL CORD HYGIENE AND THE RISK OF NEONATAL
SEPSIS AMONG NEONATES PRESENTING AT KAHAWA HEALTH
CENTRE IN NAIROBI COUNTY, KENYA**

By

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DEDICATION

I dedicate this thesis, first of all to the Most High Almighty God, the First Cause, the Maker of all things, the All-knowing and who gives His wisdom generously without fault to anyone who asks.

Secondly, this thesis is dedicated to my parents and siblings who have always been there for me. In particular, to my mother, Prof. Margaret Moindi Keraka, whom I am perpetually indebted to, for her unceasing encouragement that pushed me through the most difficult times.

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LIST OF ABBREVIATIONS AND/OR ACRONYMS

aOR:	Adjusted Odds Ratio
ANC:	Antenatal Clinic
APGAR:	Appearance, Pulse, Grimace, Activity & Respiratory Effort
CCC:	Comprehensive Care Clinic
CHS:	College of Health Sciences
CHW:	Community Health Worker
CI:	Confidence Interval
C/S:	Cesarean Section
DALY:	Disability-Adjusted Life Years
ENC:	Essential Newborn Care
EONS:	Early Onset Neonatal Sepsis
HIV:	Human Immunodeficiency Virus
IMCI:	Integrated Management of Childhood Illness
IQR:	Interquartile Range
KHC:	Kahawa Health Centre
KNH:	Kenyatta National Hospital
LBW:	Low Birth Weight
LIC:	Low Income Countries
LMIC:	Low- and Middle Income Countries
LOD:	Lines of Defence
LONS:	Late Onset Neonatal Sepsis
MAS:	Meconium Aspiration Syndrome
MoH:	Ministry of Health

NICU:	Neonatal Intensive Care Unit
NMR:	Neonatal Mortality Rate
NS:	Neonatal Sepsis
OR:	Odds Ratio
PAF:	Population Attributable Fraction
PCR:	Polymerase Chain Reaction
PI:	Principal Investigator
PMTCT:	Prevention of Mother to Child Transmission
PN:	Parenteral Nutrition
SIRS:	Systemic Inflammatory Response Syndrome
SPH:	School of Public Health
SSA:	Sub-Saharan Africa
SVD:	Spontaneous Vertex Delivery
TBA:	Traditional Birth Attendant
UoN:	University of Nairobi
UTI:	Urinary Tract Infection
WBC:	White Blood Cell Count
WHO:	World Health Organization

DEFINITION OF OPERATIONAL TERMS

Neonatal mortality:	Death occurring within the first one month of life.
Neonatal sepsis:	A bacterial, fungal or viral systemic infection in the neonate, characterized by biochemical and clinical symptoms such as diminished activity, fever, feeding difficulties or jaundice, symptoms which are deleterious to the child.
Omphalitis:	Localized infection of the umbilical stump, characterized by redness, swelling, warmth, pain or purulence.
Participant/respondent:	Refers to either the neonate or the mother in the mother-neonate pair depending on the context.
Umbilical cord hygiene:	Ensuring a dry cord with no sign of redness, warmth, swelling or pus by air drying the cord, use of methylated spirit/chlorhexidine to the base of the cord and sponge bathing the neonate until the cord heals.
Proper/improper cord care:	Based on total scores of five indicators comprising of method of folding the napkin, rooming-in, bathing, handwashing and substance application, an aggregate score equal to or above the median constituted proper cord hygiene, while scores below the median were considered as improper cord hygiene.

ABSTRACT

Introduction: Neonatal sepsis could be defined as a bacterial, fungal or viral systemic condition characterized by bio-chemical and clinical symptoms and attended by significant morbidity and mortality. Three-quarters of all annual neonatal deaths in developing countries are attributable to neonatal sepsis. In primary care settings, poor cord hygiene due to unclean handling of the infant's cord is a major contributor to the occurrence of neonatal sepsis.

Objectives: To identify umbilical cord care practices among mothers attending the Kahawa Health Centre (KHC) and assess the relationship between umbilical cord hygiene and neonatal sepsis, its population attributable fraction (PAF), as well as the influence of other neonatal and maternal factors.

Methods: A case-control study was conducted at the KHC to assess the umbilical cord-hygiene-neonatal sepsis relationship among neonates presenting to the facility between August and October 2018. All those who were premature, of low birth weight or with congenital anomalies were excluded. All cases were selected, while controls were systematically random-sampled to achieve the required sample size of 312 neonates.

Analysis: Exposure variables were summarized using descriptive statistics. A multivariable logistic regression model was fitted to evaluate the association between umbilical cord hygiene and neonatal sepsis adjusting for the effect of potential confounders. Subsequently, a population attributable fraction (PAF) was estimated.

Results: Chlorhexidine/surgical spirit were the applied agents by 79.2% of controls' compared to 35.6% of the cases' caregivers. Other recommended cord care practices were reported more among the control than the case respondents. The proportion of mothers with improper hygiene was 35.3%: 72.1% among the cases and 16.3% among the controls'

caregivers. The odds of neonatal sepsis were 13 times higher (OR=13.24; 95% CI: [7.5; 23.4]) among infants whose caregivers had improper hygiene compared to those who had proper hygiene. None of the neonatal and maternal covariates confounded the umbilical cord hygiene-neonatal sepsis association. This odds ratio gave a PAF of 66.7% (95% CI: 62.5; 69.03).

Conclusions: Improper cord hygiene is prevalent among the population served by KHC showing a strong positive association of improper cord hygiene with neonatal sepsis. The high PAF estimate implies that up to 67% of newborn infections could be prevented by observing proper cord hygiene methods among the caregivers.

Recommendations: A proper cord hygiene protocol should be included within the antenatal care package.

CHAPTER 1: INTRODUCTION

1.0 Introduction

This chapter outlines the background, problem statement and justification of the study. In addition, the study's research objectives and hypotheses are included.

1.1 Background

Neonatal mortality (death occurring within the first 28 days of life) accounted for 45.1% of all child deaths world over in 2015, representing a 15% upsurge in a span of 15 years (Liu et al., 2016). The leading causes of neonatal mortality globally are preterm birth complications, intrapartum-related events and neonatal sepsis (Oza et al., 2015; Liu et al., 2016). These three constitute 75% of all neonatal deaths (Division of Policy and Strategy, 2013; UNICEF, 2014). In the developing world, neonatal sepsis causes 1.6 million deaths per year (Vergnano et al., 2005). Owing to the non-specificity of neonatal sepsis' presentation in neonates, there has been a general lack of consensus on the definition of neonatal sepsis (Wynn et al., 2014). Nevertheless, Shane et al. (2017) define neonatal sepsis as a bacterial, fungal or viral systemic condition characterized by bio-physiological changes (e.g. abnormal leucocyte count, aberrant temperature or even tachycardia) and clinical symptoms (e.g. presence of fever, feeding difficulties or umbilical discharge) and attended by significant morbidity and mortality.

Maternal and neonatal factors might comprise the multifaceted causes of neonatal sepsis but umbilical cord hygiene has been identified as a key determinant (Mullany et al., 2007; Ambe et al., 2008; Blencowe et al., 2011). Contextually in Kenya, a hygienic umbilical

cord refers to a dry umbilical stump without signs of redness, warmth, swelling, pain, foul smell or pus (Sanitation, 2010; Bugaje et al., 2010). To maintain a hygienic cord, appropriate umbilical care is necessary. Appropriate care could be achieved by either applying methylated spirit/chlorhexidine to the base of the cord, air drying the cord to allow for natural healing or sponge-bathing neonates without immersing them in water (Whitmore, 2010; Saleh et al., 2015).

The probability for entry of pathogenic micro-organisms through the umbilical cord is high in low-resource settings (Amare, 2014; Akter et al., 2016). This could be attributable to the prevailing sub-optimal hygienic conditions in the environment of the baby that could result in a localized umbilical cord infection (omphalitis) (Karumbi et al., 2013), with potential spread of the microorganisms into the bloodstream via the patent umbilical vessels resulting in septicemia or infection of other organs (WHO, 1998). Although clean birth practices are highly advocated for their role in averting the risk of omphalitis and neonatal infection, in many developing settings, cultural norms that dictate cord care practices may compromise cord hygiene (Blencowe et al., 2011; Waiswa et al., 2015). Across cultures and regions, the rationale for applying a wide variety of substances on the cord is to hasten cord separation and healing (Whitmore, 2010; Sacks et al., 2015; Amare, 2014; Coffey and Brown, 2017). These substances, which include cow dung, charcoal, hot fermentation, mustard oil, ghee, ash or other non-septic applications, are significantly correlated with an increased risk of omphalitis and neonatal sepsis (Mullany et al., 2007; Goel et al., 2015; Ambe et al., 2008). The WHO (2013) recommends that dry cord care be employed within health facilities or home deliveries taking place in low mortality settings (less than 30 deaths per 1000 births). Antimicrobial agents such as chlorhexidine/surgical spirit are advocated for home births within high neonatal mortality settings particularly, as a

substitute for harmful traditional compounds (WHO, 2013). In Kenya, at a neonatal mortality rate of 22 deaths per 1000 births (KDHS, 2014), some health workers employ dry cord care as recommended by the Ministry of Public Health and Sanitation (2010), while others have adopted the use of preventive chlorhexidine (Ministry of Health, 2016), resulting in controversy on the standard cord care.

Besides umbilical cord hygiene, neonatal and maternal factors may contribute to the risk of neonatal sepsis. Potential neonatal determinants of sepsis comprise prematurity, low APGAR (appearance, pulse, grimace, activity & respiratory effort) score (<7 at 5 minutes) and neonatal resuscitation (Kumar et al., 2016; Hasan and Mahmood, 2011). Premature babies and those with asphyxia due to poor health scores at birth could develop neonatal sepsis as these conditions are immunologically deleterious (Collins et al., 2018). Neonatal sepsis could result in those resuscitated at birth due to direct exposure to pathogens from the medical equipment (Hasan and Mahmood, 2011). Maternal factors that may contribute to neonatal sepsis include primi-parity, being less than 20 years of age, intrapartum fever, prolonged labor, unclean vaginal examination and inadequate antenatal education (Hasan and Mahmood, 2011; Jabiri et al., 2016). In particular, in rural Uganda, inadequate antenatal education on the importance of care-seeking for treatment of maternal bacterial infection and timely identification of danger signs in the newborn predisposed to development of neonatal sepsis (John et al., 2015). In Kenya, inadequate mothers' knowledge on cord care, improper cord care and handling methods have also been documented (Amolo et al., 2017).

Though easily preventable, neonatal sepsis is potentially fatal if caregivers are not vigilant in safe topical umbilical cord care, early identification of neonatal sepsis and initiation of

treatment (Stewart et al., 2016). In Kenya, there is insufficient documentary evidence on the significance of umbilical cord hygiene in the occurrence of neonatal sepsis.

1.2 Problem statement

Child mortality rates are direct indicators of a country's quality of life and socio-economic standing (Bawah and Zuberi, 2004). Importantly, in most developing countries, neonatal sepsis is a major contributor to child mortality (Oza et al., 2015). Every year, about four million neonatal deaths occur world-wide (Liu et al., 2012); the vast majority taking place in Sub-Saharan Africa, with a reported neonatal mortality rate of 31 per 1000 live births (UNICEF, 2014). It has been shown that three quarters of all neonatal deaths in Africa stemmed from infections (Garces et al., 2017); septicemia accounting for 31.1% of these deaths (Oza et al., 2015).

Kenya ranks among countries with the highest neonatal mortality rates registering an estimated 22.2 deaths per 1000 live births in 2015, which translates to half of all deaths seen in the first year of life (KDHS, 2014). Neonatal sepsis accounts for around 10-30% of these deaths (KDHS, 2014). The prevalence of neonatal sepsis during the first week of life was found to be 13.5% in Kilifi (Berkley et al., 2005), and 23.9% in a County referral hospital in Central Kenya (Geyt and Hauck, 2016).

The umbilical cord, being patent, is an ideal medium for direct entry of pathogenic microorganisms into systemic circulation. The significance of poor cord hygiene in the development of neonatal sepsis can be pointed to a lack of specific guidelines from the Ministry of Health on comprehensive cord care practices (Ministry of Health, 2016). The

WHO stipulates for use of chlorhexidine in regions with a neonatal mortality of more than 30 deaths per 1000 live births (WHO, 2013). Mothers are exposed to varying advice from health workers that could resort them to suboptimal cord care practices that contribute to the perpetuation of omphalitis which is a possible avenue for neonatal sepsis. Improper umbilical cord care is further compounded by a range of traditional practices, some of which promote the use of topical applications such as saliva that could heighten the risk of omphalitis (Kinanu et al., 2016; Karumbi et al., 2013). With paucity of information about proper cord care methods, lack of proper cord care is an alarming problem in low income communities in Kenya.

In Nairobi, Obimbo et al. (1999) showed that about 60% of postnatal mothers had deficient knowledge on cord hygiene, 44% exhibited poor cord practices, while 79% showed uncertainty in cord handling. Moreover, 50% of health workers' knowledge on postnatal cord care did not conform to international specifications. Patients who seek services from Kahawa Health Centre, and other health facilities in peri-urban Kenya, are predominantly of low socio-economic status with limited financial capacity to attend private hospitals. Due to understaffing in public facilities, postnatal education on good cord care may not be adequately provided. Mothers in these areas are hence likely to employ improper methods of cord care predisposing their neonates to sepsis. Neonatal sepsis could be a contributor to the high neonatal mortality at KHC which has been reported anecdotally. This study thus seeks to elucidate the importance of good cord care practices in the mitigation of neonatal sepsis in low-resource settings.

1.3 Justification

Despite the importance of proper cord care in the prevention of neonatal infection, there is a dearth of studies that demonstrate the association between umbilical cord hygiene and systemic infection especially in poor settings (Saleh et al., 2015; John et al., 2015; Goel et al., 2015); with a sizeable number of studies paying attention to other factors associated with neonatal sepsis (Mullany et al., 2007; John et al., 2015; Jabiri et al., 2016; Gebremedhin et al., 2016). This study, therefore, seeks to underscore the contributory role of inadequate umbilical cord hygiene in sepsis occurrence within the first month of life. Granted the absence of specific guidelines on comprehensive cord care practices in Kenya, it is anticipated that results from this study will show the link between cord care and neonatal sepsis development and hence, might inform decisions aimed at shaping and elaborating national guidelines on appropriate cord care practices as an essential primary prevention strategy. Review of published literature reveals a striking absence of studies that highlight umbilical care practices and their association with neonatal sepsis in the country. By emphasizing the importance of cord hygiene, it is anticipated that this will lead to a reduction in neonatal sepsis and mortality. This addresses the Sustainable Development Goals of achieving an under-five mortality of less than 25/1000 live births and neonatal mortality of as low as 12/1000 live births, by 2030 world-wide (United Nations, 2015).

1.4 Research Questions

The study strove to answer the following questions:

- 1) What are the umbilical cord care practices employed by mothers/care-givers attending Kahawa Health Centre?

- 2) Is umbilical cord hygiene associated with neonatal sepsis among neonates presenting at Kahawa Health Centre?
- 3) Is the umbilical cord hygiene-neonatal sepsis relationship confounded by neonatal and maternal factors at Kahawa Health Centre?
- 4) Does umbilical cord hygiene contribute significantly to the occurrence of neonatal sepsis?

1.5 Objectives

1.5.1 Broad Objective

The broad objective of this study was to evaluate the relationship between umbilical cord hygiene and neonatal sepsis among neonates presenting at Kahawa Health Centre.

1.5.2 Specific Objectives

Specifically, the objectives were:

- 1) To describe the cord care practices among mothers/care-givers attending Kahawa Health Centre.
- 2) To assess the association between umbilical cord hygiene and occurrence of neonatal sepsis among neonates presenting at Kahawa Health Centre.
- 3) To evaluate the effect of neonatal and maternal factors confounding the umbilical cord hygiene-neonatal sepsis relationship among neonates presenting at the Kahawa Health Centre.

4) To estimate the population attributable fraction for the umbilical cord hygiene-neonatal sepsis relationship.

1.6 Research hypotheses

Null hypotheses

H₀1: Umbilical cord hygiene is not significantly associated with occurrence of neonatal sepsis among neonates presenting at Kahawa Health Centre.

H₀2: Neonatal and maternal factors do not influence the umbilical cord hygiene-neonatal sepsis relationship among neonates presenting at the Kahawa Health Centre.

Alternate hypotheses

H_a1: Umbilical cord hygiene is significantly associated with occurrence of neonatal sepsis among neonates presenting at Kahawa Health Centre.

H_a2: Neonatal and maternal factors influence the umbilical cord hygiene-neonatal sepsis relationship among neonates presenting at the Kahawa Health Centre.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter attempts to outline the definitions of neonatal sepsis as well as its two main forms: Early onset neonatal sepsis (EONS) and late onset neonatal sepsis (LONS). Over and above the burden of neonatal sepsis, umbilical cord hygiene, neonatal and maternal risk factors of neonatal sepsis have also been included.

2.1.1 Definition of neonatal sepsis

There is no universally agreeable definition of sepsis. Thus, various definitions have been provided (Wynn et al., 2014; Vergnano et al., 2005; Shane et al., 2017; Jiang et al., 2016; Balk, 2014; Gomella et al., 2004). Formerly, diagnosis of sepsis was based on the clinician's acumen or in the event of cardiovascular depression (shock/hypotension) or a positive blood culture (Balk, 2000). This cardinal attempt was highly ambiguous.

An operational description of sepsis as a systemic inflammatory response to a proven insult was used widely but this lacked specificity and was overly sensitive (Balk, 2000). Due to its broad diagnostic spectrum, all patients with an inflammatory reaction with or without organ dysfunction were included. Considering this, it was renamed septic syndrome, based on the notion that by use of this definition, infected/septic patients could not be distinguished from the non-infected patients (Bone et al., 1989).

A systemic inflammatory response syndrome (SIRS) term was adopted purposively for the prompt identification of an infected patient. SIRS can be defined as a nonspecific inflammatory response to clinical injury, where any two of the following four criteria are

demonstrated: an abnormal white blood cell (WBC) count (increased or decreased for age or >10% immature/band neutrophils), abnormal core temperature (>38.5° or <36°C), tachycardia (heart rate >90 beats/min)/bradycardia, or tachypnea/mechanical ventilation (Bone et al., 1992). With the two being present at least one must be abnormal leucocyte count or temperature derangement (Goldstein et al., 2005). Several studies have employed SIRS as a prerequisite to diagnose neonatal sepsis (Goldstein et al., 2005; Balk, 2014). Rectal measurement for core temperature is considered the most accurate and reliable method (Smith, 2014), but neonatal infection complications could arise owing to the invasiveness of the method (Pestourie et al., 2014; van den Berg et al., 2000). Axillary temperature is therefore recommended as a safer non-invasive alternative (Smith et al., 2013). In one study, axillary and rectal temperature measurements were found to be statistically similar in neonates above 29 gestational weeks (Charafeddine et al., 2014). However, accurate core temperature in preterm and full-term neonates can be estimated by addition of 0.3°C and 0.4°C respectively (Lantz and Ottosson, 2015).

Gomella et al. (2004) have defined neonatal sepsis as an invasion of the circulatory system by pathogenic bacteria, fungi or viruses characterized by hemodynamic changes such as abnormal leucocyte count, aberrant temperature or even tachycardia and other clinical symptoms, occurring in the first month of life. Alongside the SIRS definition, Shane et al. (2017) also describe sepsis in terms of bio-physiological and clinical changes stemming from the aforementioned micro biomes, which have injurious consequences to the host. Nonetheless, SIRS' diagnostic criteria for sepsis is still very sensitive and inaccurate in predicting diagnosis, resulting in the preference for the clinical diagnostic criteria (Schroth and Blatt, 2017).

Clinical signs and symptoms of neonatal sepsis are comprehensively included in all body systems (Shah and Padbury, 2014; Gerdes, 2004; Shane et al., 2017). Clinically, neonatal sepsis is characterized by cardiopulmonary changes (presence of fever, cold extremities, respiratory distress), gastrointestinal disturbances (vomiting, abdominal distension, diarrhea), central nervous system symptoms (lethargy/irritability, excessive/high-pitched cry, bulging of anterior fontanelle), skin features (unexplained jaundice, umbilical discharge, poor peripheral perfusion, pallor, sclerema or rash), or metabolic changes (hypo/hyperglycemia, metabolic acidosis) (Verma et al., 2015; van Herk et al., 2016; Shane et al., 2017; WHO, 2013a). In an Indian tertiary referral pediatric unit, the main clinical features in septic infants were refusal to feed, hypothermia, respiratory distress and shock (Jajoo et al., 2015). On the basis of clinical symptoms, certain systemic infections of the newborn collectively represent neonatal sepsis, including meningitis, septicemia or severe pneumonia (Bang et al., 1999; WHO, 1995; Jajoo et al., 2015).

2.1.2 Early versus late onset neonatal sepsis

The two form categorization of neonatal sepsis is derived from its time- and age-dependent initial appearance. Early onset neonatal sepsis (EONS) are those that manifest within the first 72 hours of life and which stem mainly from a trans placental or ascending infection from the mother's genitourinary tract (Wynn et al., 2014; van Herk et al., 2016). It is associated with conditions and infections the mother may have had in late pregnancy and other maternal circumstantial birth factors such as prelabour rupture of membranes, chorioamnionitis and preterm labor. In these situations, translocation of organisms can occur through intact membranes or directly to the fetus when eventual rupture of the membranes occurs (Stronati and Borghesi, 2016; Myntti et al., 2017). When the pathogens

are aspirated by the fetus, they traverse blood vessel walls to the luminal blood with resultant systemic infection (Stronati and Borghesi, 2016). EONS often manifests as pneumonia or meningitis (Simonsen et al., 2014; Pawar et al., 2016).

Late onset neonatal sepsis (LONS) is seen from day 4-28, and ensues from the nosocomial and community environs postnatally and less often from maternal genitalia (Dong and Speer, 2015; van Herk et al., 2016). Occurrence of LONS is inversely proportionate to gestational age; it is preponderant in preterm than in term neonates (Tsai et al., 2014; Gentile et al., 2014). Nosocomial sepsis occurs when the intactness of the skin barrier is interfered with either by biomedical equipment, prolonged intubation (nasogastric tubes, endotracheal tubes), central venous catheters, exchange transfusion, chest tube drainage, use of total parenteral nutrition or other invasive procedures (Dong and Speer, 2015; Tran et al., 2015; Shane et al., 2017). LONS often manifests as umbilical cord redness, inflammation and infection (omphalitis) (Stronati and Borghesi, 2016).

2.2 Burden of neonatal sepsis

As of 2013, approximately 41.3% of the 6.3 million under-five deaths occurred during the neonatal period (Wang et al., 2014). These were attributable to prematurity, infectious processes and birth asphyxia (Lawn et al., 2008; Victora et al., 2015). Internationally, neonatal sepsis is the third leading cause of all deaths in the first month following parturition (UNICEF, 2014). Neonatal sepsis accounts for 15% of all early period (first 72 hours of life) neonatal deaths, and almost half (47.6%) of all neonatal deaths in the late neonatal period (more than 72 hours of life) (Oza et al., 2015). The prevalence of neonatal sepsis is approximately 16% in Sub-Saharan Africa (Ranjeva et al., 2018). In a study to

demonstrate causes of deaths in the neonatal age group in several developing countries, neonatal sepsis was leading at 33.1% followed by prematurity, asphyxia, congenital anomalies and other causes (Garces et al., 2017).

In a multicenter cohort study among inborn very low birth weight (<1500g) babies in Brazil, incidence of proven sepsis was 24% and that of clinical sepsis was 23% (de Souza Rugolo et al., 2014). Incidence of EONS was found to be 28% in a retrospective cohort study done in Indonesia (Hayun, 2015). Clinical sepsis was observed among 39% of home-delivered neonates in India (Jajoo et al., 2015). Still in India, septicaemia in the newborn was found to be 28.3% (Goel et al., 2015). In another cohort study in Taiwan, LONS was demonstrated in 14.2% of the neonatal intensive care unit (NICU) study participants, with an incident rate of 3.71 episodes per 1000 neonate-hospital days (Tsai et al., 2014).

The epidemiological burden of neonatal sepsis in the African setting has also been characterized. In a cross-sectional study in Zambia, prevalence of culture-proven sepsis was established at 33% (Kabwe et al., 2016). In rural Uganda, prevalence of neonatal sepsis was found to be 21.8% (John et al., 2015). In Kilifi, the prevalence of invasive bacteraemia was 8.1%, 13.5%, 12.1% and 12.8% in the 1st day of life, <7 days, 7-60 days, and under 60 days respectively (Berkley et al., 2005), at an overall rate of 5.46 cases per 1000 live births. In the same facility in the period between 2007-2009, a prospective study found an incidence of 11% of culture-proven sepsis among out-born neonates and 5% among in-born neonates (Talbert et al., 2010). After 48 hours of admission, paediatric inpatients in this referral center had a risk of sepsis of 5.9 per 1000 admissions which was 40 times higher than community acquired sepsis in this region (Aiken et al., 2011).

The humanistic burden that neonatal sepsis inflicts on the population is perceivable economically in terms of the high levels of morbidity and mortality, lengthened hospital-stay, increased medical costs and developmental challenges with/without repeated sepsis in the neonates' later life (Tsai et al., 2014; Aiken et al., 2011; Simonsen et al., 2014; de Souza Rugolo et al., 2014; Tiru et al., 2015). Compared to infants with no LONS, those neonates with clinical or proven sepsis experienced higher rates of mortality in a Brazilian study (de Souza Rugolo et al., 2014). In a government hospital in India, a case fatality rate of 14% was observed among out-born neonates with clinical sepsis (Jajoo et al., 2015). In Vietnam's largest neonatal unit, a high case fatality rate of 96% was recorded (Tran et al., 2015) and represented 22% of all neonatal deaths in this setting. In Taiwan, proportion of deaths explainable by sepsis was 23.1% (Tsai et al., 2014). In Kilifi, 33% of infant deaths were secondary to community acquired sepsis and in the same setting, there was a positive feedback loop of progressive stay-in-hospital and an increased risk of hospital-acquired bacteraemia (Aiken et al., 2011). Accelerated rate of deaths were observed following microbiological sepsis at a first level referral in Kilifi; 33.4% on admission day1 and 36.2% by day 60 (Berkley et al., 2005). Delay in initiation of sepsis treatment inflates mortality rate (Ekwochi et al., 2016). As of 2014 in Sub-Saharan Africa (SSA), a base estimate of approximately 9.93-16.40 billion dollars was incurred in the treatment of neonatal sepsis (Ranjeva et al., 2018). It has been reported that outpatient cost following post-hospitalization for neonatal infection could be more than double the inpatient charges in the long run (Tiru et al., 2015). Similarly, the economic impact of neonatal sepsis was quantified in terms of loss of about 5.29-8.73 million disability-adjusted life years (DALYs) in SSA (Ranjeva et al., 2018).

Long-term neuro-developmental consequences following definite bacteraemia and its accompanying inflammation in preterm individuals have been documented (Rand et al., 2016). Late-onset bacteraemia was associated with mental/intellectual impairment at 10 years (Bright et al., 2017). Other studies have indicated the possibility of life-long post-septic syndrome and sequelae in the child such as post-infectious hydrocephalus or cerebral palsy, as well as lifetime implications on other family member's physical and psychological well-being (Biggar and Dahlem, 2017; Ranjeva et al., 2018).

2.3 Umbilical cord hygiene status

A hygienic umbilical cord is one which is dry and clean - without redness, wetness or a purulence at the stump and base (Sanitation, 2010). In conjunction, unhygienic cord status could be assessed in certain late signs in the infant such as pus discharge, yellowness of eyes or soles of feet and extremes of temperature (Bugaje et al., 2010). Cleanliness of the cord is achievable by aseptic cord handling and treatment from the time of delivery to the postnatal environ (Whitmore, 2010; Saleh et al., 2015; Sanitation, 2010; Bugaje et al., 2010).

The World Health Organization (WHO) recommends for the use of Chlorhexidine Digluconate 7.1% (delivering 4% chlorhexidine) in home delivered infants or infants born in high mortality regions, and dry cord care for health facility-delivered infants or those born in low mortality regions. The WHO also stipulates that bathing should be restricted until after the first day or at least after six hours in cultural-strict settings (WHO, 2013). It is recommended that Essential Newborn Care (ENC) guidelines should include application of topical antiseptics such as chlorhexidine to reduce neonatal sepsis (Akter et al., 2016). In a community based randomized trial in Tanzania and in different systematic reviews, chlorhexidine was demonstrated to be protective (Imdad et al., 2013; Sinha et al., 2015;

Sazawal et al., 2016). In Kenya, national guidelines on perinatal care are not very clear on thorough cord handling (Ministry of Health, 2016).

According to the Kenya Demographic Health Survey (2014), NMR is 24% higher (26 versus 21 deaths per live births) in urban areas than in rural areas (KDHS, 2014). This is linked directly to the rural-urban migration leading to an alarming increase in informal settlements. These inter-city slums are characterized by overcrowding, unsafe water, appalling living and health conditions and consequently, an unclean environment with marked susceptibility to infections. Consequently, umbilical cord hygiene is compromised which has a significant implication in the occurrence of septicemia in the newborn (Saleh JA, 2015).

Umbilical cord infections have been identified as a major contributor in the predisposition to neonatal sepsis (Coffey and Brown, 2017; Blencowe et al., 2011; Mir et al., 2011; Goel et al., 2015). Neonatal omphalitis is a leading cause of neonatal sepsis in the developing world (Stewart et al., 2016; Jayaswal et al., 2016). Unhygienic cord care practices in third-world countries are common and promote the occurrence of cord infections ensuing into systemic sepsis (Ambe et al., 2008; Bugaje et al., 2010; Goel et al., 2015). Though data are scarce on the epidemiology of omphalitis, several studies have attempted to quantify the frequency of umbilical cord infection (Sawardekar, 2004; Mir et al., 2011; Madan et al., 2016; Kinanu et al., 2016). For instance, the incidence of neonatal omphalitis in a sub-set of low-income communities in Pakistan was estimated at 217/1000 live births contributing to about 9% of neonatal sepsis (Mir et al., 2011). In a referral hospital in Oman, of all admissions, 6.7% were due to omphalitis (Sawardekar, 2004). In this setting, unplanned

home deliveries had an incidence of 6.8% of omphalitis most probably arising from non-sterility of the babies' surroundings.

Cord care practices are variable and often culture related. In Bangladesh, a study focusing on home-births, found that the odds of neonatal mortality were 3.81 times significantly higher in those who left the cord dry compared to those who applied topical antiseptics (Akter et al., 2016). Historically, Nepalese women performed ritualistic cutting of the cord with unsterile knife/blade/sickle followed by application of antiseptic/ghee/toothpaste/ash/nothing (Sharma et al., 2016). These high-risk practices were adjudged as a plausible explanation of the high rates of tetanus, sepsis and neonatal mortality registered in Nepal. Similarly, traditional birth attendants (TBAs), community health workers (CHWs) and traditional healers were interviewed and admitted to use of harmful traditional applications such as crushed charcoal, burned cotton/nutmeg, ash, leaves recipes, palm oil or animal excrement, for reasons cultural/spiritual. These community stakeholders nevertheless recognized the need to adopt new cord care practices such as topical chlorhexidine to curb newborn sepsis which was perceived as pus on cord, delay in cord drying, refusal to feed or fever (Walsh et al., 2015).

Interviewees in Sierra Leone revealed aspects of unclean cord care such as use of pounded cassava on the umbilical cord, about 80% did not delay bathing, and approximately 63% used unclean instruments to cut the cord (Sharkey et al., 2017). Further, in Uganda, it was noted that the TBAs advised mothers to apply remedies that increased umbilical cord infection (John et al., 2015). About 45.1% of neonates with neonatal tetanus in Kilifi had hyperaemic cord stumps (Ibinda et al., 2015) and was higher in home births. In Pumwani,

the prevalence of omphalitis was as high as 37.6% (30.48% to 44.72%) (Kinanu et al., 2016). Symptoms such as foul umbilical discharge, redness and umbilical swelling indicate infection of the umbilical cord (omphalitis) (Jayaswal et al., 2016).

Mother's knowledge on cord hygiene directly imparts on newborn care (Islam et al., 2018; Obimbo et al., 1999). In a rural village in India, out of 60 postnatal mothers, 70% had meagre knowledge on cord-care and physical hygiene whereas 63.3% had dissatisfactory practice (Missiriya, 2016). This was accredited to constraints in time, remoteness of residence from point of care and lack of a care-taker. Variation in knowledge has been reported; in contemporary communal areas in Nigeria, mothers were well versed on the importance of good cord care. These mothers had good cord care practices: majority used cord clamps, washed with soap and water prior to handling the cord, cleaned with methylated spirit thrice per day, applied nothing following cord cleaning and had good technique involving cleaning the base before the stump of the cord (Afolaranmi et al., 2018). In this sub-region of West Africa, residing in rural areas and within health-center deliveries were significant predictors of good cord care. This is because, unlike health professionals, the attendants assisting in home deliveries are likely to engage in socio-cultural cord practices such as cutting with non-sterile blade or thread and traditional substance application such as cow dung (Jayaswal et al., 2016; Jajoo et al., 2015). Furthermore, a study conducted in Pumwani Maternity Hospital identified modifiable factors contributing to umbilical cord infection to include mother's level of education, source of water and primiparous mother, factors which could be directly/indirectly related to unhygienic practices of cord care (Kinanu et al., 2015).

2.4 Other risk factors for neonatal sepsis

Various neonatal characteristics and maternal factors have been linked to neonatal sepsis (Jabiri et al., 2016; Gebremedhin et al., 2016).

2.4.1 Neonatal risk factors

There are neonatal factors that have been found to be strongly associated with neonatal sepsis development such as low APGAR score, prematurity, low birth weight (LBW), birth asphyxia, congenital anomalies, amniotic fluid problems (meconium-staining), invasive procedures (resuscitation, intubation at birth), multiple gestation and sex (Gomella et al., 2004; Shane et al., 2017). For instance, lower APGAR scores are important risk factors for neonatal sepsis (NS) (de Souza Rugolo et al., 2014). The risk of EONS was approximately 14 times in neonates whose APGAR score was <7 at one minute (Hayun, 2015). In Bangladesh, neonates with an APGAR score <7 at 5 minutes had about 3 times odds of neonatal sepsis (Hasan and Mahmood, 2011). In Indonesia, the risk of EONS was 14 times higher in neonates with an APGAR score of <7 at one minute (Hayun, 2015).

Resuscitation at birth has been designated as an independent factor for sepsis in neonates (de Souza Rugolo et al., 2014). In this group, those who did not cry at birth and had to be resuscitated had three times higher odds of occurrence of neonatal sepsis (Hasan and Mahmood, 2011). Further, prematurity has been established as a prominent predictor of neonatal sepsis (Simonsen et al., 2014; Tsai et al., 2014; Tran et al., 2015; Camacho-Gonzalez et al., 2013; de Souza Rugolo et al., 2014; Bright et al., 2017; Verma et al., 2015; Kumar et al., 2016; John et al., 2015; Jajoo et al., 2015). A study conducted in Bangladesh and Indonesia showed that neonates born at <37 gestational weeks were about 3 times and 13 times respectively, more likely to develop neonatal sepsis than those with >37

gestational weeks (Hasan and Mahmood, 2011; Hayun, 2015). This might be explained by the increased susceptibility to invasive microbes owing to low antibody level/immunodeficiency as well as a dysfunctional immunological response to microbes (Collins et al., 2018; Wynn et al., 2015; Gentile et al., 2014).

To a greater extent, low birth weight (LBW) is a known marker for serious infection (Alcock et al., 2017; Camacho-Gonzalez et al., 2013; de Souza Rugolo et al., 2014; Verma et al., 2015; Hayun, 2015; Tran et al., 2015). A study conducted in India on neonates in the Neonatal Intensive Care Unit (NICU) showed that birth weight less than 2.5 kg had a significantly higher proportion (89.3%) of culture positive sepsis than those born with >2.5kg (Kumar et al., 2016). Another 68% of all sepsis admissions in another NICU in India occurred among the low birth weight neonates (Jajoo et al., 2015). In Taiwan, 50% of all LONS seen during the cohort study was observed in infants with less than 1500g (very low birth weight) (Tsai et al., 2014).

Equally, sex has been flagged to have an impact on neonatal sepsis (NS) incidence (Kung et al., 2016; Wynn et al., 2015). In India, males were 1.87 times more likely to develop NS than their female counterparts (Verma et al., 2015). A possible explanation could be that females have two X chromosomes on which seat immune-protective gamma globulin synthesizers that provide a more adept innate immunity (Muenchhoff and Goulder, 2014).

A Brazilian study among inborn low birth weight babies reported parenteral nutrition (PN) as a significant independent factor for blood stream infections (de Souza Rugolo et al., 2014). In a NICU in Taiwan, (Kung et al., 2016) respondents who received parenteral nutrition had six times higher odds of NS than those who did not and this association was

found to be an independent and significant characteristic. This could possibly be explained by the trauma to the non-fully developed neonatal intestinal epithelial barrier inflicted by PN with subsequent intravascular shift of gut-derived micro biomes (Alcock et al., 2017; Demehri et al., 2015). Another plausible explanation could be contamination of the catheter used as a portal of entry for the PN leading to direct bloodstream contamination (Garland et al., 2008). Other invasive procedures leading to damage to gut or blood vessel damage and microbiological sepsis involve placement of endotracheal/nasogastric tubes/central venous catheters, exchange transfusions or chest drainage procedures (Dong and Speer, 2015; de Souza Rugolo et al., 2014; Tran et al., 2015; Shane and Stoll, 2014; Medeiros et al., 2016; Kung et al., 2016).

2.4.2 Maternal risk factors

These include socio-demographic, birth circumstances factors, antenatal history and postnatal factors.

2.4.2.1 Socio-demographic factors

Various maternal demographic and socio-economic factors could influence strongly the possibility of neonatal sepsis in their infant including age of mother, parity and education level. Neonates whose mothers were aged less than 20 years, primiparous and from a poor background were associated with higher likelihood of neonatal sepsis (de Souza Rugolo et al., 2014; Hasan and Mahmood, 2011). Infants whose mothers' education did not go beyond high school level were at a higher risk of suspected or definite septicemia (Bright et al., 2017). Findings on parity were however contrasted in a Zambian study whereby

higher odds of NS were found among neonates in NICU whose mothers had increased parity (Kabwe et al., 2016).

2.4.2.2 Birth circumstantial factors

These include prelabour/prolonged rupture of membranes (>18 hours), place of delivery, type of delivery, type of health provider and maternal peri-partum fever (>38.5°, urinary tract infection or chorioamnionitis).

With roughly six times higher odds of neonatal sepsis in infants whose mothers had an intrapartum fever of >38.5°C compared to those without fever, maternal intrapartum fever was found to be a significant predictor for neonatal sepsis (Hasan and Mahmood, 2011; Verma et al., 2015). In Eastern Uganda, blood culture showed sepsis occurred at 1.65 higher odds (OR=1.65; 95% CI: 0.63; 4.32) in those delivered by traditional midwives due to exposure to unclean environmental conditions (John et al., 2015).

Those with foul smelling liquor due to prolonged rupture of membranes (>24 hours) equally had approximately six fold greater chances of observing neonatal sepsis in their neonates. Higher incidence of chorioamnionitis among mothers of neonates with sepsis has been reinforced in other studies as well (de Souza Rugolo et al., 2014; Verma et al., 2015; Chan et al., 2015). Additionally, unclean and frequent (three times or more) vaginal examination is a common risk factor for neonatal sepsis occurrence (Verma et al., 2015).

In Ethiopia, deliveries that occurred in a health-facility setting were found to contribute significantly to the incidence of neonatal sepsis. The risk of NS for neonates born at health centers was 4.2 more likely than those born at home. This might be explained by ignorance

on maternal danger signs such as prolonged labor and delay in care-seeking witnessed by mothers especially in low income countries (LIC) before eventually reporting to said health facilities (Kung et al., 2016). Instrumental/caesarian section deliveries were related to higher proportions of NS than vaginal deliveries (Woldu et al., 2014).

2.4.2.3 Antenatal history

These include number of antenatal clinic (ANC) visits, screening for infections, maternal dysuria, health education, tetanus toxoid immunization, pregnancy-related infection and poor maternal nutrition. Women who did not receive, or had irregular antenatal checkups and those not immunized or treated for bacterial infection had greater chances of neonatal sepsis in their neonates (Hasan and Mahmood, 2011; John et al., 2015). In Ethiopia, neonates whose mothers had concurrent urinary tract infections (Imdad et al.) were 2.9 times more at risk of developing NS (Woldu et al., 2014). Lack of and inadequate advice on aspects such as need for care-seeking, recognition of danger signs in pregnancy, post-partum and in the newborn had an overall influence on neonatal sepsis (John et al., 2015; Islam et al., 2018).

2.4.2.4 Post-partum history

Though there is no published data on post-partum risk factors for neonatal sepsis, anecdotal evidence from hospital settings shows the mother's state of mental and physical health could impact on level of care offered to the neonate leading to neonatal sepsis. Postnatal factors comprise post-delivery complications and illnesses such as postpartum depression and poor nutritional status that could impair the mother's physical, mental and emotional functional well-being leading to possible lowered standard of care to the

newborn. In Zimbabwe, 43% of infants' septicaemia would have been averted had mothers initiated breastfeeding within the first hour after giving birth (Mugadza et al., 2017). In addition, poor breast-feeding postnatally has been linked to higher chances of neonatal sepsis (John et al., 2015; Islam et al., 2018). This could be inferable to the high levels of protective immunoglobulins (primarily IgA) and other anti-inflammatory factors found in human colostrum (Palmeira and Carneiro-Sampaio, 2016).

2.5 Theoretical and conceptual frameworks

2.5.1 Theoretical framework

Betty Newman's System Model (Neuman, 1996) is the theoretical model adopted for this study. The model views the client as a system. Within this system are five sub-systems: physical/physiological, psychological, socio-cultural, developmental and spiritual. The client's health status (client wellness) is a function of their energy reserves where at optimal health, there is maximum energy, and at the other extreme is death which represents total depletion of energy (entropy). To achieve stability and optimal cellular and motor function, energy levels are therefore constantly being monitored by the client's Lines of Defence (LOD) and resistance. Depletion of the energy state arises when environmental stressors interact with the client with resultant breakdown of the LOD. These stressors are either internal (intrapersonal) or external (interpersonal and extra-personal). The created environment is client patterned with the potential to alter the client's stability and hence culminate to illness development (Neuman, 1996).

In this study, the neonate is the open system. The neonatal LOD such as the skin, immunoglobulins and mucus membranes, defend the neonate from external and internal

stressors that the client faces. The internal stressors encompass the neonatal risk factors which include age, sex, gestation, APGAR score, invasive medical procedure, meconium aspiration and type of feed. The external stressors are the environmental factors (that is, umbilical hygiene profile) and maternal characteristics (including socio-demographic, antenatal, intrapartum and post-partum profiles). Newman recognizes that the environmental stressors are an integral part of the system when addressing the health of an individual. In this study, the focus is on umbilical cord hygiene which comprises aspects regarding cord-handling, napkin folding method, rooming-in, bathing method and substance application. These stressors could act individually or interact in a web of causation to attack the neonate's LOD, bringing about energy depletion and subsequent disease occurrence (neonatal sepsis).

Newman states that intervention modalities to prevent infection can be introduced at the primary (when the stressor is suspected or identified), secondary (when symptoms occur and treatment instituted) and tertiary (maintenance after active treatment) levels (Neuman, 1996). In this study, at the primary level, the main focus is adherence to good cord hygiene to prevent neonatal sepsis occurrence. Secondary prevention, once neonatal sepsis occurs, is by prompt treatment with antibiotics. Neurological developmental and other sequelae resulting from neonatal sepsis are addressed by tertiary prevention measures involving rehabilitation and stabilization of the client.

2.5.2 Conceptual Framework

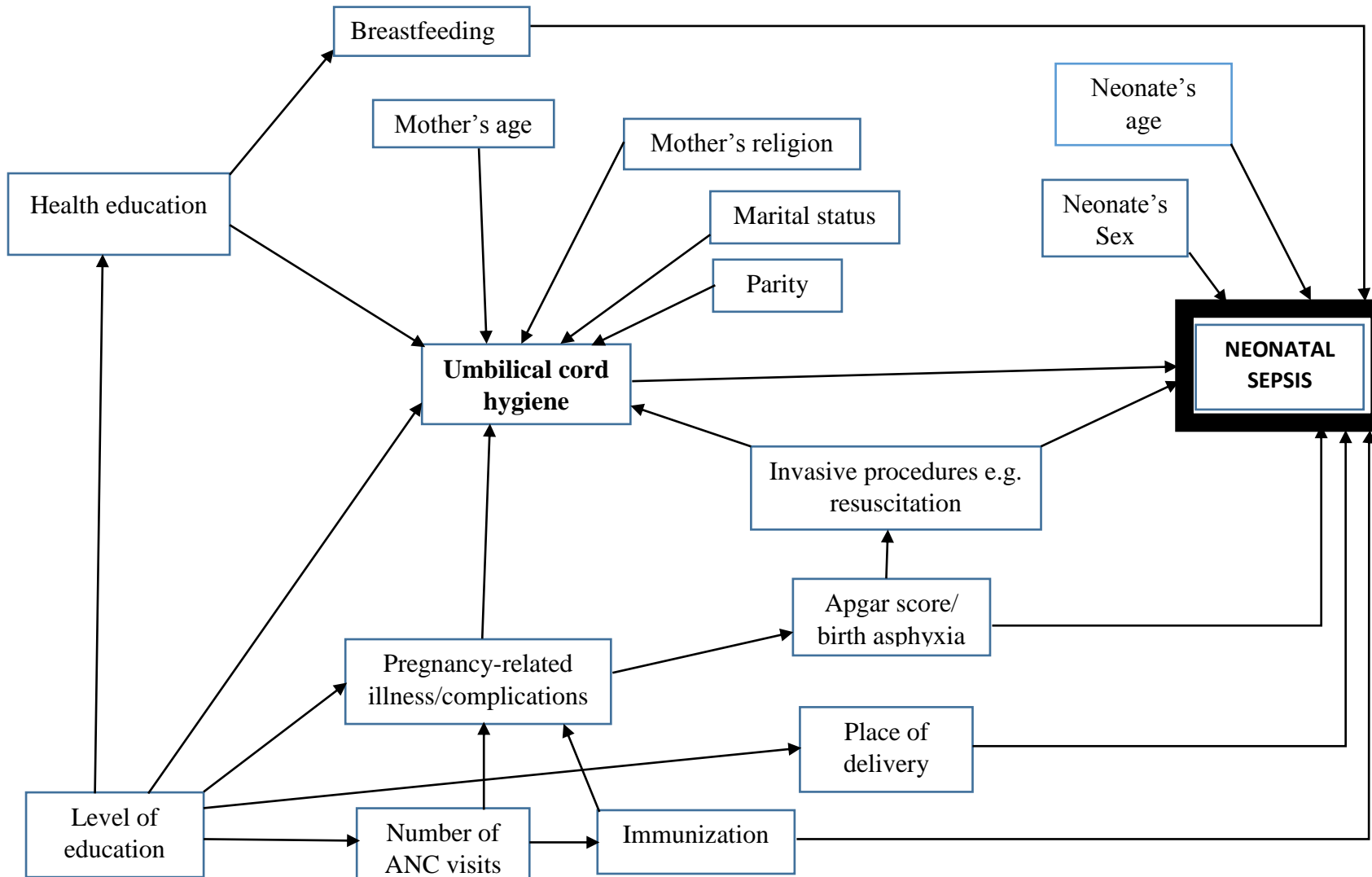


Figure 1: Causal diagram of umbilical cord hygiene and other factors thought to influence on neonatal sepsis occurrence among neonates at Kahawa Health Centre, Kenya.

CHAPTER 3: METHODOLOGY

3.0 Introduction

3.1 Study area

The study was conducted at Kahawa Health Centre (KHC). This is a level three local authority governmental facility in the northern part of Nairobi County, bordering Kiambu County. Its jurisdiction is in the Kahawa County Assembly Ward, Roysambu constituency, Ruaraka location in Kasarani division and in Ruaraka sub-county. The estimated catchment population for this health centre is about 52,193 persons and includes the adjacent peri-urban/inter-city localities of Kongo estate, Kahawa Soweto, Kamae, Kiwanja, Kamiti, Kahawa North, Kahawa South, Kiamumbi, Kiangiciri, Maziwa, Kamuthi, Saa Mbaya, Githurai 44, Zimmerman, Mirema, and even patients residing as far as Ruiru. Most of these areas are predominantly informal settlements with 99% of inhabitants being youths and young adults.

Services availed in the health centre include maternity, curative outpatient, provider initiated testing of human immunodeficiency virus (HIV), counselling and antiretroviral therapy, tuberculosis diagnostics, paediatric services and laboratory services. Paediatric services that are offered at the facility include well-baby clinic, immunization, prevention of mother-to-child transmission (PMTCT) of HIV including polymerase chain reaction (PCR) monitoring and evaluation, nutritional support and growth monitoring and seropositive management at the comprehensive care clinic (CCC). Among ailments treated in the paediatric department include respiratory tract infections, gastroenteritis, skin diseases, helminthiasis, eye infection and sepsis. The paediatric outpatient sees about 100 children per day. Anecdotal reports connote high neonatal mortality rates in this area.

Pediatric staff include two nurses and two outpatient clinical officers, one CCC clinical officer, two clerks, three laboratory technologists, one pharmacy technologist, one CCC peer educator (serving adult population as well), one HIV testing counselor (for family counseling) and two mentor mothers (sero-exposed expert/trained mothers who help newly-diagnosed mothers and who are paid by non-governmental organizations supporting the KHC).

Main economic activities of this population are subsistence farming, informal small-scale trading, domestic provision of services, unskilled manual and *Juakali* sector labourers. The income range is within poverty and below poverty levels (less than \$5/day); less than 2% of households can afford three meals in a day. Kahawa residential areas are a mixture of informal and formal settlements characterized by overcrowding. Only a few houses have constant supply of piped water, though characterized by frequent water shortages.

3.2 Study design

A facility-based unmatched case-control study design was employed to identify the determinants of neonatal sepsis. The rationale for the choice of the design relates to the rarity of neonatal sepsis within the facility's neonatal catchment population, thus rendering the health centre a ready source of case patients. Although population-based controls would conceivably be more preferable, potential differences in health-seeking behaviour between hospital cases and population-sourced controls suggest the need to recruit controls from the same facility as cases.

3.3 Study population

The study population comprised all neonates presenting to the Kahawa Health Centre (KHC) for pediatric services over a two month period of August to October 2018. Case and control patients were selected from this population based on a predefined set of eligibility criteria (set out in section 3.6).

3.4 Outcome definition

3.4.1 Case definition

A case patient was a 0-28 day-old neonate, a resident of the study area, presenting to KHC within the two-month study period with elevated axillary temperatures of $\geq 37.5^{\circ}\text{C}$ and any one of the following symptoms of infection: purulent discharge (from ear/eye/umbilicus), respiratory distress/fast breathing (more than 60 breathes/minute), severe abdominal distension, poor feeding (persistent vomiting (last three feeds)/refusal to feed/inability to suck/weak suck), altered mentation (lethargic/unconsciousness/convulsions) or skin changes (deep jaundice/ periumbilical redness) (WHO, 2013a).

3.4.2 Control definition

Controls were neonates similarly defined as cases (though devoid of sepsis symptoms), presenting to the well-baby clinic during the same two-month time period. They had to be residents of the study area.

3.5 Primary exposure definition

Umbilical cord hygiene was defined based on WHO's "five cleans" for postnatal care of the stump (WHO, 1998). These included: *handwashing* with soap and water before and after handling the cord, *folding the napkin* below the stump for adequate air exposure, *rooming-in*, *sponge-bathing*, and *application* of antimicrobial in endemic areas/replacing harmful traditional applications. These were included as close-ended questions in the questionnaire. Scoring was standardized such that those responses that were desirable as per WHO essential newborn care guidelines received a higher value (≥ 1). A lesser value (0) was coded for responses inconsistent with WHO essential newborn care guidelines (Afolaranmi et al., 2018; Amolo et al., 2017; Teklehaimanot et al., 2016). The aforementioned five variables' scores were amalgamated to generate a total score representing cord hygiene. In this study, those scoring below median were considered to have improper cord hygiene, whereas those with a score equal to or above the median were deemed to have proper cord hygiene.

3.6 Selection criteria of the participants

3.6.1 Inclusion criteria

- Primary visit neonates (incident cases).
- Infants whose guardians had consented to participation.

3.6.2 Exclusion

- Premature babies with gestational age less than 37 weeks.
- Babies who had a lower than 2000g birth weight.
- Neonates with congenital anomalies.

3.7 Sample size determination and sampling technique

3.7.1 Sample size determination

Sample size was determined as specified by Kelsey *et al* (1996) for case-control studies;

$$n_1 = \frac{(Z_\alpha + Z_\beta)^2 \bar{p} \bar{q} (r + 1)}{r (p_1 - p_2)^2}$$

$$n_2 = rn_1$$

and

$$p_1 = \frac{p_2 OR}{1 + p_2 (OR - 1)}$$

$$\bar{p} = \frac{p_1 + rp_2}{r + 1}$$

$$\bar{q} = 1 - \bar{p}$$

Whereby: n_1 = the number of neonatal sepsis cases; n_2 = the number of controls, the neonates without neonatal sepsis; p_1 = the proportion of cases with an unhygienic

umbilical cord; p_2 = proportion of controls with an unhygienic umbilical cord specified at 37.6% (Kinanu et al., 2016). Notably, $Z_{\alpha/2} = 1.96$ for the 2-tailed confidence level of 95%; $Z_{1-\beta} = -0.84$ for the desired statistical power of the study set at 80%; and $r=2$ as the specified ratio of controls to cases. The odds ratio (OR) for the umbilical cord hygiene-neonatal sepsis association was guesstimated at 2. With an anticipated 5% non-response rate (Gebremedhin et al., 2016), the required sample size was 312 mother/neonate pair: 104 cases and 208 controls.

3.7.2 Sampling strategy and recruitment

Considering that KHC registers around two to three neonatal sepsis cases per day, to attain the computed sample of 104 cases, all cases (who met the aforementioned eligibility criteria) presenting to the facility within the two-month study period were prospectively recruited. Recruitment of cases occurred at paediatric outpatient consultation rooms. Controls were systematically randomly sampled from the well-baby clinic of the facility frequency-matched by day of presentation. Therefore, because of the random sampling of controls, replacement of non-eligible participants was not possible.

3.8 Study variables

The dependent variable was neonatal sepsis. This was binary in nature: present or absent. The primary exposure (independent variable) was umbilical cord hygiene status which was also dichotomous: proper or improper cord hygiene. Other predictor variables included maternal and neonatal factors. Maternal factors consisted of socio-demographic factors (age of mother, level of education, marital status, parity and religion), the antenatal history of the mother (number of antenatal care (ANC) visits, history of receiving health

education, tetanus toxoid immunization, prenatal maternal bacterial infection, birth attendance, place of delivery and type of delivery), intrapartum factors (prelabour/prolonged rupture of membranes and number of vaginal examinations) and post-natal history factors (history of illness or pregnancy related complications such as postpartum depression, nutritional status or other comorbidities). Neonatal risk factors included low APGAR scores of <7 at 5 minutes (whose signs included scores of appearance, pulse, grimace, activity, and respiration), neonate's age, sex and invasive procedures (use of medically invasive instruments/resuscitation at birth). These variables were assessed as described in Table 1. A conceptual framework depicting the relationship between the independent and dependent variables is displayed in Fig. 1.

Table 1: Independent and dependent variables together with their measurements

Variables	Measurement of variable
Neonatal sepsis (nominal)	This was denoted in a binary form: Present or absent.
Age of mother (continuous)	This was expressed in years.
Mother's level of education (ordinal)	The level of education attained by the mother. It was classified into four levels: 1=No formal education, 2=Primary school, 3=High school education, 4=College/graduate education.
Marital status (nominal)	This was captured in three categories: Single, Married or Other (divorced, widowed and separated).
Mother's religion (nominal)	This was expressed as Protestant, Catholic, Orthodox or Muslim.
Place of delivery (nominal)	This was grouped into two levels: Health institution or home delivery.
Type of delivery (nominal)	Mothers' delivery mode was categorized into three classes: Cesarean section (CS), Spontaneous vaginal delivery (SVD) or Instrumental (forceps/vacuum).
Health education (nominal)	Mothers were ranked by whether they had antenatal education on cord care (1) or not (0).
Number of ANC visits (continuous)	The number of ANC visits made by the mother. This were captured as 1, 2, 3 or ≥ 4 .
Immunization (nominal)	Tetanus toxoid-containing vaccines are administered at recommended intervals in pregnant women. The rationale for this vaccine is to protect both the mother and her child from

	tetanus during delivery (Khan et al., 2015). Mothers were classified into two groups: 1=Immunized, 0=Not immunized.
Pregnancy-related complications (nominal)	This was inclusive of all labor-related complications such as, prelabour rupture of membranes (PROM), chorioamnionitis /meconium aspiration syndrome (MAS) and elevated maternal temperature. It also included any history of bacterial infection in pregnancy. Neonatal colonization could occur through vertical transmission from maternal infections (Chan et al., 2015). Common infectious diseases routinely screened antenatally include urinary tract infections, HIV, hepatitis B, syphilis, genital herpes, rubella, chlamydia, gonorrhoea and bacterial vaginosis. It was measured in two categories: 1=Present, 2=Not present.
Neonate's age (continuous)	This was captured in days.
APGAR score (discrete)	APGAR (Appearance, Pulse, Grimace, Activity, and Respiration) scores are assigned to the newborn at 1, 5 and 10 minutes from the moment of birth. The signs observed and scored include heart rate, respiration, muscle tone, reflex irritability and color (Dalili et al., 2015). The 5-minute score has been correlated with developmental vulnerability (Razaz et al., 2016). Actual values of APGAR score at five minutes were recorded from the Mother and Child Health Booklet Kenya.
Invasive procedures e.g. resuscitation, ventilator	Resuscitation at birth using biomedical techniques. This was retrieved from the Mother and Child Health Booklet Kenya. It

support (nominal)	was represented by two categories: 1=Yes, 0=No.
Number of children (discrete)	This was measured as parity (number of babies delivered).
Neonates' Sex (nominal)	The neonate's sex was captured as either male or female.
Cord exposure (ordinal)	Mothers were questioned if cord was kept exposed, that is, if napkin was folded below or above the stump. Two groups were generated: 0=Above the cord, 1=Below the cord.
Substance application (nominal)	This was scaled into four levels: 0=Saliva/Ash, 1=None (air-drying)/Water, 2=Silver sulphadiazine/Topical antibiotic, 3=Surgical spirit/Chlorhexidine. In regards to treatment efficacy in reduction of cord infection methylated spirit and 4% chlorhexidine are comparable (Oishi et al., 2004; Shwe et al., 2018). Effectiveness of chlorhexidine at cord healing is better than either silver sulphadiazine, topical antibiotic, povidone iodine or dry cord care (Imdad et al., 2013; Stewart et al., 2016). Further, there is no significant difference between silver sulphadiazine, povidone iodine or topical antibiotic such as bacitracin (Imdad et al., 2013). Equally, use of dry cord care was found to be commensurable to cleaning with water (Imdad et al., 2013). Application of saliva or other traditional substances has been shown to predispose to omphalitis as compared to air drying (Kinanu et al., 2016).
Hand washing (nominal)	With regards to handwashing, it was graded into two categories: 0=No, 1=Yes. Further the substance used to wash

	hands was categorized into three levels: 0=None, 1=Water only and 2=Water and soap.
Breastfeeding practice (nominal)	Mothers were asked if early breastfeeding was initiated and if exclusivity of breastfeeding was practiced. Mother-neonate pairs were in three sets: 0=Within one hour, 1=One-six hours, 2=More than six hours. For exclusivity, three groups were generated: 0=Breastmilk, 1=Formula, 2=Mixed, 3=Other.
Bathing method (nominal)	Neonates were bathed in either of two ways: Immersion bathing (0) or sponge bathing (1).
Umbilical cord hygiene	To delineate cord hygiene, a dichotomous variable was generated: 0=Proper hygiene, 1=Improper hygiene. This was based on the WHO's 'five cleans': Handwashing, diaper/napkin application method, bathing method, substance application and rooming-in (WHO, 1998). These were amalgamated and the median score used as the cut-off (Afolaranmi et al., 2018; Berhan and Gulema, 2018). Those scoring less than the median were considered as improper hygiene and those with a score equal or more than the median as proper hygiene.

3.9 Study procedures

Prior to commencing the data collection, the researcher trained two research assistants who were registered clinical officers with a diploma in clinical medicine and surgery. The research assistants were trained on obtaining the informed written consent from willing

mothers and on screening patients using the predetermined selection criteria. They were also trained on complete neonatal medical examination and the general approach of the questionnaire for thorough completion. During the two month study period, on receiving written consent from the primary care-givers, neonates visiting the Kahawa Health Centre for service provision were recruited until a sample size of 312 neonates was achieved. Cases and controls were recruited prospectively using the sampling strategy described in section 3.7.2. All neonates meeting the inclusion criteria were examined clinically in the pediatric outpatient or well-baby clinic consultation rooms for signs of neonatal sepsis by the principal investigator and trained research assistants. Appropriate treatment was then initiated. The researchers verbalized and clearly explained the consent form in Swahili or English to the primary care-giver. The neonate's respective consenting mother was interviewed by the research assistants using semi-structured questionnaires in a private room of the health centre for relevant socio-demographic, maternal and other neonatal profile data which were entered into predesigned data collection forms.

3.10 Data collection

To minimize deviations in data collection, research assistants (registered clinical officers) were trained by the principal researcher on the study material content, required study procedures, comprehensive newborn medical examination, screening and filling the pretested questionnaire properly, with an aim to meet study objectives and ensure validity. The principal investigator/trained researcher went to the health centre of interest and physically examined the eligible neonate study participants to elicit clinical features of neonatal sepsis. Neonates were recruited sequentially until the intended sample size was achieved. The researchers administered predesigned semi-structured questionnaires to consenting mothers/care-givers to capture the different factors affecting neonatal sepsis.

The questionnaires helped to highlight the different umbilical cord care practices, socio-demographic, maternal and neonatal indicators for neonatal sepsis in Kahawa Health Centre. All information was entered into predesigned data collection forms that contained socio-demographic, neonatal and maternal sections.

3.11 Pretesting of the study tool

Pretesting of the semi-structured questionnaire was done at the Lang'ata Health Centre's outpatient department prior to actual start of the study. Lang'ata Health Centre is a level three governmental facility located in Lang'ata constituency of Nairobi County. It is of a similar status as KHC with regards to the health services it avails and the base population it serves. Pretesting of the instrument was crucial in ensuring the research assistants were familiarized and understood the study tool, checking language clarity, preciseness of translation, as well as accurate data documentation. Pretesting the study tool ensured validity and reliability of study findings. The results generated from this pretest were, however, not part of the study's final analysis and interpretation.

3.12 Data processing and analysis

The questionnaires were checked for completeness and coded. Incomplete data was resolved on the same day of data collection, rather than after completion of the study period to ensure consistency and precision, then entered into EpiData spreadsheet and validated. The dataset was exported to Stata software, version 13 (Stata Corporation, College Station, Texas, USA) for cleaning and analysis. This involved making frequency tables and cross-tabulation for categorical variables to generate descriptive statistics. For continuous variables, data was summarized by means, medians and ranges.

Binary logistic regression was used to screen for association of each predictor on neonatal sepsis in the univariable analyses. The predictor variables with a likelihood ratio test (LRT) $P < 0.05$ were deemed as significant. These qualifying variables were further screened for an association with umbilical cord hygiene at 5% significance level. Those which further qualified were considered as potential confounders to the cord hygiene-neonatal sepsis relationship and therefore were included in the multivariable analysis to eliminate confounding at $P < 0.05$. Here, upon backward step-wise exclusion of variables in the multivariable model, those that resulted in more than 30% change in the effects of umbilical cord coefficient were interpreted as important confounders to the umbilical cord hygiene-neonatal sepsis association and retained in the full model (Dohoo et al., 2012). Ultimately, umbilical cord hygiene was analyzed for the population attributable fraction (PAF).

Population attributable fraction is a measure of effect that describes the disease burden in a population that could be prevented following risk factor elimination. For a valuable and valid PAF, three assumptions are eminent: (1) the risk factors of interest should have a clear causal relationship with the disease, (2) modifiability of the exposure or interventions to eliminate the exposure should lead to realization of unexposed disease state and, (3) there should be a practical cut-off point that is attainable for the category at elevated risk (Rockhill et al., 1998). In this setting, the PAF shows the proportion of neonatal sepsis that could be prevented by adhering to proper cord care.

The population attributable fraction (PAF) was calculated using the formula described in (Dohoo et al., 2012):

$$AF_p = pd \left(\frac{aOR-1}{aOR} \right)$$

Where: AF_p is the population attributable fraction

pd is the proportion of total cases in the population arising from the risk factor improper hygiene

aOR is the adjusted odds ratio for unhygienic group relative to the hygienic group

3.13 Dissemination plan

Data resulting from the analysis and interpretation of this study was disseminated through a publication in the F1000 Research publication platform (<https://doi.org/10.12688/f1000research.19544.1>). Further, a copy of this dissertation will be submitted to the office of the Nairobi City County's Director of Health Services for information on comprehensive cord care and to consider implementing the study's recommendations on revision of national guidelines on the same.

3.14 Minimisation of errors and biases

Personal data collection by the principal investigator (PI) and trained assistants improved data quality. To minimize errors, two independent data entry clerks were employed to enable double-entry of data into the EpiData data base. The principal researcher cross-checked the computerized data base against the questionnaires that had been administered. During data collection, the mother-child booklet were referenced to ascertain information

regarding some antenatal and perinatal information such as the number of antenatal visits, the neonate's date of birth, neonatal APGAR score and resuscitation history. Additionally, the research assistants were trained by the researcher on study procedures and proper questionnaire filling.

3.15 Ethical considerations

The research commenced after receiving written clearance from the Kenyatta National Hospital (KNH)-University of Nairobi (UoN) Ethics and Research Committee (appendix IV) and the Nairobi County Health Services (appendix V). Approval was sought from the Deans/Directors of Schools and Chairmen of the Department. Before questioning, written informed consent was also obtained with a signature from study participants (mother/index care-giver) (appendix I & II). They were informed all about the study aims, objectives, procedure and potential application, with assurance of anonymity of their bio data in the questionnaires by use of serial number identification. Participation was voluntary and withdrawal from participation was allowed without stigmatization in service delivery. No incentives were offered during recruitment. Those neonates who were found to be critically ill during examination received immediate medical attention, treatment promptly effected with antibiotics and thereafter referred for admission upon stabilization if there was need. The neonates' key measurements were taken as part of the clerkship during examination. Only upon stabilization were their mothers approached for informed consent for conduction of the interviews later. Disruption of services was minimized by having all cases and controls re-examined and interviewed in a separate private room only after they had received treatment or any other patient management as per the standard hospital procedures. The researchers demonstrated the recommended cord care methods and skills to the women identified as practicing poor cord hygiene in order to educate them on better

umbilical cord care. They also benefited by receiving information on the danger signs related to septic illness for early recognition and hence prompt initiation of treatment.

3.16 Limitations of the study

Recall of past exposures was likely to be more complete in respondents whose neonates were cases rather than controls introducing recall bias in the study with estimates away from unity. This was reduced by ascertaining information from the mother-child booklet. To a further extent, there was likely to be differential reporting between cases' and controls' caregivers related to cord care consequently biasing the effect estimates away from null; the cases' mothers could possibly have given false information regarding the exposure variables related to cord care. There was also a possibility of reverse causality where some mothers resorted to applying a substance to the cord as a way to treat an already septic neonate.

CHAPTER FOUR: RESULTS

4.0 Introduction

This chapter discusses in detail, the presentation and the interpretation of the findings obtained from the field. It presents the background information of the respondents and research findings based on the objectives of the study. Descriptive and inferential statistics have been used to analyse the data. This has mainly been done using logistic regression models.

4.1 Socio-demographic characteristics of study participants

A total of 312 participants (104 cases, 208 controls) were recruited into the study but those who consented to participate were 306, giving a 98.1% response rate. Of the 208 potential controls, three declined consent. Additionally, three others did not meet the eligibility criteria and were excluded, leaving 202 eligible controls that participated. A flow diagram illustrating the recruitment and enrollment process is shown in Figure 2.

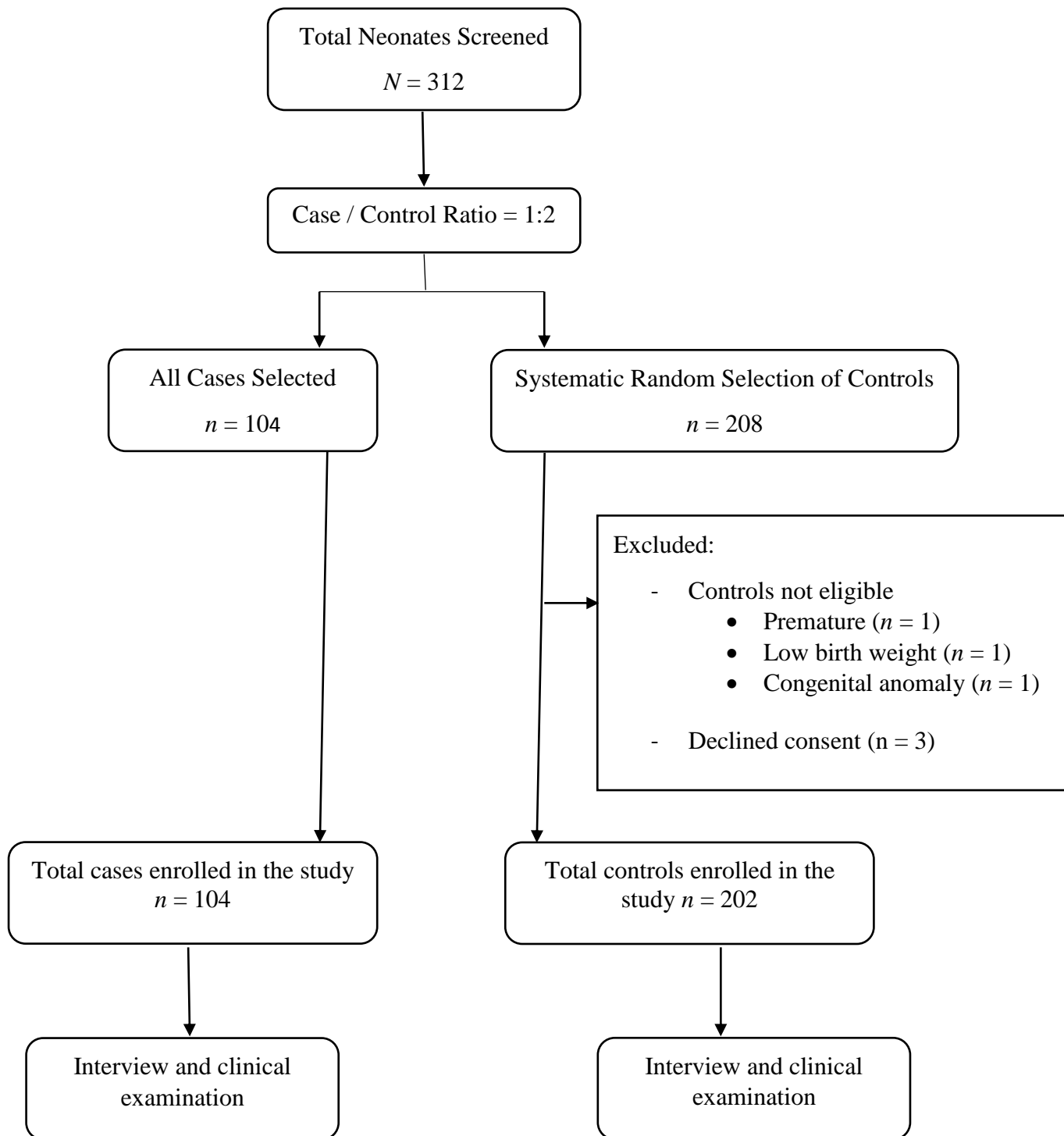


Figure 2: Study flow chart

Descriptive statistics for the demographic variables are indicated in Table 2. Notably, males comprised 55.8% ($n=58$) of cases and 47.0% ($n=95$) of controls. The mean neonatal

age was 19.7 days; the mean age of cases and controls being 16.5 days (Range: 5-28 days) and 21.3 days (Range: 3-28 days) respectively. Regarding marital status, 69.2% (n=72) of cases' mothers were married compared to 81.7% (n=165) of controls'. Distinctly, only 13.5% (n=14) of the cases' caregivers had received up to tertiary level of education compared to 22.3% (n=45) of the controls'.

Table 2: Demographic characteristics of the respondents, KHC, Kenya, 2018 (N=306)

VARIABLE	Values	Cases (n = 104) n (%)	Controls (n = 202) n (%)
Neonate's sex	Male	58 (55.77)	95 (47.03)
	Female	46 (44.23)	107 (52.97)
Neonate's age (days)	Mean	16.5	21.3
	Range	5 – 28	3 – 28
Maternal age (years)	Mean	26.16	27.12
	Range	17 - 44	17 – 44
Marital status	Single	26 (25.00)	29 (14.36)
	Married	72 (69.23)	165 (81.68)
	Separated	6 (5.77)	7 (3.47)
	Divorced	0 (0.00)	1 (0.50)
Education Level	No formal	3 (2.88)	2 (0.99)
	Primary	36 (34.62)	62 (30.69)
	Secondary	51 (49.04)	93 (46.04)
	College/ University	14 (13.46)	45 (22.28)
Religion	Protestant	69 (66.35)	119 (58.91)
	Catholic	23 (22.12)	61 (30.20)
	Orthodox	10 (9.62)	21 (10.40)
	Muslim	1 (0.96)	0 (0.00)
	Pagan	1 (0.96)	1 (0.50)

4.2 Cord care practices and umbilical cord hygiene among respondents

4.2.1 Cord care practices

A description of the participants' cord care practices is displayed in Table 3. In this population, majority of mothers reported use of chlorhexidine/surgical spirit (64%, $n=197$). Among cases, slightly over a third (35.6%, $n=37$) had surgical spirit/chlorhexidine applied as compared to about four-fifths (79.2%, $n=160$) of the controls. Of concern, saliva/ash was applied among 10.6% ($n=11$) of cases compared to 2.5% ($n=5$) of the controls (Figure 3).

In this study setting, about two thirds (65.7%, $n=201$) of mothers fastened their babies' diapers below the umbilical stump. Roughly 30% (29.8%, $n=31$) of the case respondents revealed that they folded the neonate's napkin below the cord in comparison to 84% (84.2%, $n=170$) of the control participants (Figure 4).

Almost four fifths (78.1%) of caregivers declared that they washed their hands when changing the napkins/diapers. This consisted of 54.8% ($n=57$) of the cases' and 90.1% ($n=182$) of the controls' mothers (Figure 5). Regarding the cleansing substance employed by those who reported handwashing, only 44.4 ($n=136$) used both water and soap. In particular, whereas 61.4% ($n=124$) of controls' mothers stated they used water and soap before cord handling, only 11.6% ($n=12$) of cases' mothers did the same (Figure 6).

The practice of rooming-in was followed by approximately all (99.4%, $n=304$) of the participants. Amongst these were 98.1% ($n=102$) of the cases and all the controls (Figure

7). Sponge-bathing was the bathing practice recorded by most (64.4%, n=197) of the participants in the present study. However, only 28.9% (n=30) of the cases were sponge-bathed (Figure 8).

Table 3: Cord care practices among mothers/primary care-givers, KHC, Kenya, 2018 (N=306)

VARIABLE	Values	All mothers (n=306) n (%)	Cases (n=104) n (%)	Controls (n=202) n (%)
Substance application	Surgical spirit/ Chlorhexidine	197 (64.38)	37 (35.58)	160 (79.21)
	Topical antibiotic/ Silver sulphadiazine	8 (2.61)	2 (1.92)	6 (2.97)
	None/ Water	85 (27.78)	54 (51.92)	31 (15.35)
	Saliva/ Ash	16 (5.23)	11 (10.58)	5 (2.48)
Cord exposure	Below cord	201 (65.69)	31 (29.81)	170 (84.16)
	Above cord	105 (34.31)	73 (70.19)	32 (15.84)
Handwashing	Yes	239 (78.10)	57 (54.81)	182 (90.10)
	No	67 (21.90)	47 (45.19)	20 (9.90)
Washing substance	Water and soap	136 (44.44)	12 (11.54)	124 (61.39)
	Water only	103 (33.66)	45 (43.27)	58 (28.71)
	None	67 (21.90)	47 (45.19)	20 (9.90)
Rooming-in	Yes	304 (99.35)	102 (98.08)	202 (100.00)
	No	2 (0.65)	2 (1.92)	0 (0.00)
Bathing method	Sponge-bathing	197 (64.38)	30 (28.85)	167 (82.67)
	Immersion in water	109 (35.62)	74 (71.15)	35 (17.33)

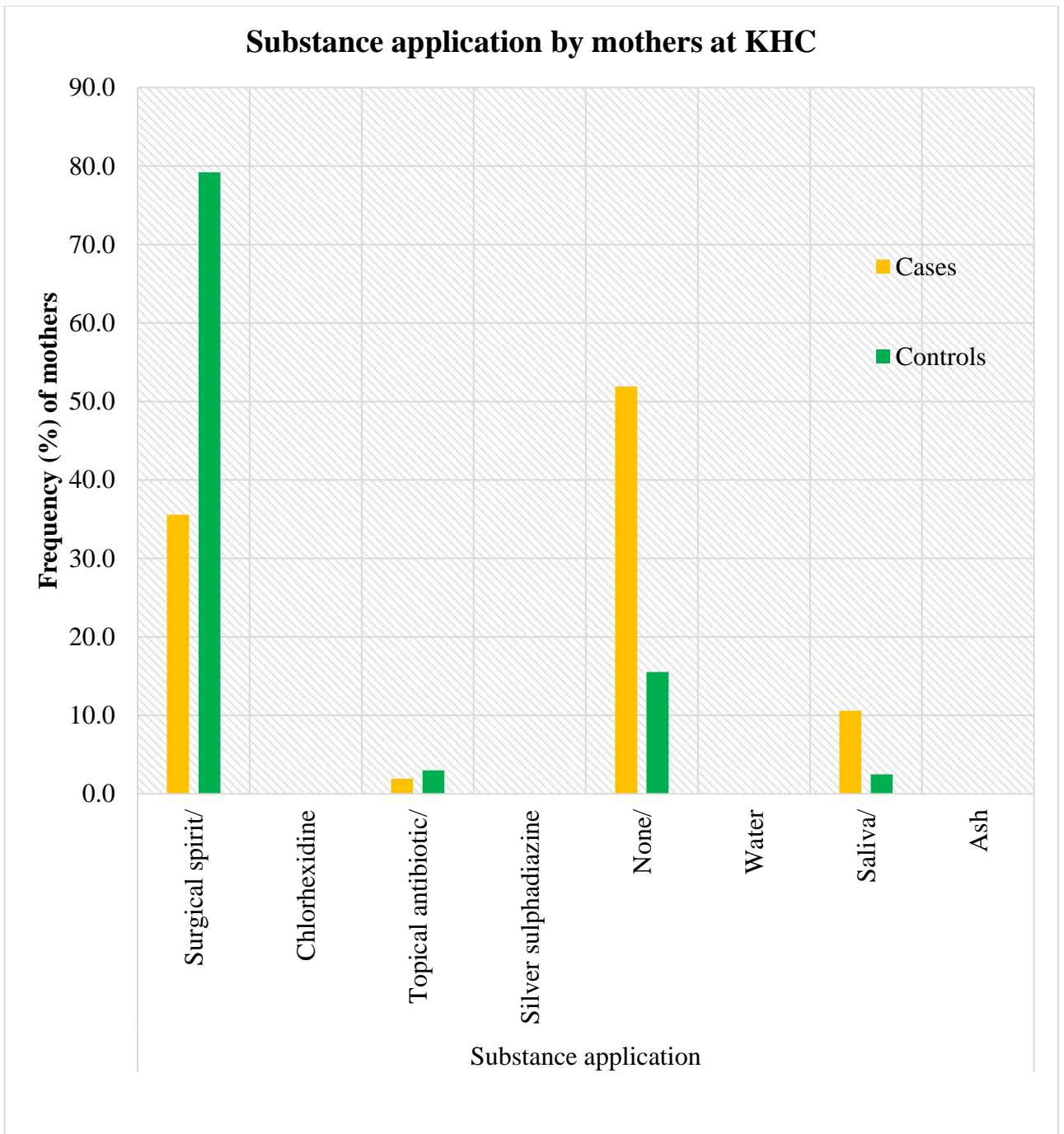


Figure 3. Substance applications used by mothers/primary care-givers, KHC, Kenya, 2018 (n=306)

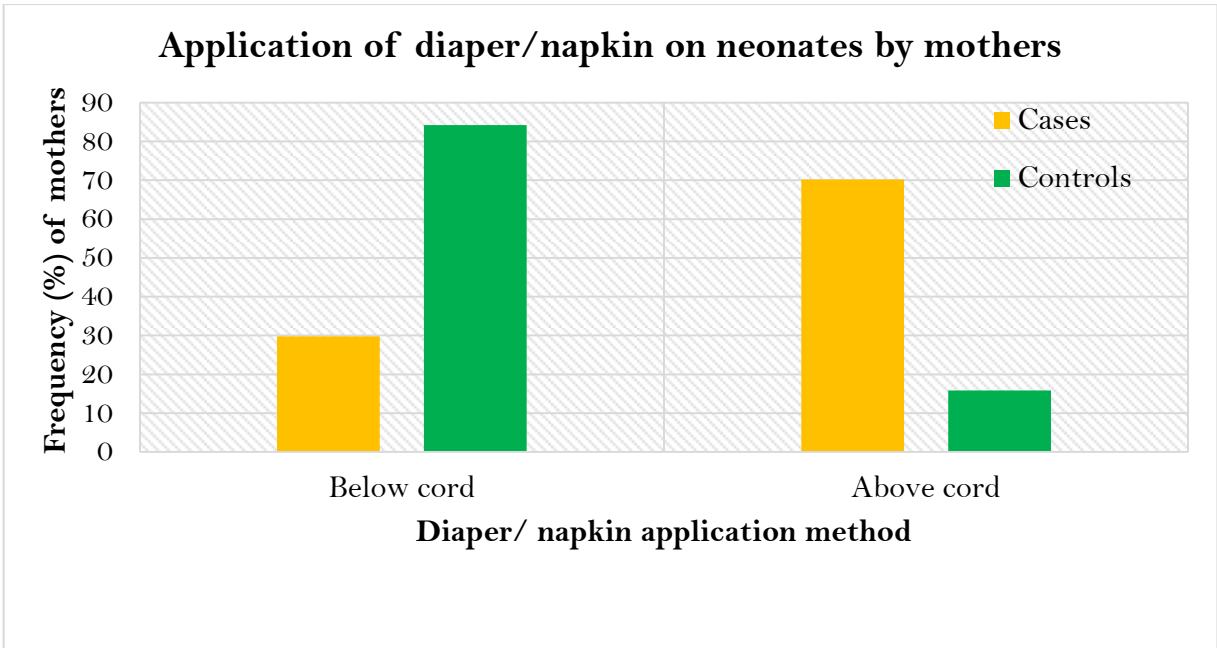


Figure 4. Exposure of the neonate’s cord among mothers/primary care-givers, KHC, Kenya, 2018 (n=306)



Figure 5. Handwashing practice by mothers/primary care-givers, KHC, Kenya, 2018 (n=306)

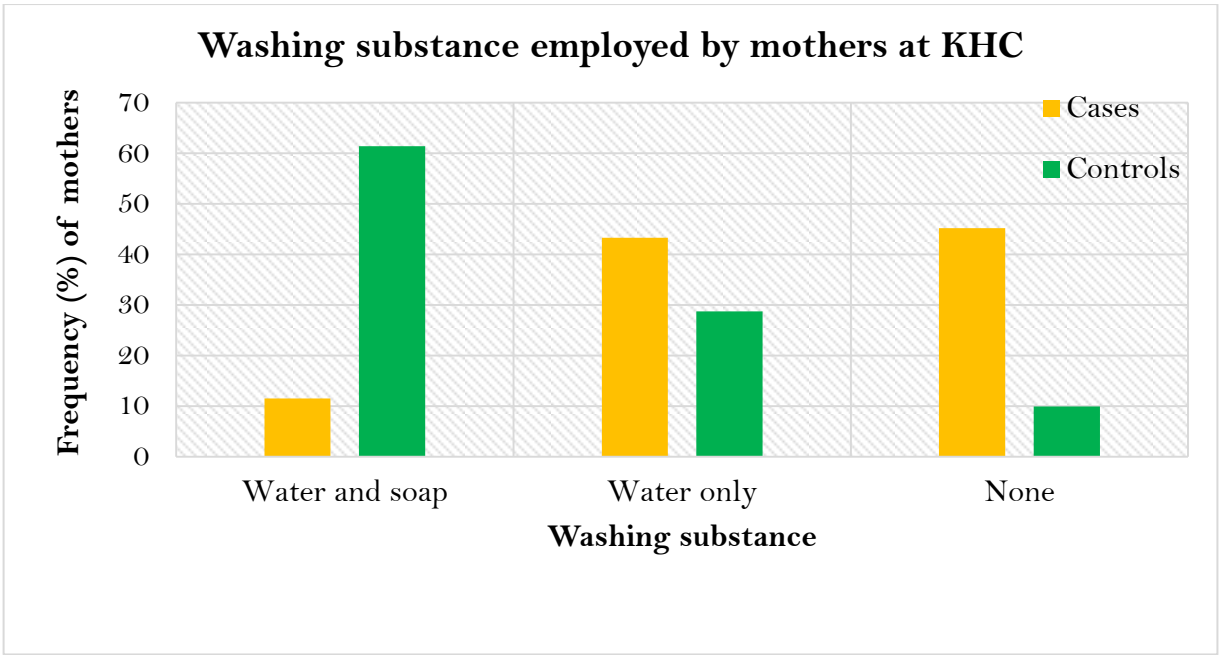


Figure 6. Handwashing substances used by mothers/primary care-givers, KHC, Kenya, 2018 (n=306)

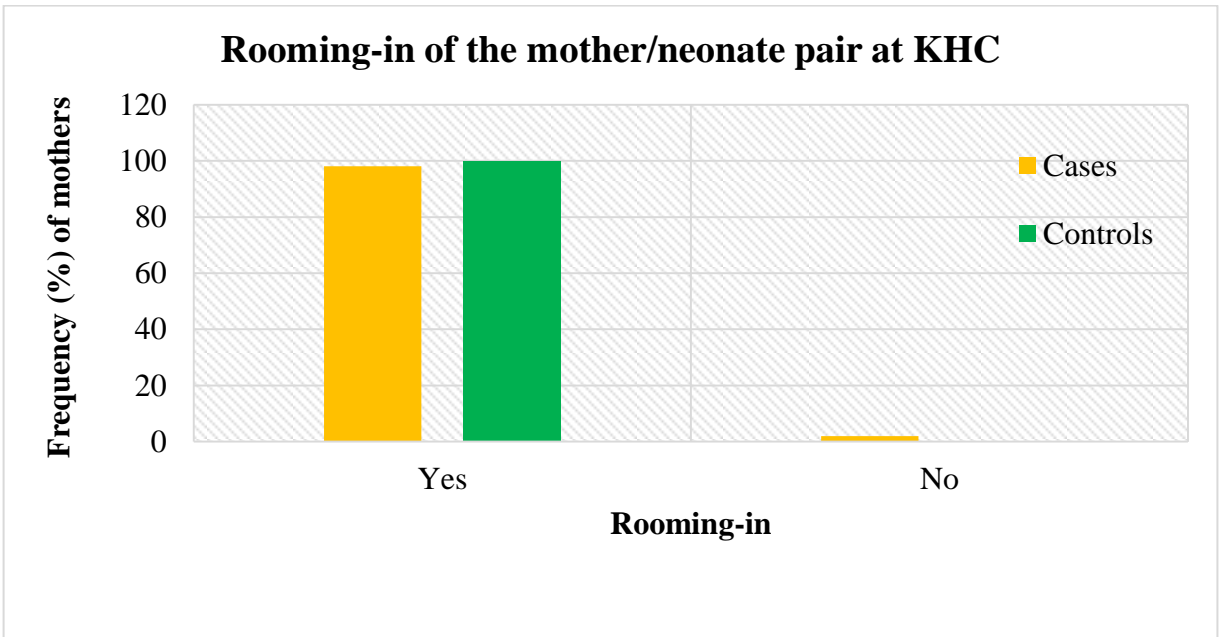


Figure 7. Rooming-in of the mother/neonate pair at KHC, Kenya, 2018 (n=306)

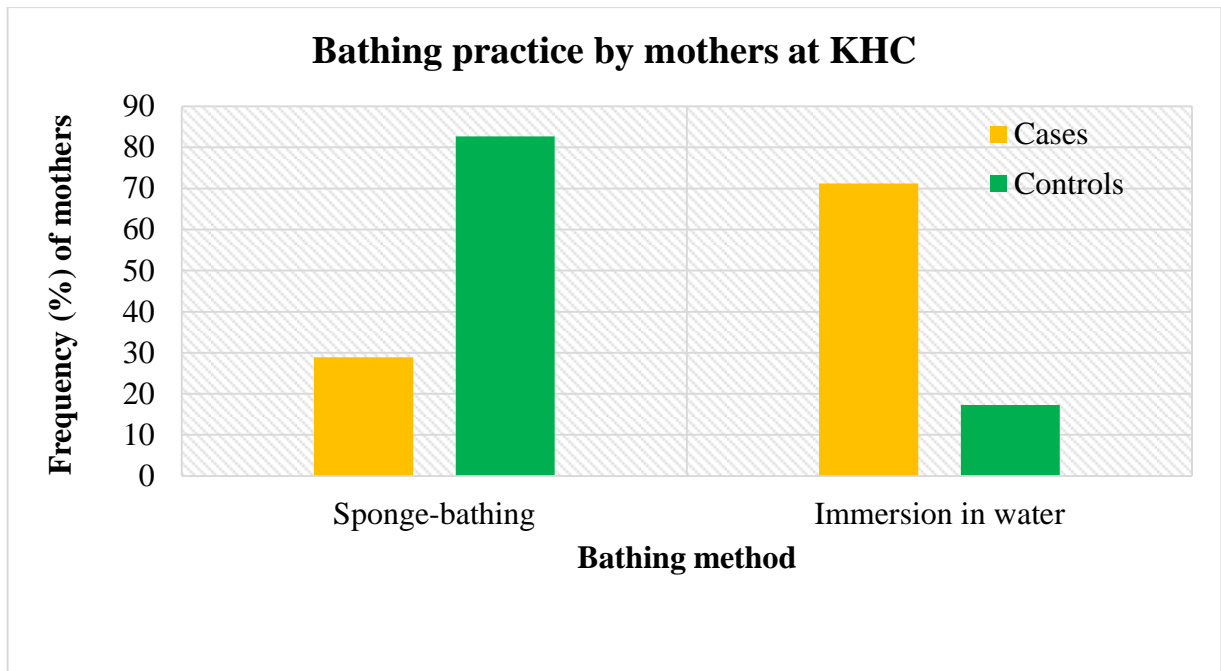


Figure 8. Method of bathing the neonate among mothers at KHC, Kenya, 2018 (n=306)

4.2.2 Umbilical cord hygiene

Umbilical cord hygiene was measured using the cord care practices' variables among mothers including *substance application*, *cord exposure*, *handwashing*, *washing substance*, *rooming-in* and *bathing method*. Amalgamation of these variables' codes gave a total score of 13. Hence, the median score was preset at 7. The mean of the total scores among all mothers was 7.56 (SD=2.31; range: 2-10). Among the cases, the mean of the total scores observed was 5.40 (SD=1.98; range: 2-10; median=5), while among controls it was 8.67 (SD=1.56; range: 4-10; median=9). Total scores below the preset median were termed as improper hygiene and scores that were equal to or above the preset median considered to have proper hygiene. The proportion of mothers/care-givers who had improper hygiene practices among cases was 72.1% (n=75). On the contrary, as demonstrated on Table 4, proper hygiene was observed more among the controls (83.7%, n=169) (Figure 9).

Table 4: Umbilical cord hygiene risk factor and neonatal sepsis among neonates attending KHC, Kenya

VARIABLE	Category	Cases (n=104) n (%)	Controls (n=208) n (%)
Umbilical cord hygiene	Proper	29 (27.88)	169 (83.66)
	Improper	75 (72.12)	33 (16.34)

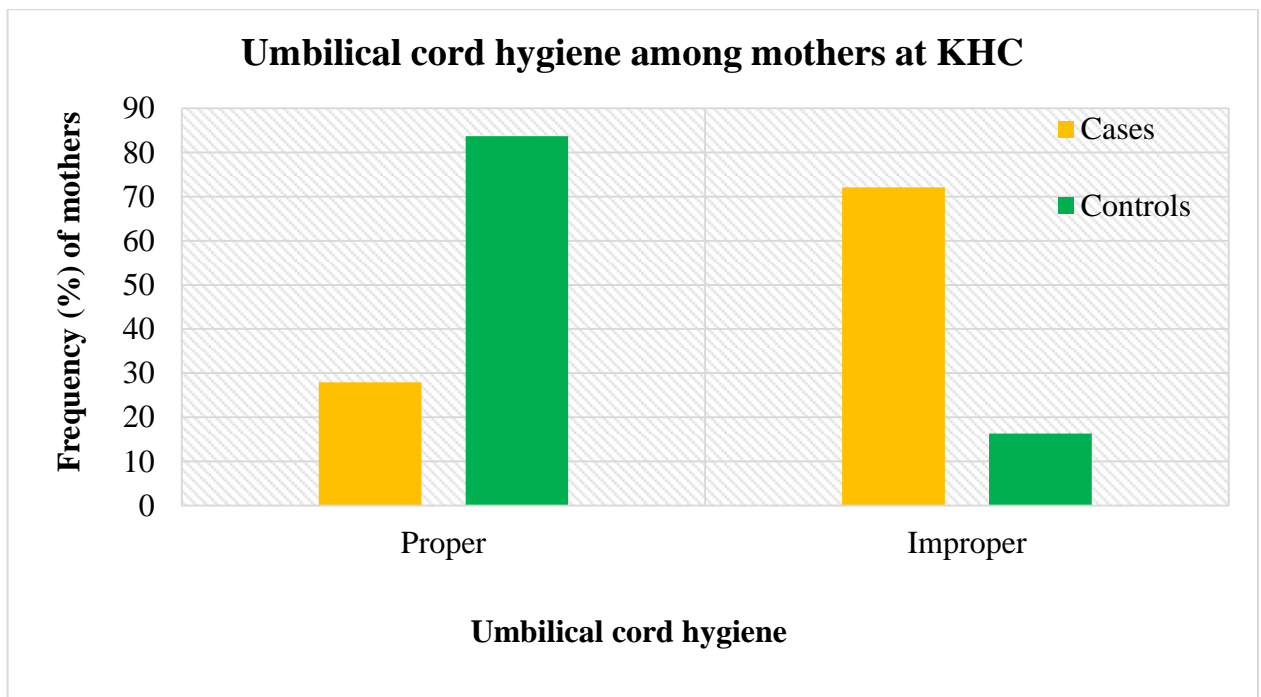


Figure 9. Umbilical cord hygiene among mothers/primary care-givers, KHC, Kenya, 2018 (n=306)

4.3 Association between umbilical cord hygiene and occurrence of neonatal sepsis

Hypothesis: There is strong evidence ($P < 0.001$) of there being an association between umbilical cord hygiene and neonatal sepsis among neonates presenting at Kahawa Health Center. The null hypothesis is hence rejected while the alternate hypothesis holds.

The crude association between cord hygiene and neonatal sepsis is captured in Table 5. Notably, the odds of neonatal sepsis in infants who had improper hygiene was approximately 13 times higher (OR=13.24; 95% CI: [7.5; 23.4]) compared to those with proper hygiene.

Table 5: Univariable analysis of umbilical cord hygiene risk factor for neonatal sepsis among neonates attending KHC, Kenya

VARIABLE	Category	Odds Ratio	95% CI	P-value ($P \leq 0.05$)
Umbilical cord hygiene	Proper	Ref	-	<0.001
	Improper	13.24	7.50; 23.38	

CI, confidence interval.

4.4 Effect of potential confounding factors

4.4.1 Screening individual variables for association with the outcome

As displayed on Table 6, of the variables screened, neonatal factors registering a significant association with neonatal sepsis were low APGAR score ($P = 0.001$), invasive procedures ($P = 0.007$) and neonate's age ($P < 0.001$). With respect to maternal factors, marital status ($P = 0.05$), initiation of breastfeeding ($P = 0.006$), type of feed ($P < 0.001$) and pregnancy-related events ($P = 0.005$) were found to be significantly associated with neonatal sepsis (Table 7).

Table 6: Univariable results for the association between neonatal factors and neonatal sepsis among neonates attending KHC, Kenya

VARIABLE	Category	Odds Ratio	95% CI	P-value
APGAR score*	<7	9.47	2.01; 44.70	0.001
	>7	ref		
Invasive procedures*	Yes	2.84	1.32; 6.10	0.007
	No	ref		
Neonate's sex	Male	0.70	0.44; 1.13	0.147
	Female	ref		
Neonate's age*	-	0.89	0.85; 0.93	<0.001

Variables eligible for an assessment of their association with the primary exposure ($P \leq 0.05$). CI, confidence interval.

Table 7: Univariable results for the association between maternal factors and neonatal sepsis among neonates attending KHC, Kenya, ($P \leq 0.05$)

VARIABLE	Category	Odds Ratio	95% CI	P-value
Maternal age (years)	Mean	0.97	0.93; 1.01	0.159
Level of education	No formal	2.74	0.44; 16.91	0.187
	Primary	1.06	0.62; 1.81	
	Secondary	Ref		
	College /University	0.57	0.24; 1.13	
Marital status*	Single	2.05	1.13; 3.73	0.050
	Married	Ref		
	Divorced /Separated	1.72	0.56; 5.13	
Mother's religion	Protestant	Ref		0.181
	Catholic /Orthodox	0.69	0.42; 1.15	
	Other	3.45	0.31; 38.74	
Place of delivery	Home delivery	0.72	0.07; 7.04	0.251
	Primary public	1.62	0.94; 2.81	
	Public hospital	Ref		
	Private hospital	0.85	0.43; 1.67	

Health education	Received	0.59	0.33; 1.07	0.086
	Not received	Ref		
Parity	-	0.84	0.66; 1.07	0.149
Number of ANC visits	Zero	Ref		0.525
	One	0.5	0.07; 3.65	
	Two	0.28	0.04; 1.87	
	Three	0.29	0.05; 1.83	
	≥Four	0.36	0.06; 2.24	
Tetanus toxoid immunization	Immunized	0.51	0.10; 2.56	0.416
	Non-immunized	Ref		
Initiation of breastfeeding*	Within one hour	Ref		0.006
	One-six hours	2.85	1.49; 5.43	
	More than 6 hours	1.29	0.74; 2.24	
Type of feed*	Breastmilk only	Ref		<0.001
	Formula	1.61	0.26; 9.80	
	Mixed/Other	5.26	2.46; 11.25	
Pregnancy-related events*	Present	2.04	1.24; 3.36	0.005
	Absent	Ref		

Variables eligible for an assessment of their association with the primary exposure ($P \leq 0.05$). CI, confidence interval.

4.4.2 Screening eligible variables for association with the primary exposure

The neonatal and maternal variables factors which were significantly associated with sepsis were eligible for an evaluation of an association with the primary exposure and were tested for this association as presented in Table 8. This was to assess whether they confounded the improper hygiene-neonatal sepsis relationship. Following the assessment, these variables: *low APGAR score, invasive procedure, neonate's age, marital status, type of feed* and *pregnancy-related events* reached statistical significance in their association with improper hygiene. Consequently, the afore-mentioned six variables having met criteria for confounding, were offered to the multivariable model to adjust for their potential confounding effect.

Table 8: Association between the qualifying covariates and umbilical cord hygiene among neonates at KHC, Kenya, 2018.

VARIABLE	Values	Odds Ratio	95% CI	P-value
APGAR score^a	>7	ref	-	0.001
	<7	8.91	1.89; 42.02	
Invasive procedures^b	Yes	2.29	1.07; 4.89	0.033
	No	ref	-	
Neonate's age^c		0.94	0.91; 0.98	0.001
Marital status^d	Single	2.08	1.15; 3.78	0.047
	Married	ref	-	
	Divorced /separated	1.62	0.54; 4.83	
Initiation of breastfeeding	Within one hour	ref	-	0.624
	One-six hours	1.05	0.61; 1.81	
	More than six hours	1.375	0.72; 2.62	
Type of feed^e	Breastmilk only	ref	-	<0.001
	Formula	0.55	0.06; 5.01	
	Mixed	4.81	2.25; 10.28	
Pregnancy-related events^f	Yes	1.63	1.00; 2.65	0.046
	No	ref	-	

^{a,b,c,d,e,f} Variables eligible for inclusion in the multivariable analysis ($P \leq 0.05$). CI, confidence interval.

4.4.3 Multivariable analysis of all eligible factors for neonatal sepsis

Results of the multivariable analysis are presented in Table 9. Multivariable analysis was done using a backward-stepwise approach where the least significant variable (based on the WALD *P*-values below), was eliminated from the full model while assessing for a 30% effect on umbilical cord hygiene as the primary variable of interest. It was found that, in the full model with umbilical cord hygiene, none of the six factors assessed actually confounded the primary association between umbilical cord hygiene and neonatal sepsis. Therefore, they were eliminated from the model; accepting the null hypothesis that neonatal and maternal factors do not influence the umbilical cord hygiene-neonatal sepsis relationship among neonates at KHC. The adjusted Odds Ratio (aOR) remained similar to the crude Odds Ratio of 13.34 (95% CI: 7.50 – 23.38, *P*<0.001) as contained in Table 5.

Table 9: Multivariable analysis for association between umbilical cord hygiene and qualifying covariates with neonatal sepsis among neonates at KHC, Kenya, 2018.

VARIABLE	Values	Odds Ratio	95% CI	WALD p-value
Umbilical cord hygiene	Proper	ref	-	<0.001
	Improper	11.02	5.82; 20.87	
APGAR score	>7	ref	-	0.328
	<7	3.28	0.30; 35.36	
Invasive procedures	Yes	1.42	0.36; 5.63	0.616
	No	ref	-	
Neonate's age		0.88	0.84; 0.93	<0.001
Marital status	Single	1.26	0.57; 2.80	0.836
	Married	ref	-	
	Divorced /separated	1.21	0.28; 5.24	
Type of feed	Breastmilk only	ref	-	0.009
	Formula	4.38	1.60; 11.96	
	Mixed	4.26	0.50; 36.44	
Pregnancy-related events⁺	Yes	1.56	0.82; 2.99	0.175
	No	ref	-	

None of the assessed factors resulted in a >30% change in the regression coefficient for umbilical cord hygiene. CI, confidence interval.

4.4 Estimation of the PAF for the umbilical cord hygiene-neonatal sepsis relationship

The adjusted odds ratio (aOR) of 13.34 (95% CI: 7.50 – 23.38, $P < 0.001$) was used to compute the population attributable fraction (PAF). Using the formula on section 3.12, this resulted in an estimated PAF of 66.7%. This signifies that roughly 67% of neonatal sepsis in the population could be prevented by observing proper umbilical cord hygiene.

CHAPTER FIVE: DISCUSSION

5.0 Introduction

This chapter discusses the study's results in relation to the aim and objectives as well as relevant comparisons made with findings from different studies in literature. The primary aim of this study was to evaluate the relationship between umbilical cord hygiene and neonatal sepsis among neonates presenting at Kahawa Health Centre. In this chapter, discussions of results are categorized according to the study's specific objectives: cord care practices among mothers, umbilical cord hygiene - neonatal sepsis association, its population attributable fraction (PAF) and potential confounding effect of sociodemographic, neonatal and maternal factors on the umbilical cord hygiene - neonatal sepsis association.

5.1 Cord care practices among respondents

To address the first specific objective, this study set to explore the existing cord care practices during the neonatal period in the community served by the KHC. The study found that in this community, the main cord care procedures involved aspects of substance application, with a majority of caregivers cleansing their hands using water and soap (44%), exposing the cord (66%), sponge-bathing (64%) as contrasted with immersion method and practicing rooming-in (99%) of the mother-infant couplet. This is in line with WHO cord care recommendations on satisfactory cord care; the series of steps for essential cord care in high mortality regions should include use of select topical antimicrobial agents as alternatives to harmful applications, handwashing, air drying of the umbilical stump, sponge bathing and rooming-in (WHO, 2013; WHO, 1998).

This study found that the most commonly (64%) used agents for treatment of the cord were chlorhexidine or surgical spirit. In other studies, percentages reaching heights of 73% of mothers who chose the aforementioned antimicrobials as the principal cord care application substances have been observed (Afolaranmi et al., 2018; Abhulimhen-Iyoha et al., 2011; Abegunde et al., 2017). This is in agreement with the recommended WHO application substance in such a low resource area (WHO, 2013; Stewart et al., 2016). However, there was a statistically significant difference between the 36% of cases whose caregivers who used surgical spirit/chlorhexidine and the 79% of sepsis-free controls, highlighting the importance of use of surgical spirit in prevention of sepsis.

Of concern was the significant number of mothers who used non-recommended practices which included water or nothing (air-drying) and ash/saliva; amongst cases, 52% and 11% of mothers declared that they used water/nothing or ash/saliva, respectively. Such unclean traditional substances as saliva are a probable nidus of infection as they are likely to be contaminated with bacteria/spores (Goel et al., 2015; Abhulimhen-Iyoha et al., 2011; Peterside et al., 2015). In similar poor settings, difference in findings in respect to the most popularly applied substance has been observed. For instance, in Pumwani Maternity Hospital, Kenya, applying nothing (air drying) was most prevalent at 55%, followed at 25% by surgical spirit, as well as use of saliva and water both at 10% (Kinanu et al., 2016).

Elsewhere, methylated spirit was the main cord care method in Ghana (Nutor et al., 2016) and in Nigeria (Afolaranmi et al., 2018; Opara et al., 2012; Abegunde et al., 2017); while brick ash was reportedly highly used in Zambia (Sacks et al., 2015). Findings from another study carried out in Benin reported that inappropriate/harmful substances were applied by

81% of caregivers (Agossou et al., 2016). In Ethiopia and Nigeria, dry cord care was widely exercised (Callaghan-Koru et al., 2013 ; Chidiebere et al., 2015). The differences might be due to the influence of deeply entrenched cultural norms that supersede adoption of advocated clean cord care applications (Coffey and Brown, 2017; Ambe et al., 2008; Walsh et al., 2015).

In this study, about two thirds of mothers fastened the babies' diapers below the umbilical stump. This is in consonance with WHO stipulations that dictate that the diaper should be tied below the cord (WHO, 1998). There was a clear distinction among cases and controls, with only 30% of cases and 84% of controls' mothers reporting to fasten diapers below the cord. A study by Kinanu et al. (2016) found similar results where 54% neonates' diapers were applied below the cord. The umbilical stump being an acquired wound is a nidus for entry of pathogenic bacteria from the newborn's excreta and this is well recognized among the health care community who are privy to WHO guidelines (WHO, 2013a; WHO, 2013; Kinanu et al., 2016).

About four-fifths (78%) of caregivers mentioned that they washed their hands while changing the diapers (55% of cases and 90% of controls). Another study done in one public hospital in Nairobi, Kenya, supported this finding where 52% of mothers washed their hands under running water and 48% used water in basins (Kinanu et al., 2016). Comparably, in Parakou, Benin, 73% of mothers expressed that they washed their hands prior to cord care provision (Agossou et al., 2016).

Further, with regards to the washing substance in the current study, majority of mothers (44%) used water and soap. Mothers who washed with plain water were 37% while those who did not wash their hands at all were 22%. Findings in this study were corroborated by a Nigerian study which documented most of the study population (47%) to have used water and soap in the care of their hands, followed by water only (40%) (Afolaranmi et al., 2018). Nonetheless, a study in Karamoja in Uganda, contrasted the finding, reporting that handwashing was not observed by majority (90%) of mothers before change of diaper/napkin leading to their neonates exhibiting signs of infection (Hopp, 2017). The difference could be ascribed to the Ugandan study area being primarily a semi-arid region of the country compared to the urban slum dwelling setting of this study. While handling the neonate's cord, it is recommended that handwashing with both water and soap is observed to achieve umbilical cord hygiene in the infant's care (WHO, 1998; Blencowe et al., 2011).

Over 99% of the mothers in this study slept in the same room as the baby. The finding from a study in Pumwani Maternity Hospital in Kenya supports this result where 93.3% of mothers were shown to practice rooming-in (Kinanu et al., 2016). It is recommended that mothers and their newborns should sleep in one room throughout without separation (WHO, 2013). It has been cited that rooming-in promotes better coupling of mother and newborn, boosting their skin contact and hence increasing colonization rates of non-pathogenic organisms from the mothers' normal skin flora to the baby, thereby lowering umbilical cord infection rates (WHO, 1998; Whitmore, 2010; MacDonald, 2016).

To achieve dry cord care and hastened healing, the bathing practice is key. Wiping the baby with a wet cloth was dominant among controls in the present study. Similarly, sponge-bathing has been shown in another study to be the main bathing practice compared to immersion-bathing (Kinanu et al., 2016). However, majority of cases were immersed in water. In Benin, 93% of mothers tub bathed babies in water and only 7% wiped them with a wet cloth which was linked to concomitant umbilical cord infection (Agossou et al., 2016). The WHO recommends that the first bath should be delayed for at least six hours and umbilical stump should be kept dry until the cord falls off (WHO, 1998); the reason being that immersion bathing leads to delay in cord separation and increased susceptibility to sepsis (Ayyildiz et al., 2015).

Based on the five cord practices aforementioned, the cord hygiene variable in the present study was represented by 72% of cases and 16% of controls having failed to observe good cord hygiene. In North Benin, a study reported that, as per study's specifications of cord hygiene, 58.6% of mothers had practiced poor quality care, 31.9% had good quality care, with none of the mothers reaching excellent quality of cord care (Agossou et al., 2016).

5.2 Umbilical cord hygiene-neonatal sepsis association, confounding and PAF

The results of the present study showed that there was a statistically significant association between umbilical cord hygiene and neonatal sepsis among infants of the Kahawa Health Centre. Compared to babies whose mothers observed proper cord hygiene, the odds of developing neonatal sepsis among babies of mothers who had improper cord hygiene was roughly 13 times higher (OR=13.24; 95% CI: 7.50; 23.38, $P<0.001$) and this key association was not confounded by any of the examined factors. According to Bradford

Hill Criteria, such a strong association has been shown to be less due to chance, bias or confounding even by residual factors and might actually suggest causality (Cox, 2018). However, this finding might need to be validated by studies in other settings.

In India, a previous study has elucidated a strong association ($P < 0.001$) between unhygienic care of the cord and sepsis (among 63.4% of cases and 8.6% of controls) (Goel et al., 2015). Likewise, a study in Bangladesh showed a relative risk of 1.15 for an association between unclean cord care and neonatal sepsis (Mitra et al., 2018). The strength of association is lower than the results of this study perhaps attributable to other stronger predictors of neonatal sepsis in the population. Similar observation was made in Nigeria where unhygienic cord care had a significant impact in resultant neonatal infection (Saleh et al., 2015).

With the strong odds ratio, this study actually yielded a high overall population attributable fraction (PAF) estimate of 67% for umbilical cord hygiene. This implies that in the population, 67% of neonatal sepsis cases could have been averted in the study setting, if poor cord hygiene had been eliminated and assuming umbilical cord hygiene was causal.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.0 Introduction

The conclusion and recommendations are included in this chapter. The conclusion summarizes the findings based on the study's specific objectives. The recommendations drawn aim at addressing neonatal sepsis through its central predisposing factors.

6.1 Conclusion

1. The findings of this study showed that unhygienic cord care practices were predominantly among mothers of the cases than of the controls. A lower percentage of mothers using surgical spirit/chlorhexidine, as well as those washing hands with soap and water, was observed in this study compared to other studies that have been done in the same setting. Majority of the cases practiced unhygienic methods such as use of saliva, immersion bathing, not washing hands and covering the cord with diapers.
2. This study provides evidence that improper cord hygiene practices were positively associated with a higher chance of getting neonatal sepsis among infants of Kahawa Health Centre. Compared to neonates whose mothers had observed proper cord hygiene, the odds of developing neonatal sepsis among babies of mothers who had poor cord hygiene was roughly 13 times higher.
3. The umbilical cord hygiene-neonatal sepsis association was not confounded by any of the covariates measured.

4. With the strong odds ratio, this study actually yielded a high overall PAF estimate of 67% for umbilical cord hygiene. The implication is that if improper cord hygiene practices were eliminated, neonatal sepsis could be reduced by 67% in the population.

6.2 Recommendations

Based on this study, key recommendations made to mitigate the neonatal sepsis burden include:

- 1) Currently, the national guidelines for quality perinatal care given by the Ministry of Health (MoH) advocate for dry umbilical cord care. The Head, Division of Child and Adolescent Health in the MoH, should spearhead revision of the guidelines to introduce an antenatal cord care package that:
 - stresses on the importance of comprehensive proper cord care practices (use of antimicrobial agents on the umbilical cord, tying diapers below the cord, handwashing with soap and water when handling the cord, rooming-in and sponge-bathing) as recommended by the World Health Organization.
 - lays emphasis on modifiable risk factors of neonatal sepsis to focus on strengthening health education specifically on exclusive breastfeeding, minimization of invasive procedures and addressing pregnancy-related complications.
- 2) The Nairobi County Director of Medical Services should roll out the WHO recommended cord hygiene protocol by retraining the county health care staff/nurses, who should in turn mount sustained awareness campaigns on proper

cord hygiene practices to mothers and other caregivers in underserved population settings within the county, in a manner that impacts behavioral changes in home and primary care settings.

- 3) Given that this study highlighted use of unhygienic applications such as saliva particularly among the cases, a population-based robust follow-up study that explores community behaviour and practices on newborn cord care and its subsequent relation to neonatal sepsis is recommended.

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APPENDICES

I: WRITTEN CONSENT FORM

Study Title: Umbilical cord hygiene and the risk of neonatal sepsis among neonates presenting at Kahawa Health Centre.

Principal Researcher: Dr. Phoebe Moraa Keraka

Institution: University of Nairobi, School of Public Health

Phone number: 0725634826; **E-mail address:** phoebemoraa09@gmail.com

Introduction

I am a postgraduate student in the School of Public Health conducting a research on the influence of umbilical cord hygiene on neonatal sepsis at Kahawa Health Centre. As the principal investigator I would like to request you to be part of this study. This consent form will provide you with the information concerning the study for your perusal in order to make a decision on your participation. The form comprises the description of contents, methods, aims, potential benefits and your rights as a participant. You will have the opportunity to freely raise your concerns and ask questions at any time before and during the study on the nature, methods employed or benefits/risks to be accrued. Approval for the research was obtained from the Kenyatta National Hospital (KNH)-University of Nairobi (UoN) Ethics and Research Committee. For your concerns or further enquires, you may contact the key researcher through the phone number or email address given above or the ethics Secretary or Chairperson, KNH-UoN Ethics and Research Committee Telephone No. 2726300 Ext. 44102, E-mail: uonknh_erc@uonbi.ac.ke. Remember that your

agreement to be involved in the study is completely at your own convenience and you may withdraw at any time you feel uncomfortable without prejudice on service provision.

Information and Purpose: The interview you are about to be enrolled into is part of a research study whose purpose is to investigate umbilical cord hygiene, and other influencing factors in terms of sociodemographic, neonatal and maternal indicators, as important determinants of neonatal sepsis. A mother will be asked about her and her neonate's experiences before, during and after delivery including her practices surrounding neonatal care. With permission from the mother/care-giver, the principal investigator/trained researcher will examine the neonate for clinical features of neonatal sepsis. The ultimate aim is to gain a better understanding of the umbilical hygiene-sepsis relationship.

Participation Protocol: On agreeing to participate in the study, your participation will involve the following: physical examination of your child and an interview whereby you will be required to fill in a structured questionnaire as instructed by the interviewer. Completing this questionnaire will take you approximately thirty (30) minutes. The series of questions will consist of your demographic data and practices used by yourself or other primary care-provider to achieve umbilical cord cleanliness and healing. Other questions will focus on the mother-neonate economic, social, antenatal, perinatal and postnatal environment and experiences. You may answer the questions that are agreeable to you. It is not mandatory to fill in the whole questionnaire. You may contact the principal investigator for clarification. You may terminate the interview and discontinue your participation whenever you feel like without penalization.

Benefits and Risks: Based on the information you provide, you will be provided with medical skills on better care of the umbilical cord. You will also acquire knowledge on the

danger signs to be vigilant on for early recognition of septic illness in your child. The researcher will analyze the data obtained to identify important factors that influence umbilical cord hygiene and the development of neonatal sepsis. On request, you will be given feedback on results and recommendations and these will be forwarded to other health workers and the county government as well. Further, new health policy formulation may be beneficial to you and better guidelines could be developed and be enforced in your hospital and community setting.

There is the potential risk of emotional distraught to mothers whose inattention to umbilical cord care may have contributed to sepsis. Privacy of participants' record will be ensured by use of code number instead of personal identification when filling the questionnaires. All questionnaires will be under locked cabinets accessible only to the principal investigator. Hence, anonymity will be ensured and confidentiality enhanced.

There will not be any cost charges for you to be recruited as a participant neither will there be any compensation arrangements.

Informed Consent Form

Participant declaration

I have read the written consent form and have understood the nature of the study, the methods to be used and its potential risks and benefits as explained to me by the researcher. I have had all my questions answered satisfactorily. My confidentiality has been assured. My rights to participate voluntarily or withdraw freely are well known to me.

By signing this consent form, I _____

certify that I agree to voluntarily participate in this study according to the terms of agreement.

Signature: _____ **Date:** _____ /0 ____ /2018

Researcher's declaration

I, the undersigned, declare that I have comprehensively explained the research details to the above-named participant to obtain their voluntary consent for participation in the study.

Principal Researcher's Name: _____

Signature: _____ **Date:** _____ /0 ____ /2018

Research Assistant's Name: _____

(if it is not the Principal researcher who will take the consent)

II: RIDHAA YA KUSHIRIKI KATIKA UTAFITI

Mada ya Utafiti: Usafi wa kitovu na hatari ya ugonjwa wa neonatal sepsis katika watoto wachanga wanaowasilisha katika Kituo cha Afya cha Kahawa.

Mtafiti Mkuu: Dk. Phoebe Moraa Keraka

Taasisi: Chuo Kikuu cha Nairobi, Shule ya Uuguzi

Nambari ya simu: 0725634826; Anwani ya barua pepe: phoebemoraa09@gmail.com

Utangulizi

Mimi ni mwanafunzi wa uzamili katika chuo kikuu cha mafunzo ya Afya kwa Umma; ninashiriki katika utafiti wa ushawishi wa usafi wa kitovu kwenye neonatal sepsis katika Kituo cha Afya cha Kahawa. Kama mtafiti mwelekezi ningependa kukuomba uwe mmoja wa watafiti wa kazi hii. Ridhaa hii ya kushiriki katika utafiti itakupa habari kuhusu utafiti wenyewe ili ufanye uamuzi wa kushiriki kwako. Fomu hii inajumuisha maelezo ya: yaliyomo, mbinu za utafiti, malengo, faida na haki zako kama mshiriki. Una uhuru wa kupiga msasa maelezo haya na kuuliza maswali wakati wowote kabla, na pia wakati wa kujifunza juu ya asili, mbinu zilizoajiriwa au faida / hatari zinazoshirikishwa. Idhini ya utafiti imepeanwa na Hospitali kuu ya Kitaifa ya Kenyatta (KNH) – Chuo kikuu cha Nairobi (UoN) vilevile kutoka kwa Kamati ya Kitaifa ya Maadili na Utafiti. Ukiwa na swali lolote au habari muhimu za kuzingatia, unaweza kuwasiliana na mtafiti mkuu kupitia nambari ya simu au anwani ya barua pepe iliyotolewa hapo juu au Katibu wa Maadili au Mwenyekiti, KNH-UoN Kamati ya Maadili na Utafiti Namba ya **2726300 Ext. 44102**, **Barua pepe: uonknh_erc@uonbi.ac.ke**. Kumbuka kwamba makubaliano yako ya kushiriki katika utafiti ni kwa iari yako mwenyewe na unaweza kujiondoa wakati wowote unahisi hofu na kuathirika katika utoaji wa huduma yako.

Taarifa na Kusudi: Mahojiano unayotaka kujiandikisha ni sehemu ya utafiti ambayo lengo lake ni kuchunguza ukanda wa usafi wa chupa ya uzazi, na mambo mengine muhimu yanayoathiri moja kwa moja masuala ya kijamii, uzazi, kama vipimo muhimu vya neonatal sepsis. Mama atahojiwa kuhusu uzoefu wake wa kujifungua kabla, wakati na baada ya kujifungua ikiwa ni pamoja na tabia zake zinazohusu huduma za uzazi. Kwa ithini kutoka kwa mzazi / mtoaji huduma, mtafiti mkuu / msaidizi wa utafiti atachunguza hali ya kliniki ya vipimo vya kliniki ya watoto wachanga. Lengo kuu ni kupata ufahamu bora wa uhusiano wa usafi na ugonjwa wa neonatal sepsis.

Itifaki ya Kushiriki: Kwa kukubali kushiriki katika utafiti huu, ushirika wako utahusisha yafuatayo: uchunguzi wa mwili wa mtoto wako na mahojiano ambayo utahitajika kujaza swali la muundo msingi kama ilivyoielezwa na mhojiwa. Kukamilisha maswali haya itachukua muda wa dakika thelathini (30). Mfululizo wa maswali utajumuisha data yako na tabia zako za kibinadamu au wewe mwenyewe au mtoa huduma wa msingi ili kufikia usafi na uponyaji wa kitovu. Maswali mengine yatazingatia mazingira ya kiuchumi, kijamii, uja uzito, majira ya uzazi na baada ya kujifungua pamoja na uzoefu. Unaweza kujibu maswali ambayo yanakuhusu. Sio lazima kujibu maswali yote. Unaweza kuwasiliana na mchunguzi mkuu kwa ufafanuzi. Unaweza kusitisha mahojiano na kuacha ushiriki wako wakati wowote unapokuwa na hofu.

Faida na Hatari: Kwa maelezo umuhimu unayoyatoa, utaanufaika kwa ujuzi bora wa utunzaji wa kitovu. Naye mpenzi wako pia atapata ujuzi mwafaka kuhusu dalili za hatari; na namna ya kutambua mapema ugonjwa wa neonatal sepsis katika mtoto wako. Mtafiti atachambua data yako ili kutambua mambo muhimu ambayo yanathibitisha usafi wa kitovu na maendeleo ya neonatal sepsis. Kwa ombi lako mwenyewe, utapewa maoni juu ya matokeo ya utafiti na mapendekezo yatapelekwa kwa wafanyakazi wengine wa afya na serikali ya kata pia. Zaidi ya hayo, matayarisho mapya ya sera za afya yanaweza kuwa na

manufaa kwako na jamii kwa jumla. Aidha, miongozo bora inaweza kuendelezwa na kutekelezwa katika mazingira yako ya hospitali na jamii.

Hatari moja mahususi ni uwezekano wa kuwa na wasiwasi wa kihisia kwa mama ambao kutokuwa na hisia za huduma ya kwamba inaweza kuwa na mchango wa sepsis. Faragha ya rekodi ya washiriki itakuwa hata hivyo kuhakikisha kwa kutumia namba ya nambari badala ya kitambulisho cha kibinafsi wakati wa kujaza maswali. Maswali yote yatakuwa chini ya ulinzi bora, makabati yaliyofungwa na yatapatikana tu kwa uchunguzi mkuu. Kwa hivyo, habari muhimu itasalia kuwa siri ya mhojiwa na maadili mema ya kikazi yataimarishwa.

Hakutakuwa na mashtaka yoyote ya gharama kwa wewe kuajiriwa kama mshiriki wala hakutakuwa na mipango yoyote ya fidia.

Ridhaa

Azimio la mshiriki

Nimeisoma fomu ya ridhaa iliyoandikwa na nimeelewa hali ya utafiti, mbinu za kutumiwa na hatari zake, vilevile na faida zake kama nilivyoelezwa na mtafiti. Maswali yangu yote yamejibiwa kwa namna ya kuridhisha. Usiri wangu umehakikishiwa. Haki zangu za kushiriki kwa hiari au kujiondoa kwa uhuru zinajulikana kwangu.

Kwa kutia sahihi fomu hii ya idhini, mimi

.....

.....

nathibitisha kwamba mimi nakubaliana kwa hiari yangu kushiriki katika utafiti huu kwa mujibu wa masharti ya makubaliano.

Sahihi ya aliyehojiwa: Tarehe: ----/ 0---/2018

Azimio la Mtafiti

Mimi, mtafiti, naapa kwamba nimeelezea kikamilifu maelezo ya utafiti huu na mshiriki aliyetaguliwa hapo juu kupata kibali cha hiari cha kushiriki katika utafiti huo.

Jina la Mtafiti Mkuu:

Sahihi ya mpelelezi/msaidizi wa utafiti: **Tarehe:** .../ 0.../2018

Jina la Msaidizi wa Utafiti:

(ikiwa si mtafiti Mkuu ambaye atachukua idhini)

III: QUESTIONNAIRE

Evaluation of Factors Associated with Neonatal Sepsis at Kahawa Health Centre Questionnaire

(To be administered in English)

Filling instructions: This questionnaire is for data collection on determinants of umbilical cord hygiene and other factors and how these influence neonatal sepsis occurrence. Honesty and completeness in responding to these questions will be appreciated and treated with strict confidentiality. Please tick (√) or cross (×) or write in the provided spaces. Thank you for your understanding and cooperation.

Form Serial Number	
Date of completion of the instrument	dd-mm-year
Has informed consent been obtained?	Yes No, if NO END
For cases, is this the first/primary visit since the baby has been ill?	Yes No, if NO END
Is the study participant a case or control?	Case, if case go to I5 Control, if control go to I4
Neonatal sepsis screening among Hospital Controls	Fever/Temp $\geq 37.5^{\circ}\text{C}$ (Y/N)
If Y to ANY, END. Send to the paediatric clinic for complete clinical examination and treatment. If N, go to I5.	Temperature: _____ $^{\circ}\text{C}$ (enter the exact temp)
	Purulent discharge (ear/eye/umbilical) (Y/N)
	Respiratory rate >60 breaths/min (Y/N)
	Respiratory rate: _____ breaths/min (enter the exact figure)
	Severe abdominal distension (Y/N)
	Feeding intolerance/ Vomiting (Y/N)
	Lethargy/convulsions (Y/N)
	Jaundice/Periumbilical Redness (Y/N)
Was the baby born at gestation ≥ 37 weeks?	Yes
LNMP: dd_____ /mm_____ /yr_____	No, if NO END
DOB: dd_____ /mm_____ /yr_____	
Was the baby's birth weight >2000gm?	Yes
Birth weight: _____ grams	No, if NO END
Did the baby have any congenital anomaly (ies)?	Yes, if YES END
	No
Neonate's Date of Birth (dd-mm-year)	
Neonate's sex	Male

	Female
Caregiver's Sex	Male
	Female
Mother's Date of Birth (dd-mm-year)	
What is your age at delivery? (Years)	
What is your marital status?	Single
	Married
	Divorced
	Widowed
	Separated
What is the highest level of education you have completed?	No formal schooling
	Primary
	Secondary
	College/ University
	Post Graduate
	Declined
What is your religious affiliation?	Protestant
	Catholic
	Muslim
	Orthodox
	Other
What is your place of residence?	
What is your parity status? (Gravida ___ Para ___ Abortions: Yes ___ No ___ Unknown ___)	
What substances do you apply on the umbilical cord?	None
	Surgical spirit
	Povidone iodine
	Topical antibiotic
	Silver sulphadiazine
	Other (specify)
Where did you deliver?	Home
	Health institution
Who assisted in your delivery?	
Skilled health worker _____ Unskilled health worker (TBA/ family member _____)	
How do you fold the neonate's napkin?	Below the cord
	Above the cord
Before handling the umbilical cord, do you wash your hands with water?	Yes, if YES go to U5
	No
What do you use to wash hands?	Water only
	Water and soap
Do you sleep in the same room as your baby?	Yes
	No
How do you bathe your child?	Immersion in water

	Sponge bathing
What was the APGAR score of the child on delivery (did the neonate cry immediately at birth?)	
APGAR score at 1 minute _____ 5 minutes _____ 10 minutes _____ (from the mother-child booklet)	
Was there resuscitation/use of invasive medical procedure when the child was born? (from mother-child booklet)	Yes No
Did the infant have a central line (peripherally inserted central catheter line, umbilical line, central venous line)?	Yes No
Was the amniotic fluid infected during birth (presence of foul smell or green-colored amniotic fluid)? (from mother-child booklet)	Yes No
What is the baby currently feeding on?	Breast-milk Formula Mixed Other (specify)
What type of delivery did you experience?	SVD C/S Instrumental (forceps/vacuum)
Following delivery, how soon did you initiate breastfeeding?	Within one hour One-six hours More than six hours Did not breastfeed
How many antenatal clinics did you attend? (verify from mother-child booklet)	Zero One Two Three Four or more
Did you have any history of maternal urinary tract infection during the pregnancy?	Yes No
Did you receive the tetanus toxoid immunization?	Yes No
Before and after delivery, did you receive any health education on umbilical cord care and newborn danger signs?	Yes, if YES go to B8 No
What was the source of your health information?	Health worker Traditional Birth Attendant Family member

	Other (specify) _____
Was there prolonged rupture of membranes (PROM >24 hours prior to delivery)?	Yes No
If yes, specify duration of ROM: _____ hours	
Did you experience any complications or any other negative symptoms following delivery?	Yes No
Specify the complication: _____	

REPORTING PHYSICIAN

First name _____	Surname _____
E-mail _____	Address _____
Date completed _____	

****End of questionnaire****

Thank you completing this form and for your kind cooperation

IV: KNH-UoN – ERC APPROVAL LETTER



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel: (254-020) 2726300 Ext 44355



KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: <http://www.erc.uonbi.ac.ke>
Facebook: <https://www.facebook.com/uonknh.erc>
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC



KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/323

August 29, 2018

Dr. Phoebe Moraa Keraka
Reg. No.H57/88209/2016
School of Public Health
College of Health Sciences
University of Nairobi

Dear Dr. Keraka

RESEARCH PROPOSAL – UMBILICAL CORD HYGIENE AND THE RISK OF NEONATAL SEPSIS AMONG NEONATES PRESENTING AT KAHAWA HEALTH CENTRE (P438/06/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 29th August 2018 – 28th August 2019.


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) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- f) 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*).
- 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.

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

Yours sincerely,



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

- c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH-UON ERC
The Assistant Director, Health Information, KNH
The Director, School of Public Health, UON
Supervisors: Dr. Peter K. Njoroge, Dr. Marshal M. Mweu

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NAIROBI CITY COUNTY

Telegrams: "PRO-MINHEALTH", Nairobi
Telephone: Nairobi 217131/313481
Fax: 217148
E-mail: pmonairobi@yahoo.com



COUNTY HEALTH OFFICE
NAIROBI
NYAYO HOUSE
P.O. Box 34349-00100
NAIROBI

When replying please quote

Ref. No. CMO/NRB/OPR/VOL.1/2018/91

COUNTY HEALTH SERVICES

October 8, 2018

Dr. Phoebe Moraa Keraka
Reg. No. H57/88209/2016
School of Public Health
College of Health Sciences
University of Nairobi

RE: RESEARCH AUTHORIZATION

This is to inform you that the Nairobi City County Operational Technical Working Team reviewed your documents on "**Umbilical Cord Hygiene and the Risk of Neonatal Sepsis among Neonates presenting at Kahawa Health Centre**".

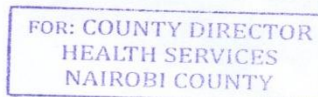
I am pleased to inform you that you have been authorized to undertake the study at Kahawa Health Centre in Nairobi County.

On completion of the study, you will submit **one hard copy and one copy in PDF** of the research findings to our operational research technical working group.

for: 

R. K. MULI

For: COUNTY DIRECTOR OF HEALTH SERVICES



Cc: SCMOH - Kasarani

VI: MAP OF KAHAWA HEALTH CENTRE

