OUTCOMES OF NEWBORNS WITH SURGICAL CONDITIONS AT MOI TEACHING AND REFERRAL HOSPITAL: THE CONTEXT OF A STRUCTURED STANDARD OPERATING PROCEDURE FOR NEWBORN TRANSPORT

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2021

Outcomes of Newborns with Surgical Conditions at Moi Teaching and Referral Hospital: The Context of a Structured Standard Operating Procedure for Newborn Transport

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A Thesis Submitted in Partial Fulfilment of the Requirements for the Degree of Doctor of Philosophy in Public Health of the Jomo Kenyatta University of Agriculture and Technology

2021

DECLARATION

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

Signature …….... Date ……...

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This thesis has been submitted for examination with our approval as the university supervisors.

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DEDICATION

To my loving wife Irene, and sons Saula Jr, Kithinji and Masaba, for their patience and support

To all children who are survivors of gastroschisis and oesophageal atresia

ACKNOWLEDGEMENTS

I wish to thank the following for their dedicated support:

- My supervisors for their diligent guidance.
- All the clinicians working in the Newborn Units/Labour Wards of the 5 county referral hospitals in western Kenya (Iten, Kapenguria, Bungoma, Busia, Kisii) for participating in the training and subsequent introduction of the structured SOP for transport of newborns with surgical conditions.
- Parents/guardians who voluntarily consented for enrolment of their newborns into the study.
- MTRH for funding this research through MTRH Intramural Research Fund.
- My research assistants, Ms. Lillian Simiyu, Ms. Esther Maina & Ms. Everlyne Mvungu, MTRH.
- Ms. Fenny Ontiri Moke, KEMRI-Kisumu, for her assistance in data entry and cleaning.
- Prof. Ann Mwangi, SOM-Moi University, for her assistance in data analysis.
- Faculty and staff, Centre for Public Health Research (CPHR), KEMRI.
- Faculty, School of Public Health, Jomo Kenyatta University of Agriculture and Technology.

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LIST OF ABBREVIATIONS AND ACRONYMS

ARM Ano-Rectal Malformation

HICs High-Income Countries

IV Intra-Venous

KDHS Kenya Demographic Health Survey

Kg Kilogram

LBW Low Birth Weight

L/MICs Low/Middle -Income Countries

Mmol/L Millimole per litre

MTRH/MU - IREC Moi Teaching and Referral Hospital/ Moi University-Institutional Research and Ethics Committee

MOH Ministry of Health, Kenya

NICU Newborn Intensive Care Unit

PPHN Persistent Pulmonary Hypertension of the Newborn

SOP Standard Operating Procedure

SPO2 Peripheral capillary oxygen saturation

S.T.A.B.L.E.	Sugar and Safe Care, Temperature, Airway, Blood, Lab work, and Emotional support
UK	United Kingdom
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
VLBW	Very Low Birth Weight
WHO	World Health Organization

OPERATIONAL DEFINITIONS OF TERMS

Hypoxia: Newborn's S_PO_2 below 90%

Hypoglycaemia: Newborn's random blood sugar less than 2.5 Mmol/L with reagent strips (Wright & Marinelli, 2014)

Hypothermia: Newborn's skin temperature below 36.5^0C (WHO, 1993)

Hypovolaemia: Newborn's Capillary Refill Time more than 3 seconds (Thakre *et al*, 2010)

Low Birth Weight: Birth weight less than 2.5 Kg irrespective of gestational age (Klaus & Far-off, 2001)

Newborn/Neonate: Child under 28 days of age

Preterm baby: Baby born before 37 completed weeks of gestation from medical history and clinical examination

Respiratory distress: Respiratory rate above 60/minute in a quiet baby associated with deep lower chest in-drawing with or without nasal flaring and or expiratory grunting (Warren & Anderson, 2010)

Very Low Birth Weight: Birth weight below 1.5 Kg

Surgical conditions: Broad range of diseases in which surgical care plays a role.

Clinical status of the newborn: Presence or absence of one or more of the following conditions:

a. Hypoxia
b. Hypoglycaemia
c. Hypothermia
d. Hypovolaemia
e. Respiratory distress

f. Need for immediate resuscitation

Referral and transport characteristics – refer to:

a. Mode of transport
b. Duration of transport
c. Communication before and during referral & transport
d. Pre-transport stabilization
e. Care during transport, Escort and Specimens
f. Documentation

ABSTRACT

World over, neonatal mortality contributes significantly to the under-five mortality rate, and 10% of neonatal deaths in L/MICs are due to surgical conditions. In Kenya, newborn surgical care is only provided in two tertiary-level hospitals, one each in Eldoret and Nairobi. As the majority of the newborns with surgical conditions are born or seek initial care in the lower-level health facilities, appropriate referral and transport of these newborns to the tertiary-level hospitals often underlie their survival. This study was conducted to evaluate the outcomes of newborns with surgical conditions at the Moi Teaching and Referral Hospital (MTRH), in the context of a structured Standard Operating Procedure (SOP) for newborn transport. A Cluster Randomized Controlled Trial that was based on Post-Test – Only Control-Group design, was conducted. Ten clusters (county hospitals that refer neonates with surgical conditions to the MTRH) were randomly selected and randomized into two groups (Intervention Group-A and Control Group-B) of 5 hospitals each. A structured SOP for transport of newborns, that was based on the WHO guidelines on transfer and referral of sick neonates (WHO, 2003), was introduced in the Newborn Units/Labour Wards of the referring county hospitals in the intervention group (Group A) via an education module. Thereafter, a blinded research assistant enrolled a total of 126 newborns referred and transported from the selected county hospitals upon their admission at the MTRH (63 from the hospitals in Group A, and 63 from the hospitals in Group B). Data was collected on their socio-demographic, referral and transport characteristics; clinical diagnosis; and clinical status at admission. The newborns were then followed up until discharge or death. The outcomes of the newborns in the two groups were compared to assess the effect of the structured SOP. The statistical tests that were applied to the data included chi-square and Fisher's exact tests for the categorical variables and Wilcoxon rank sum test for the continuous variables, and p values < .05 were considered statistically significant. Predictors of neonatal mortality were determined by regression analysis using Cox Proportional-Hazards Model. One-hundred and twenty-six (126) newborns were enrolled into the study between February 2018 and January 2019. The median age at admission was 4.1 days (99 [IQR=77, 128] hours) for the newborns referred from the county hospitals in the intervention group (Group A), and 4.6 days (112 [IQR=75, 137] hours) for those referred from the county hospitals in the control group (Group B). Only 14 (22.2%) mothers in Group A and 12 (19.0%) mothers in Group B had optimal antenatal care during pregnancy. The top 4 surgical conditions in both groups were gastroschisis (27.0% in Group A, 19.1% in Group B), hydrocephalus (14.3% in Group A, 22.2% in Group B), Hirschsprung's disease (7.9% in Group A, 20.6% in Group B), and ano-rectal malformations (ARM) (17.5% in Group A, 11.1% in Group B). The majority of the newborns referred from the county hospitals in Group A were accorded pre-transport clinical stabilization and care during transport, as compared to those referred from the county hospitals in Group B. There was a statistically significant difference (P<.05) in all parameters that measured the clinical status of the newborns at admission, between those referred from the county hospitals in Group A, and those referred from the county hospitals in group B. The all-cause in-hospital mortality rate was 3.2% in Group A, and 28.6% in Group B

(P<.001). The median duration of hospital stay was 11 (IQR=8, 17) days in Group A, and 18 (IQR=9, 28) days in Group B. Statistically significant predictors of neonatal mortality were weight at admission (< 2500g) (Hazard Ratio: 0.118; 95%CI: 0.016-0.888; P<.05), and Respiratory Rate (> 60 breaths/minute) (Hazard Ratio: 3.221; 95%CI: 1.078-9.626; P<.05). Overall, the structured SOP significantly improved the outcomes of newborn with surgical conditions, referred and transported to MTRH. However, the newborns had delay in accessing neonatal surgical care; and the majority of their mothers had sub-optimal antenatal care during pregnancy despite the apparent high health-facility delivery.

CHAPTER ONE

INTRODUCTION

1.1 Background information

Globally, maternal and neonatal health is a key determinant of sustainable development as envisaged by the WHO in 1990. The focus of the fourth Millennium Development Goal was to reduce the under–five mortality rates by two thirds between 1990 and 2015 (Ambey & Gupta, 2014). Despite failure to meet this target by most nations, it still remains an important component of the world's new global agenda in the Sustainable Development Goals whose targets are to be achieved by 2030 (UNICEF, 2015).

However, the trends on child survival have been on the rise globally with most interventions having their highest impact on reducing the post-neonatal mortality rate. In order to maintain and further improve child survival, the focus on newborn care is gradually becoming critical since the share of all under-five deaths that occur in the neonatal period (the first 28 days of life) is increasing (Wardlaw *et al*, 2014).

In Kenya, the under-five mortality rate is 52 deaths per 1000 live births, with nearly 35% of the under-five deaths occurring during the neonatal period. Whereas the under-five mortality rates have reduced tremendously over the last 12 years, the reduction in neonatal mortality rates has been marginal (Mmbaga *et al*, 2012; KDHS, 2014). The gains made in reducing the under-5 mortality in Kenya have been largely due to programs in childhood immunization, exclusive breast feeding and malaria prevention. Programs that focus on newborn health have hardly been given due emphasis in the health sectors of both the national and county governments. Figure 1.1 shows the global causes of under-5 mortality, with newborn deaths contributing 46%.

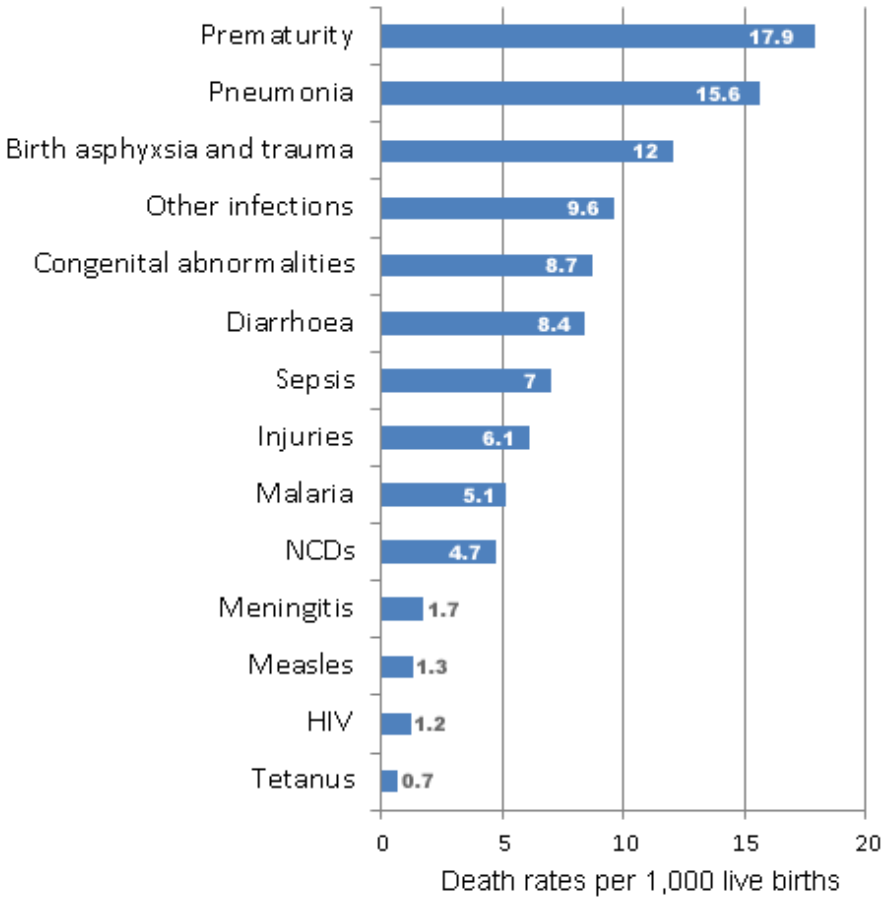

Figure 1.1: Causes of Deaths among Children under 5 years, globally, 2016. (Source: WHO-MCEE methods and data sources for child cause of death 2000 – 2016)

The incidence of congenital malformations, which are a major cause of neonatal mortality, varies with geographical regions but it is estimated that 3 – 7% of children are born with structural birth defects worldwide (Carmona, 2005). In the United States of America, congenital malformations reportedly affect 2 – 5% (Sekhobo & Druschel, 2001). In Asia, the reported incidences in India and China are 2.5% and 1.5% respectively (Parmer *et al*, 2010). A few hospital-based studies in Africa have reported incidences of 1.5% in Egypt and 2.5% in East Africa (Muga *et al*, 2009; Ndibazza *et al*, 2011; Shawky & Sadik, 2011). However, the incidences particularly in the Sub-Saharan African countries are underestimated due to absence of birth defect registries, poor diagnostic capabilities and unreliable medical records.

Many of these congenital malformations are life threatening, and are only amenable to operative intervention. With the WHO estimating that approximately 10% of all neonatal deaths in Sub-Saharan Africa and Southern Asia are due to congenital malformations, neonatal surgery therefore demands priority from the public health perspective (Paul & Singh, 2004).

Neonatal surgery is a highly specialized and perhaps the most sophisticated field of paediatric surgery that deals mainly with surgical correction of congenital anomalies, many of which would be fatal if not corrected. Other surgical conditions targeted by neonatal surgery include complications that arise from newborn infections and trauma. Modern neonatal surgery is still a very new field as the first neonatal surgical unit was established in Liverpool, UK, in 1953 (Rickham, 1992). Thereafter, many such specialized centres were gradually established world over. With improved understanding of the neonatal physiology and the development of the concept of surgical neonatal intensive care units (NICU), survival of newborns with surgical conditions started improving.

In Africa, the outcomes of neonatal surgery are scantly documented, with units in northern African countries as well as South Africa reporting better surgical outcomes. In Kenya, Kenyatta National Hospital was the only centre that was offering neonatal surgery for over three decades until a second paediatric surgery unit was established at Moi Teaching and Referral Hospital in 2003 (Kyambi, 1990).

1.2 Statement of the Problem

The burden of surgical conditions in newborns in low/middle income countries (L/MICs), and hence their outcomes, are largely unknown due to paucity of population-based research. These conditions include congenital malformations, surgically-treated-infections, and trauma. Studies indicate that congenital malformations alone comprise 9% of the global disease burden (Poenaru *et al*, 2015) and that 10% of the neonatal deaths in L/MICs are due to congenital malformations (Paul & Singh, 2004). Moreover, 6.2% to 8.9% of all admissions to the Newborn Units of the tertiary-level hospitals in L/MICs are due to surgical conditions (Ameh

et al, 2001; Ilori *et al*, 2013; Opara *et al*, 2014). Besides, 30% of the newborns transported to MTRH are referred for surgical care (Ikol *et al*, 2019).

Studies further indicate that neonatal mortality, an important indicator of neonatal health, accounts for between 35% and 50% of the under-five mortality rates in L/MICs (Muga *et al*, 2009). In Asia and Africa, neonatal deaths attributable to surgical conditions range from 24% to 62.2% (Tenge-Kuremu *et al*, 2007; Ilori *et al*, 2013). Regrettably, these surgical conditions are only amenable to neonatal surgical care, which in Kenya is only feasible in the two tertiary-level hospitals, one each in Eldoret and Nairobi, hence the need for proper referral and transport. Lack of ideal element of newborn transport is a major gap in the provision of holistic surgical care. Whereas the exact contribution of newborn transport characteristics to the overall neonatal mortality is unknown, a few studies have reported mortality rates of 25% – 35% in sick newborns transported to tertiary-level hospitals for care (Singh *et al*, 1996; Seghal *et al*, 2001; Basu *et al*, 2008).

Therefore, a study on the effect of appropriate referral and transport of newborns with surgical conditions on their outcomes in a resource-limited setting, more specifically in Kenya, was worthwhile.

1.3 Justification of the study

Globally, neonatal mortality has been demonstrated to contribute significantly to the under-five mortality rate (Wardlaw *et al*, 2014), and 10% of the neonatal deaths in L/MICs are due to surgical conditions (Ilori *et al*, 2013). Major contributors to neonatal deaths in L/MICs are captured in a 3-delay model that includes improper transport of the sick newborns during referral to tertiary-level hospitals for specialized care (Lawn *et al*, 2005). Despite the introduction of guidelines on referral and inter-facility transfer of sick neonates by WHO in 2003 (WHO, 2003), Kenya's public health sector has no existing policy on organized newborn transport (Kenyan Ministry of Health, 2014). Moreover, locally domesticated standard protocols on this important element of newborn care are lacking at the tertiary-level and county

hospitals in Kenya, and the impact of organized transport of newborns with surgical conditions on their outcomes has not been documented.

Hence the need to establish and document the effect of introducing a structured Standard Operating Procedure (SOP) for transport of newborns with surgical conditions (Appendix I) in the larger western region of Kenya. It is likely that the structured SOP for newborn transport had a positive impact on the outcome of newborns who seek surgical care at the Moi Teaching and Referral Hospital. Moreover, the outcome of this study may guide formulation of national and regional policies on referral and transport of newborns with surgical conditions in Kenya, with the view to reducing neonatal mortality rate and improving child survival in line with the Sustainable Development Goal 3 which is to: "ENSURE HEALTHY LIVES AND PROMOTE WELL-BEING FOR ALL AT ALL AGES" (Howden-Chapman *et al*., 2017, pp. 81-126).

1.4 Research questions

1. What are the referral, clinical, and transport characteristics of newborns with surgical conditions referred to and treated at the Moi Teaching and Referral Hospital?
2. What are the outcomes of newborns with surgical conditions referred to and treated at the Moi Teaching and Referral Hospital?
3. What are the predictors of mortality in the newborns with surgical conditions referred to and treated at the Moi Teaching and Referral Hospital?
4. What is the effect of introducing a structured SOP for transport of newborns with surgical conditions on their outcomes at the Moi Teaching and Referral Hospital?

1.5 Study Objectives

1.5.1 Broad Objective

To evaluate the outcomes of newborns with surgical conditions, referred to and treated at the Moi Teaching and Referral Hospital, in the context of a structured SOP for transporting newborns.

1.5.2 Specific Objectives

1. To establish the referral, clinical, and transport characteristics of newborns with surgical conditions referred to and treated at the Moi Teaching and Referral Hospital.
2. To determine the outcomes of newborns with surgical conditions referred to and treated at the Moi Teaching and Referral Hospital.
3. To determine the predictors of mortality in the newborns with surgical conditions referred to and treated at the Moi Teaching and Referral Hospital.
4. To determine the effect of introducing a structured SOP for transport of newborns with surgical conditions on their outcomes at the Moi Teaching and Referral Hospital.

1.6 Study assumptions and limitations

The study assumed that:

- The simple random sampling of the referring county hospitals that were included in the study yielded a study sample that is representative of the study population.
- The confounders that may have arisen from the inability to evaluate the pre-transfer clinical status of the referred newborns and compare it to their clinical status at admission were distributed equally among the participants in both the intervention and the control groups to enhance the internal validity of the study.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

Maternal and neonatal health has become an important public health concern both locally and globally (Ambey & Gupta, 2014). Hence, significant contribution of newborn care to improvement of child survival can no longer be ignored by any health department. Newborn care is gradually becoming a critical component of health care systems world over. It is reported that more than 4 million newborns die globally every year, with more than 98% of these deaths occurring in L/MICs (Lawn *et al*, 2005). The highest risk of newborn deaths is in Sub-Saharan Africa, and Kenya is among the 10 countries that contribute to most of these mortalities (Oza *et al*, 2014). Whereas the global neonatal mortality rate is 19 per 1000 live births, many countries in the Sub-Saharan Africa and Asia report much higher neonatal mortality rates, with India reporting 35 per 1000 live births (Narang *et al*, 2013) and Kenya reporting 22.9 per 1000 live births (KDHS, 2014). A retrospective audit at the MTRH reported an early neonatal mortality rate of 68 per 1000 live births (Yego *et al*, 2013).

Whereas the 3 leading causes of neonatal mortality in Kenya still remain birth asphyxia, birth trauma and prematurity, surgical conditions are increasingly becoming important (WHO, 2015). Figure 2.1 shows the causes of neonatal mortality in Kenya in 2015.

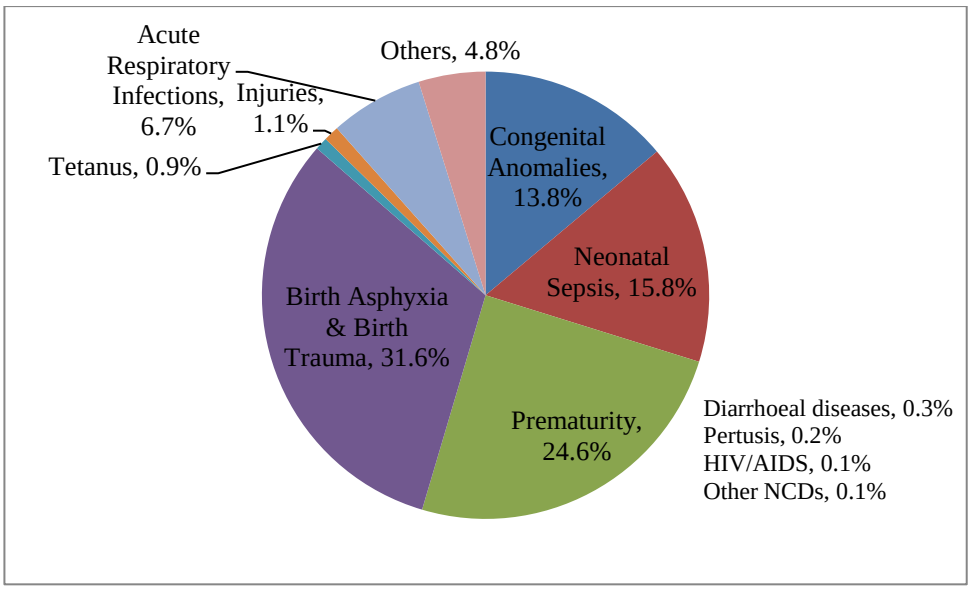

Figure 2.1: Kenya – Causes of Neonatal Mortality, 2015. (WHO, 2015)

2.2 The burden and Spectrum Surgical Conditions in the Newborn

Surgical conditions in the newborn comprise a broad range of diseases in which surgical care plays a role. These include congenital malformations, surgically treated infections and trauma. Whereas the WHO indicates the main causes of neonatal mortality as birth asphyxia, birth trauma, prematurity and neonatal infections (Ambey & Gupta, 2014), surgical disease burden in the newborn remain a silent but significant contributor to these deaths.

The burden of neonatal surgical diseases in L/MICs in general and Kenya in particular is largely unknown due to paucity of data. Retrospective studies at tertiary-level hospitals in Nigeria reported that newborns with surgical conditions comprised between 6.2% and 8.9% of all the admissions in the Newborn Units (Ameh *et al*, 2001; Irori *et al*, 2013; Opara *et al*, 2014). Moreover, the WHO estimates that approximately 10% of the neonatal deaths in Sub-Saharan Africa and South Asia are due to congenital malformations (Chirdan *et al*, 2012).

A survey among paediatric surgeons working in Africa indicates that 10% to 20% of their workload results from newborn surgery (Chirdan *et al*, 2010). A report on clinical characteristics of neonatal surgical conditions seen at a tertiary-level hospital in Egypt reported the order of the spectrum of neonatal surgical conditions as ano-rectal malformations (ARM), oesophageal atresia, congenital diaphragmatic hernia, and Hirschsprung's disease (Chirdan *et al*, 2012). Moreover, a slight variation was reported in a hospital-based study done at MTRH, Eldoret, Kenya, that revealed a different order of the spectrum of neonatal surgical conditions, in which gastroschisis (Plate 2.1), neural-tube defects, and ARM were leading (Ikol *et al*, 2019).

Plate 2.1: A newborn with gastroschisis (Source: PW Saula, 2018)

2.3 Newborn Surgery and the Role of Newborn Transport

Newborn surgery is an integral part of newborn care that is essentially driven by need for specialist intervention. It demands advanced operating theatres and newborn

intensive care facilities as well as highly trained personnel. The conditions that require surgery in the newborn are largely congenital with anorectal malformations, intestinal atresia and abdominal wall defects forming the majority (Ameh *et al*, 2015). The others include the complications that arise from birth trauma and surgically treated neonatal infections.

Due to scarcity of specially-equipped operating theatres, Newborn Intensive Care Units (NICU), and specially-trained surgeons, newborn surgical service is regionalized in many centres world over (Paul & Singh, 2004). In Kenya, newborn surgery is only feasible in the two tertiary-level hospitals, hence, referral and transport of newborns with surgical conditions to these centres for care is a necessity.

Inter-healthcare facility transport of sick newborns is crucial given that between 60% and 97.8% of newborns with surgical conditions are either born at home or in rural health facilities that are ill-equipped to adequately manage their conditions (Tenge-Kuremu *et al*, 2007; Osifo & Oriaifo, 2008; Ilori *et al*, 2013). These newborns therefore have to be referred and transported to specialized neonatal surgical units in tertiary-level hospitals for care.

Furthermore, studies have shown that improper referral and transport of newborns with surgical conditions can result in deterioration of their clinical status, which impacts directly on their morbidity and mortality (Ashokcoomar & Naidoo, 2016). Therefore, improper referral and transport of these newborns with surgical conditions is likely to be a major contributor to the high mortality rates reported by many tertiary-level hospitals in Sub-Saharan Africa and South Asia (Tenge-Kuremu *et al*, 2007; Osifo & Oriaifo, 2008; Ilori *et al*, 2013; Ugwu & Okoro, 2013). Hospital – based studies have reported mortality in newborns referred and transported to tertiary-level hospitals for specialized care that range from 18.3% (Sachan *et al*, 2016) to 32.2% (Buch *et al*, 2012). Important predictors of neonatal mortality among the referred newborn include low birth weight, prematurity, hypothermia, hypoperfusion and severe respiratory distress (Buch *et al*, 2012; Pan, 2017). Others include delay in referral, long duration of transport and delivery by unskilled birth attendant (Aggarwal *et al*, 2015; Sachan *et al*, 2016).

Similarly, inappropriate patient transport for these sick newborns is a major determinant of their survival (Tenge-Kuremu *et al*, 2008). Whereas the presumed mode of road transport for these newborns would naturally be ambulances, hospital-based studies in India reported that only 10.5% to 26.8% of the newborns used road ambulances for their transfer, with the majority using public service vehicles (Aggarwal *et al*, 2015; Sachan *et al*, 2016). Moreover, there was no proper pre-referral stabilization, documentation or communication in 28.6% of the newborns (Buch *et al*, 2012).

In order to improve the outcomes of newborn surgery in the tertiary-level hospitals, there is need to maintain the continuum of care of the newborns during referral and transport. Currently, there is limited research that focuses on referral and transport of newborns with surgical conditions particularly in resource limited settings like Kenya. Moreover, local guidelines and protocols on this important element of newborn care are lacking.

2.4 Principles of Transport of Newborn with Surgical Conditions

Transport of a newborn with a surgical condition involves a pre-transport intensive care level of resuscitation and stabilization with a continuing intra-transport care to ensure that the baby arrives at the tertiary-level hospital in a stable condition. In many centres in the High Income-Countries (HICs), organized neonatal transport teams bring the intensive care environment to the critically ill newborn before and during transport. Safe and timely transport of sick newborns is based on proper communication and effective coordination between the referring and receiving hospitals. Proper balance between the anticipated clinical complications that may arise due to delay in definitive specialized care and the benefits of further stabilization must be carefully struck (Hatch *et al*, 1995; Puri & Rolle, 2009).

2.4.1 Special Considerations

The physiology of the newborn is unique with several processes set out to eventually enable them to adapt to a new environment after birth. Hence special considerations must be made during their transport (McCloskey & Orr, 1995).

- Prematurity and neonatal sepsis predispose the newborns to apnea.
- The lungs and the retina of premature newborns are prone to damage by excess oxygen.
- Reversal of fetal circulation that leads to Persistent Pulmonary Hypertension of the Newborn (PPHN) can be precipitated by hypoxia, hypercarbia, acidosis and sepsis.
- The mechanisms of thermoregulation are less developed and the newborn has a larger body surface to mass ratio. Furthermore, non-shivering thermogenesis that is induced by oxidation of the brown fat is poor. If the abdominal viscera are exposed, the heat and fluid loss are compounded by evaporation. The resultant hypothermia leads to acidosis, impaired immune function and delayed wound healing.
- The newborn has low glycogen stores in the liver and low fat deposits thus unable to maintain normal blood sugar levels. They are therefore prone to hypoglycaemia.
- Neonatal jaundice that is a common condition in the newborn can be worsened by neonatal sepsis and intestinal obstruction.

2.4.2 Mode of Transport

Careful consideration must be made in selecting the mode of transport. The best mode would be “in utero” with the mother being advised to deliver in a health facility that also offers neonatal surgical services if antenatal diagnosis of the surgical condition could be made. Once the newborn has been delivered, the pros and cons of road and air transport must be considered on a case-by-case basis. Air transport is often hampered by its availability, affordability as well as the effects of decreased atmospheric pressure on the newborn’s closed body cavities and limited cabin space that would enable the crew to adequately attend to the sick newborn. Road transport, though readily available, is often slow and heavily dependent on the geographical terrain.

2.4.3 Pre-transport Stabilization

Neonatal transport adds significant stress to the newborn whose physiology is already weakened by the surgical condition and prematurity. If not treated adequately, these newborns deteriorate easily during the journey; and the presence of hypothermia, hypotension and metabolic acidosis have significant negative impact on their overall outcome. Furthermore, it is virtually impossible to do any meaningful procedures during transportation hence pre-transport stabilization is critical in ensuring survival of the newborn. The principles of pre-transport stabilization of the newborn must be based on the standard ABC's of newborn resuscitation that includes fluid therapy, oxygen supplementation and administration of resuscitative drugs. All equipment must be checked for completeness and function before leaving the hospital (Hatch *et al*, 1995; Puri & Rolle, 2009).

2.4.4 Communication

Proper communication between the referring clinician, the transport team and the paediatric surgeon at the tertiary-level hospital is a key ingredient of effective neonatal transport that ensures good coordination of the transport, adequate pre-transport stabilization, appropriate timing of referral and adequate preparedness of the receiving hospital (Hatch *et al*, 1995; Puri & Rolle, 2009). This can either be verbal or written or both and should include:

- Name and phone contact of the referring clinician.
- Patient's details/ history/ physical findings/ provisional diagnosis/ investigations.
- Current management and status of the baby.
- Mode of transport/expected times of departure and arrival at the tertiary-level hospital.
- Destination of the patient (Newborn Unit/ NICU).

2.4.5 Documentation and Specimens

Documentation is important in further reinforcing communication. The documents to be delivered with the baby to the tertiary level-hospital include all the above plus previous operation notes, input/output charts and results of laboratory and radiological investigations. Informed consent signed by the parents especially in a situation where the baby may require an emergency surgery and parents are not escorting is important. The mother's blood specimen for cross-matching as well as any other specimens collected from the newborn prior to transfer must be sent during transport (Lupton & Pendray, 2004).

2.4.6 Warmth

A thermo-neutral environment is an environmental temperature at which an infant can sustain a normal body temperature with minimal metabolic activity and oxygen consumption. Newborns' optimal body temperature ranges between 36.5^0C and 37.0^0C. The mechanisms of heat loss include conduction, evaporation, convection and radiation, hence maintaining ambient temperature as well as covering the exposed body surfaces will minimize heat loss (Mathur *et al*, 2005). Use of a transport incubator (Plate 3.2) would be ideal, but the baby can also be wrapped with aluminum foil (Plate 3.2), polythene bag or cotton wool (Saluja *et al*, 2011). Use of Kangaroo mother care has been linked to reduction of newborn mortality (Conde-Agudelo & Diaz-Rossello, 2016). Care of the exposed body membranes e.g. herniating viscera in gastroschisis; and administering warm fluids are vital in maintaining a thermo-neutral environment (Lupton & Pendray, 2004).

2.4.7 Tubes

Insertion of an oro-gastric/naso-gastric tube is mandatory in almost all newborns with surgical conditions (Puri & Rolle, 2009). The oral route is preferred as a more efficient larger bore tube can be inserted without compromising the nasal passages as newborns are obligatory nasal breathers. However, the oro-gastric tube can easily dislodge and the position must be checked regularly. In addition, it has to be aspirated hourly to ensure its optimum function.

The other tubes that include endotracheal tube, thoracostomy, drains and urinary catheters if present must be secured well. Extra precaution must be taken particularly when handling the newborn to prevent dislodgement of these tubes (Lupton & Pendray, 2004).

2.4.8 Care during transport

The ideal escort should be a specialized neonatal transport team but a medical doctor and/ or neonatal trained nurse can still suffice. The team should be familiar with resuscitation and care of the neonate and be able to handle critical incidents (King *et al*, 2007). The safety of the escort team and the parents must be given a priority.

Regular monitoring of the newborn's vital signs, oxygenation and perfusion must be performed (Chance *et al*, 1978). Intravenous fluids must be given to prevent dehydration and acidosis during transport. Fluid boluses need to be given as necessary depending on the assessment of perfusion. If urinary catheter is in situ, the urine output must be monitored and the oro-gastric tube must be aspirated as required (Puri & Rolle, 2009).

To maintain optimum thermoregulation, regular check on the newborn's body temperature must be conducted, and any wet clothes must be changed. Disposable diapers and one-way nappy liners are handy.

Critical incidents that can cause loss of life may be minimized by proper pre-transport stabilization (Saluja *et al*, 2011). These incidents include loss of airway due to blocked/ dislodged endotracheal tubes, exhausted oxygen supply, loss of intravenous access, deterioration in patient's clinical condition and injury to the patient/parent/co-worker. The other specific procedures would be applied as per the guidelines on care of specified neonatal surgical conditions. Figure 2.2 indicates the key pillars of newborn transport as incorporated into the structured SOP.

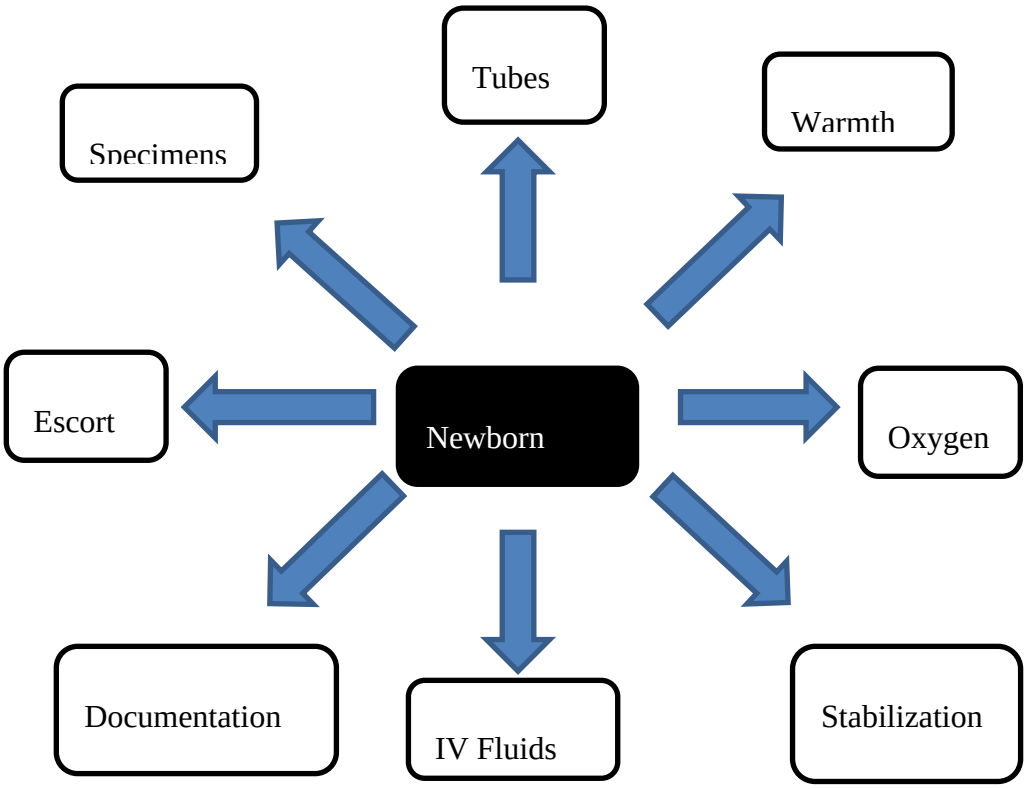

Figure 2.2: Key components of the structured Standard Operating Procedure for transport of sick newborns. (Hatch et al, 1995; Puri & Rolle, 2009).

2.5 The structured SOP for Transport of Newborns with Surgical Conditions

The main objective of this study was to assess the effect of a structured Standard Operating Procedure (SOP) for newborn transport (Appendix I) on the outcome of referred newborns with surgical conditions. The SOP was adopted from the WHO's guidelines on transfer and referral of sick neonates (WHO, 2003). The burden that maternal and neonatal ill health poses on the development of individuals, communities and societies attracted the attention of world leaders who had to adopt specific goals and targets to reduce maternal and childhood-infant mortality as part of the Millennium Declaration and later Sustainable Development Goals (Howden-Chapman *et al*, 2017; UNICEF, 2015). With the realization that many conditions that result in perinatal deaths can be prevented or treated without sophisticated and

expensive technology, education of clinicians on simple but critical interventions for the newborn during the first days of life became necessary. A guide to achieve this was then developed by the WHO in collaboration with UNFPA, UNICEF and World Bank with a common understanding of the key elements in reducing newborn deaths. The aspects that deal with the newborns were further reviewed and endorsed by the International Pediatric Association (Appendix V).

2.6 Outcomes of Newborns with Surgical Conditions

Neonatal deaths attributed to the surgical conditions in hospital - based studies in Sub-Saharan Africa range from 24% in Kenya (Tenge-Kuremu *et al*, 2007) to 62.2% in Nigeria (Ilori *et al*, 2013), thus contributing immensely to the overall neonatal mortality. A retrospective audit in a tertiary-level hospital in Nigeria reported that deaths due to neonatal surgical conditions contributed 11.8% of the overall neonatal mortality in the Newborn Unit (Ugwu & Okoro, 2013). These high mortality rates are often attributed to a 3-delay model that includes the delay in recognition of the severity of the illness, the delay in seeking and accessing care, and the delay in the provision of care once at the health facility (Lawn *et al*, 2005). This 3-delay model was developed by *Thadeus and Maine* while exploring the causes of maternal deaths, and has further been explored in analyzing perinatal deaths in L/MICs and found to be useful (Mbaruku *et al*, 2009; Waiswa *et al*, 2010). Whereas the delay in recognition of the severity of the neonatal surgical condition would solely depend on the peoples' health seeking behavior and the competence of the primary healthcare providers, the delay in accessing care is determined by the adequacy of functional neonatal referral and transport system among other factors.

The exact contribution of improper newborn transport characteristics to the overall neonatal mortality rate is unknown, but a few hospital-based studies have reported mortality rates of 25% - 35% in sick newborns transported to tertiary-level hospitals (Singh *et al*, 1996; Seghal *et al*, 2001; Basu *et al*, 2008). A study conducted in Argentina found the transported newborns to have a mean birth weight of 2482 ± 904 g and a median age of 2 days. It further found that 57% of the transported newborns

suffered clinical deterioration, and 45% had hypothermia during transport (Goldsmit *et al*, 2012). Several studies reported mortality rates among the newborns transported to tertiary-level hospitals for specialized care, which ranged from 18.3% to 36% (Seghal *et al*, 2001; Narang *et al*, 2013; Aggarwal *et al*, 2015; Sachan *et al*, 2016).

2.7 Predictors of Newborn Mortality

Pre-transport stabilization and optimal care during transport are the key pillars of care during transfer of newborns with surgical conditions. Evidence has associated hypothermia, hypoglycemia, hypovolaemia, and hypoxia with high mortality rates in transported newborns (Pan, 2017). Basu *et al* (2008) found mortality rate to be inversely related to gestational age, birth weight, and duration of transport.

Other significant predictors of mortality in transported newborns include delivery conducted by unskilled birth attendant, low birth weight, long duration of transport, poor oxygenation and delayed capillary refill time (Sachan *et al*, 2016). Rao *et al* (2015) reported the determinants of mortality of transported newborns as weight at admission less than 2000 g, prematurity, duration of transport more than 2 hours, hypoxia and delayed capillary refill time.

2.8 Adherence to Newborn Transport Norms and Guidelines

The ideal mode of transport would be *In Utero* with the mother being advised to deliver in the health facility that also offers neonatal surgical care. Unfortunately, preterm delivery, perinatal conditions and congenital malformations cannot always be anticipated, hence the continued need for transfer of newborns after delivery. Studies have shown that improper referral and transport of newborns with surgical conditions results in deterioration of their clinical status, with direct impact on their survival (Goldsmit *et al*, 2012; Ashokcoomar & Naidoo, 2016). Although the WHO published guidelines on referral and transfer of sick neonates in 2003 (WHO, 2003), domesticated local protocols on this important element of newborn care are still lacking in Kenyan hospitals.

Previous studies in L/MICs have variedly reported nonconformity to existing norms and guidelines on newborn transport. A study done in Brazil found a 29.3% low- and 46.7% average- conformity rate to the existing newborn transport norms (Albuquerque *et al*, 2012). Butt *et al* (2008) in Pakistan found that only 11.1% of the referred newborns had referral letters, further undermining communication as an important pillar of newborn transport. In Turkey, Mutlu and Aslan (2011) found common errors before and during newborn transport to be absence of intravenous lines and inadequate respiratory support. In South Africa, Hadley and Mars (2001) noted that 19% of the transported newborns with surgical conditions had oro-/naso-gastric tubes that were either connected to spigots or knotted which rendered them nonfunctional. In Kenya, the only existing policy on patient referral is largely silent on the referral and transport of newborns with surgical conditions (Kenyan Ministry of Health, 2014).

Training programs on newborn transport have been shown to improve their outcomes at tertiary-level hospitals. Kumar *et al* (2011) noted significant improvement in the clinical status of the newborns at admission following an intervention on pre-transport stabilization by a specialized neonatal transport service. Spector *et al* (2009) in Panama, and Martínez *et al* (2011) in Mexíco, further demonstrated improvements in the outcomes of transported newborns at the tertiary-level hospitals that directly resulted from the implementation of neonatal provider educational programs - *Sugar and Safe Care, Temperature, Airway, Blood, Lab work, and Emotional support* (S.T.A.B.L.E.) and newborn transport guidelines.

This study therefore set out to establish the outcomes of newborns with surgical conditions at Moi Teaching and Referral Hospital, and determine the effect of a structured SOP for newborn transport on their outcomes.

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Site

This study was carried out in the Newborn Unit of the Moi Teaching and Referral Hospital which is located in Uasin Gishu County in the North Rift region of Kenya. The Moi Teaching and Referral Hospital is the second largest referral hospital in Kenya. It serves the greater western Kenya region that include North Rift, Western, and Nyanza regions, with a population of approximately 16.2 million, which is about 40% of the country's population. It also serves the eastern parts of Uganda and South Sudan. The Newborn Unit receives referrals from 22 county referral hospitals in the region (Ikol *et al*, 2019). In this study, each referral county hospital constituted a cluster.

The 10 county hospitals (clusters) that were randomly selected for the study included Kapenguria County Referral Hospital, Kitale County Referral Hospital, Kapsabet County Referral Hospital, Bungoma County Referral Hospital, Kericho County Referral Hospital, Kisii County Referral Hospital, Busia County Referral Hospital, Iten County Referral Hospital, Webuye Sub-County Hospital and Jaramogi Oginga Odinga Teaching and Referral Hospital. Four of these county hospitals serve counties in the North Rift region, 1 in the South Rift region, 3 in the Western region and 2 in the Nyanza region; all serving a total population of approximately 7.5 million.

All the selected clusters (hospitals) were classified as the third tier of care (Level 4 &5) in Kenya's health care system. This category of hospitals shared similar characteristics, which included infrastructure indicators, equipment indicators, and the distribution of healthcare workforce (Barker *et al*, 2014). They provided both outpatient and inpatient services and are staffed with doctors, clinical officers, and nurses (Gitonga, 2013). The general care of newborns in these healthcare facilities is utmost rudimentary, and none has the capacity to provide newborn surgical care.

The selected county hospitals were further randomly allocated into 2 groups of 5 hospitals each. Group A had Kapenguria County Referral Hospital, Bungoma County Referral Hospital, Kisii County Referral Hospital, Busia County Referral Hospital and Iten County Referral Hospital. Group B had Kitale County Referral Hospital, Kapsabet County Referral Hospital, Kericho County Referral Hospital, Webuye Sub-County Hospital and Jaramogi Oginga Odinga Teaching and Referral Hospital.

The study sites in Group A were used for the intervention and those in Group B were used as control.

3.2 Study design

This was a three-year *Cluster-Randomized-Controlled Trial* which was based on *Post-Test–Only Control-Group* design, an interventional study. The choice of this study design was particularly informed by the nature of the intervention, which was an educational program (Dron *et al*, 2021). The structured SOP was a clinician-targeted intervention that intended to modify clinicians' practices on transport of newborns with surgical conditions. Hence, this study design was deemed the most suitable and practicable for achieving this goal. This study further intended to capture the indirect effect of this public health intervention which was deemed more important (Hayes & Moulton, 2017). Therefore, the outcome of interest was the impact of the structured SOP on the clinical outcomes of newborn surgical care, rather than the clinicians. The study design provided an effective way of avoiding contamination, by enabling the intervention to be done in cluster units, rather than individual units. The selection bias and the imbalance between the comparative arms that are known limitations of this study design were mitigated by blinding the research assistants who were enrolling the study participants at the Newborn Unit of the MTRH (Donner & Klar, 2004) and by strict adherence to intent-to-treat principle during data analysis.

Ten clusters (county hospitals that refer newborns with surgical conditions to the Moi Teaching and Referral Hospital) were selected by simple random sampling and randomly allocated into two groups (Group A and Group B) of 5 hospitals each.

The intervention in this study was the introduction of a structured SOP for transporting newborns with surgical conditions (Appendix I), which was targeted at both the clinicians and the healthcare delivery system, with the view to impacting on the clinicians' practices on this crucial element of perinatal healthcare delivery, and subsequently on the patient outcomes.

The structured SOP was introduced in the Newborn Units and Labour Wards of the referring hospitals in the intervention group (Group A). Hence, the newborns referred from the county hospitals in Group A were enrolled into the experimental group while those referred from the county hospitals in Group B were enrolled into the control group.

3.3 Study population

The study population comprised all newborns with surgical conditions referred to and seen in the Newborn Unit of the Moi Teaching and Referral Hospital, during the study period.

3.3.1 Inclusion criteria

All newborns (infants whose age is ≤ 28 days), with surgical conditions, that had been referred and transported to the Newborn Unit from the 10 county hospitals that had been selected for the study.

3.3.2 Exclusion criteria

- Newborns with surgical conditions that needed further transfer to another facility.
- Newborns with surgical conditions who had already had surgical treatment at the referring county hospital.
- Newborns with congenital malformations or syndromes that could not be corrected at the Moi Teaching and Referral Hospital.

3.4 Sample size determination

Since the pragmatic outcome of interest in this study was hospital neonatal mortality, an adequate sample size was considered as that that could compare two proportions (neonatal mortality rates in Group A and Group B). Hence, the standard error of the difference of the two proportions was: $\sqrt{\frac{\bar{p}(1-\bar{p})}{n_1}+\frac{\bar{p}(1-\bar{p})}{n_2}}$

Data from a similar study reported a mortality rate of 32.2% among referred sick neonates (Buch *et al*, 2012). With an assumption of equal sample size and that under the null hypothesis the mortality rate in Group A and Group B is 0.322, then the standard error of the difference:

s.e. (diff) = $\sqrt{.322/n}$

With 80% power to detect a 20% difference in the mortality rates in Group A and Group B,

$$Z_{power} = \frac{\text{test statistic}}{\text{s.e.(test statistic)}} - Z_{\alpha/2}$$

$$\boldsymbol{Zpower = \frac{0.20}{\sqrt{.322/n}} - 1.96}$$

Therefore, for 80% power,

$$\boldsymbol{n = \frac{.322(.84+1.96)^2}{.20^2} = 63}$$

Therefore, enrollment of 63 participants into experimental group (Group A) and 63 participants into the control group (Group B) was able to achieve 80% statistical power. The total sample size therefore was 126 participants.

3.5 Sampling method

The study used a multistage sampling method to select both the clusters (county hospitals) and the study participants (newborns with surgical conditions) to be included into the study. Ten clusters (county hospitals that refer newborns with surgical conditions to the Moi Teaching and Referral Hospital) were selected by simple random sampling from a sampling frame of 22. The selected hospitals were randomly allocated into two groups (Group A and Group B) of 5 hospitals each.

From a previous study, the sampling frame comprised 22 county hospitals that refer and transport newborns with surgical conditions to the Moi Teaching and Referral Hospital. These included Kitale County Referral Hospital, Bungoma County Referral Hospital, Kisii County Referral Hospital, Kapsabet County Referral Hospital, Kericho County Referral Hospital, Mbale County Referral Hospital, Lodwar County Referral Hospital, Kisumu County Referral Hospital, Webuye Sub-County Hospital, Busia County Referral Hospital, Nakuru County Referral Hospital, Kakamega County Referral Hospital, Homabay County Referral Hospital, Nandi Hills Sub-County Hospital, Nyamira County Referral Hospital, Kabarnet County Referral Hospital, Iten County Referral Hospital, Siaya County Referral Hospital, Kapenguria County Referral Hospital, Narok County Referral Hospital, Migori County Referral Hospital, and Jaramogi Oginga Odinga Teaching and Referral Hospital (Ikol *et al*, 2019).

The random sampling of the clusters was done by writing the names of all the 22 county hospitals that refer newborns with surgical conditions to the Moi Teaching and Referral Hospital on separate pieces of paper that were folded, placed into a hat and thoroughly mixed. A research assistant then randomly picked 10 pieces of paper from the hat.

The 10 clusters (county hospitals) that were selected included Kapenguria County Referral Hospital, Kitale County Referral Hospital, Kapsabet County Referral Hospital, Bungoma County Referral Hospital, Kericho County Referral Hospital, Kisii County Referral Hospital, Busia County Referral Hospital, Iten County Referral

Hospital, Webuye Sub-County Hospital and Jaramogi Oginga Odinga Teaching and Referral Hospital.

The selected clusters (county hospitals) were further randomly allocated into 2 groups of 5 hospitals each. This was done by writing the names of each of the 10 hospitals on separate pieces of paper that were placed into a hat and thoroughly mixed. The research assistant then randomly picked 5 pieces of paper with the hospital names that were allocated into the intervention group (Group A). The remaining 5 pieces of paper had the names of the hospitals that were allocated to the control group (Group B).

Thus, the intervention group (Group A) had Kapenguria County Referral Hospital, Bungoma County Referral Hospital, Kisii County Referral Hospital, Busia County Referral Hospital and Iten County Referral Hospital. The control group (Group B) had Kitale County Referral Hospital, Kapsabet County Referral Hospital, Kericho County Referral Hospital, Webuye Sub-County Hospital and Jaramogi Oginga Odinga Teaching and Referral Hospital.

The clusters (county referral hospitals) had shared characteristics. They all belonged to the third tier of care in the Kenya's health care system that provides county referral health services (Levels 4 and 5). Hence, they had similar infrastructure and equipment indicators, as well as the distribution of healthcare workforce (Barker *et al*, 2014). However, none of the hospitals provided newborn surgical care due to lack of specially equipped operating rooms, unavailability of specially trained surgeons, and lack of Newborn Intensive Care (NICU) facilities.

Since the clusters had already been sampled by simple random sampling and randomized into the 2 groups, the study participants (newborns with surgical conditions) who met the inclusion criteria were enrolled consecutively until the sample size of 63 was attained in each group.

3.6 Study Tools and Procedures

3.6.1 Training of clinicians on the structured Standard Operating Procedure (SOP)

The study intervention was done in all clusters (county hospitals) in Group A. A structured Standard Operating Procedure (SOP) for transport of newborns with surgical conditions that is based on the principles of neonatal transport (Appendix I) was adopted from the WHO guidelines on transfer and referral of sick neonates (WHO, 2003). It was domesticated to include local innovations and available facilities by incorporating the use of aluminium foil (Plate 3.2), polythene bag, and *Kangaroo Mother Care* to maintain warmth during newborn transport.

Clinicians (health care providers) who included pediatricians, medical officers, clinical officers, nurses and midwives who manage newborns in the Newborn Units and Labour Wards of the county hospitals in Group A were approached by the principal investigator through their respective medical directors. The principal investigator notified them one week prior to the scheduled visit. On the proposed date and time, the team of investigators visited the clinicians working in the Newborn Units/Labour Wards of each of the selected county referral hospitals in Group A. They administered the module on the structured SOP for transport of newborns with surgical conditions by carrying out day-long training sessions (Plate 3.1). The training included both didactic and interactive presentations. In view of the fact that educational interventions have to be sustained in order to achieve greater impact in changing practices, retraining of the clinicians had to be conducted in the selected sites at 3-monthly intervals until the end of the study period. This also catered for an unanticipated turnover of staff at those units.

The training module included a pre-test to assess the clinicians' existing knowledge in transport of newborns with surgical conditions, and thereafter the structured SOP was presented using PowerPoint with detailed explanation on each section. Group discussions were used to further clarify various aspects of the SOP. Thereafter, the clinicians were asked to introduce the structured SOP on transport of the newborns

with surgical conditions in their respective Newborn Units/Labour Wards and apply it on all subsequent newborns that were referred and transported to the Moi Teaching and Referral Hospital. Team leaders were appointed in each study site to co-ordinate and monitor the implementation of the SOP. No intervention was done in the hospitals in Group B. The study participants enrolled from all the hospitals in Group B were used as the control. Figure 3.1 illustrates the flow of the study procedure.

Plate 3.1: A Clinicians' Training Session at Kisii County Referral Hospital (Source: PW Saula, 2018)

Plate 3.2: A Portable Infant Warming Incubator at Kapenguria County Referral Hospital, & a Newborn Wrapped in an Aluminium Foil (Source: PW Saula, 2018)

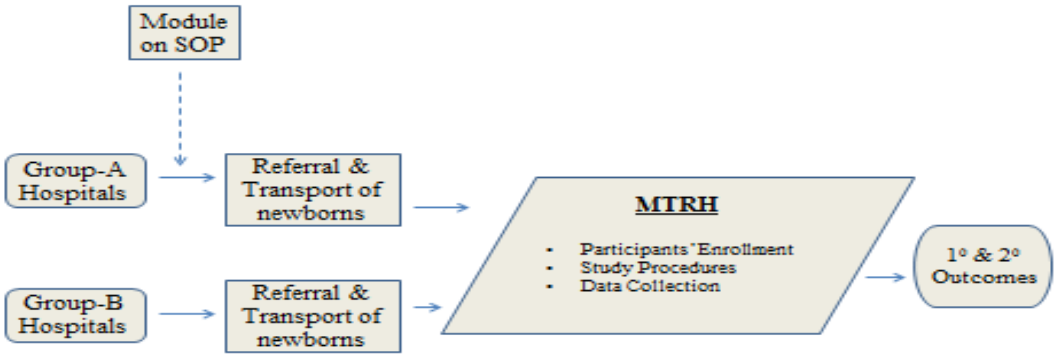

Figure 3.1: Flowchart of the Study Procedure.

3.6.2 Participants' enrolment procedures

The parent(s)/guardian(s) of all the newborns who meet the inclusion criteria were approached at the time of admission of their babies to the Newborn Unit at the Moi Teaching and Referral Hospital. They were informed about the study, the need to participate in it as well as its significance. The study procedures were clearly explained to each parent/guardian. The newborns who met the inclusion criteria were enrolled consecutively into the study once their parent(s)/guardian(s) gave informed consent. Enrollment of the study participants was done by a blinded research assistant in a separate private examination room within the Newborn Unit.

3.6.3 Clinical evaluation of the study participants at admission

One month after the introduction of the SOP on transport of newborns with surgical conditions at the county referral hospitals in Group A, all the newborns with surgical conditions, who were referred and transported from the selected county referral hospitals, met the inclusion criteria, and whose parents/guardians gave informed consent, were enrolled into the study at their admission into the Newborn Unit of the Moi Teaching and Referral Hospital. The study procedures were explained to the

parent(s)/guardian(s) detailing the purpose, the process and probable side effects. Each study participant underwent a clinical evaluation that was conducted by a designated trained blinded research assistant. All the data obtained was then entered into the data sheet. The clinical evaluation and grading of observed parameters was conducted as per the standard protocols and WHO guidelines on care of the newborns (Klaus & Fanaroff, 2001).

3.6.3.1 Measurement of the body weight

A calibrated tare - infant weighing scale was used to measure the weight of all enrolled participants at admission. With the weighing scale placed on a working table, a warm blanket was placed on the scale and the scale was reset to 0 reading. The newborn was then unwrapped and placed onto the weighing scale and the weight was read and recorded in grams.

3.6.3.2 Measurement of skin temperature

The skin temperature was measured, prior to warming the baby, using a calibrated temporal artery thermometer (Forehead thermometer) that was swiped across the newborn's forehead and the observed temperature was graded as per the WHO guidelines (WHO, 1993). A temperature reading below 36.5^0C was regarded as hypothermia. The grades of hypothermia were as follows: 36^0C – 36.5^0C as mild hypothermia, 32^0C – 36^0C as moderate hypothermia and less than 32^0C as severe hypothermia (WHO, 1993).

3.6.3.3 Assessment of Capillary-Refill-Time

The capillary refill time was measured by pressing pre-sternal area of the newborn using a finger or a thumb for 5 seconds. On release of pressure of the finger or the thumb, the skin colour at the site would appear pale-white and then slowly return to the normal pink colour. The research assistant detected and recorded the time taken for the skin colour to return to normal using a calibrated stopwatch. Delayed capillary refill time was taken as capillary refill time more than 3 seconds (Thakre *et al*, 2010).

3.6.3.4 Assessment of the respiratory rate

With the baby placed on a baby cot and exposed, the respirations were counted for 60 seconds by observing the movements of the chest once the baby was calm and the rate recorded onto the data sheet. Tachypnoea was regarded as any reading above 60 breaths per minute.

3.6.3.5 Measurement of the oxygen saturation (S_PO_2)

With the baby placed on a baby cot, a paediatric finger pulse oximeter was placed on either baby's index finger or the big toe and the S_PO_2 was read and recorded onto the data sheet. S_PO_2 reading less than 90% was regarded as hypoxia.

3.6.3.6 Measurement of Random Blood Sugar

The investigator or research assistant put on clean gloves and cleaned the baby's heel using an alcohol swab. He/she then pricked the baby's heel using a sterile needle and obtained 1 - 2 drops of capillary blood and placed it onto a glucometer strip. Pressure was applied on the puncture wound using an alcohol swab to stop any further bleeding. The strip was then inserted into a glucometer (Deshine® Handheld Glucometer) to obtain the random blood glucose reading. Any reading below 2.5 Mmol/L was regarded as hypoglycaemia (Wight & Marinelli, 2014).

3.7 Study Follow – Up and Monitoring Plan

Threats to the internal validity of this study were minimized by doing the following:

- Follow-up re-trainings of the clinicians on the structured SOP in the study sites where the SOP was introduced were done at 3 months and 6 months into the study. That helped sort out any bias that may have been introduced by the staff movement/turnover in the Newborn Units and Labour Wards of the county hospitals in the intervention group (Group A).
- A Data & Safety Monitoring Board (DSMB) comprising 3 members (consultant neonatologist, neonatal care nurse & a public health specialist)

who were not directly involved in the study was appointed by the *MU/MTRH IREC,* to monitor the implementation of the intervention and its effect on the outcomes on the study participants particularly the adverse effects. However, there were no adverse events in this study hence none was reported to the institutional ethics review committee.

- Two research assistants (a registrar in child health & paediatrics, and a neonatal nurse); both with relevant clinical background in care of newborns were recruited and trained on the study procedures. However, they were blinded to the assignment of the study participants, which was solely done by the principal investigator. The research team further held regular monthly meetings to review the progress of the research and ensure strict adherence to the study procedures.
- The instruments of measurement (Tare-infant Weighing Scale, Forehead thermometer, Pulse Oximeter, Deshine® Handheld Glucometer) were regularly calibrated and used as per the protocol prescribed by the manufacturers and the hospital's maintenance unit.
- The outcome measures that were followed up at 3 monthly intervals included:

    a. The primary outcomes on arrival following the referral and transport of the newborn. This was determined by the clinical status of the newborns at admission to the Newborn Unit of the Moi Teaching and Referral Hospital.
    b. The secondary outcomes after newborns' hospital stay (discharge or death), time to death from admission, and the duration of hospital stay.

3.8 Study variables

3.8.1 Independent variables

- Socio-demographic and maternal characteristics.
- Referral, clinical, and transport characteristics.

3.8.2 Moderating variable

- Introduction of the structured SOP at the 5 selected county hospitals that refer newborns with surgical conditions to the Moi Teaching and Referral Hospital.

3.8.3 Dependent variables

- Primary outcomes - clinical status of the newborn at admission:
  - Body temperature (^{0}C)
  - Respiratory rate (breaths/minute)
  - Capillary-Refill-Time (Seconds)
  - Random blood sugar (Mmol/L)
  - S_PO_2 (%)
  - Need for immediate resuscitation on admission
  - Duration of transport (Minutes)
- Secondary outcomes:
  - All-cause in-hospital mortality rate
  - Time-to-death from admission (Hours)
  - Duration of hospital stay (Days).

3.9 Conceptual Framework

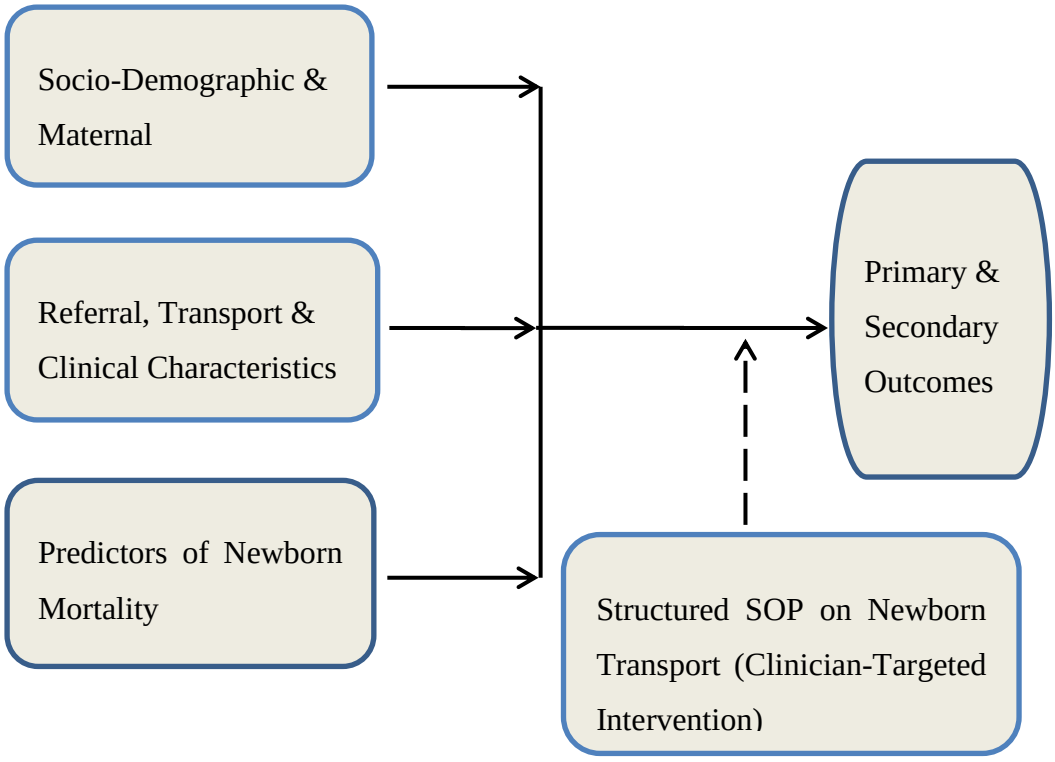

Figure 3.2: Conceptual Framework

3.10 Data Collection

The sources of data included medical records from the referring county hospitals that accompanied the referred newborns; and interviews of the escorting staff and the parent(s)/guardian(s) of the newborns with surgical conditions. This was done for those who met the inclusion criteria and whose parent(s)/guardian(s) gave a written informed consent to participate in the study. The interviews were conducted by the principal investigator and/or the trained research assistant. The data was collected using the data collection tool (Appendix II).

These data included subject number, date and time of birth, age, gender, birth weight, birth order, place of birth, person conducting delivery, mode of delivery, date and time of admission, maternal ante-natal visits, ante-natal investigation – obstetric

ultrasound, referring hospital, reason for referral, mode of transport, mode of communication of the case to MTRH, pre-transport stabilization, care during transport - Nasogastric tube, Warmth, Oxygen, IV fluids, Documentation, Escort and Specimens; surgical diagnosis; and duration of transport. A blinded research assistant carried out a clinical evaluation on the newborns at admission and recorded data on the following: Body temperature (^{0}C), Respiratory rate (breaths/Minute), Capillary-Refill-Time (Seconds), Random blood sugar (Mmol/L), S_PO_2 (%) and need for immediate resuscitation at admission.

Thereafter, the newborns were followed up for secondary outcomes. The primary outcome of interest was the clinical status of the newborns at admission, and the secondary outcome measures included the duration of hospital stay, time to death from admission, and discharge/mortality. Any additional data was sought from the clinicians managing these newborns in the Newborn Unit and filled into the data sheet by the investigator/research assistant. The outcomes of the newborns referred from the two groups of the county hospitals were then compared to assess the effect of the structured SOP.

3.11 Data management and analysis

All the data sheets/data collection tools were carefully checked for consistency and errors before double entry into a data management system – *Microsoft Access* software. It was then cleaned and exported into customized spreadsheets in *STATA* Version 16 data analysis software in a password protected computer. The spreadsheets were customized to include data validation properties. All the entered data were checked by the principal investigator for consistency and validity prior to analysis.

Analysis of the data was conducted using *STATA* version 16. Descriptive statistics that included medians and interquartile ranges were calculated for observations and measures made in each group. The statistical tests used to test for associations between study variables included chi-square test for independence for categorical

variables, and Wilcoxon signed-rank sum test for continuous variables. Fisher's exact test was used to test for associations between categorical variables whose cell counts were ≤ 5. P values < .05 were considered statistically significant. Predictors of neonatal mortality were determined by regression analysis using Cox Proportional-Hazards Model.

3.12 Ethical considerations

This study was designed to assess the outcomes of newborns with surgical conditions in the MTRH, in the context of a structured SOP for newborn transport, with the view to determining its effect on their clinical outcomes. The only intervention that was done was the introduction of the SOP by the trained clinicians at the selected county referral hospitals. Prior to commencement of the study, approval was sought and obtained from the Institutional Research Ethics Committee (FAN: IREC 1861, Appendix IV: i-iv) and the management of the Moi Teaching and Referral Hospital (Appendix IV: v). Permission to visit and carry out training of clinicians in the selected county hospitals was also obtained from their respective managements prior to each scheduled visit.

Data was collected from the newborns' referral records and interviews with the staff escorting the newborn as well as the parent(s)/guardian(s) upon obtaining a written informed consent. All the study participants had clinical evaluation and procedures done at admission to the Newborn Unit of the MTRH, with consent from their parent(s)/guardian(s). This study did not interfere with the treatment of the newborns whatsoever. All the information in the data sheets was kept confidential and all data were secured by the principal investigator in a password protected computer.

3.12.1 Informed Consent

The consent form (Appendix III) was administered in either English or Kiswahili. The application of the data collection tool, the consent form and study procedures were conducted by the principal investigator and /or a trained research assistant. The parent(s) and/or guardian(s) who could not communicate in either language were

ably assisted by a translator who would be inducted on the study procedures on need basis. In cases where the parent or guardian could not read or write, a thumb print sufficed as a mark of consent in place of a signature.

3.12.2 Patient safety consideration

The safety of the patients was not interfered with since the standards of care were not altered by any of the study procedures. The only invasive procedure that was done on the study participants was a needle prick on the heel to collect a blood sample for random blood sugar measurement. The procedure was conducted by either the principal investigator and/or the trained research assistant both of whom were/are familiar with and competent to carry out the procedure. All clinical procedures were conducted as per the existing standard protocols and guidelines.

3.13 The outcomes of the study

The primary objective of the study was to evaluate the outcomes of newborns referred and transported to the Moi Teaching and Referral Hospital, Eldoret; in the context of a structured SOP for newborn transport, with the view to assessing its effect. This information will be of great value in formulating health policies that intend to improve the outcomes of newborns with surgical conditions. The information on the referral and transport characteristics will directly contribute to the available data on the policy of patient transfer at Kenya's Ministry of Health. Furthermore, policies on health education and intervention pertaining to the treatment of newborns with surgical conditions at the county hospitals will greatly benefit from the results of this study. The SOP for transport of newborns with surgical conditions will herald the development of a comprehensive referral and transport algorithms for use by the health departments of the national and the county governments; and for training of the medical personnel.

3.14 Dissemination of results and publication policy

The results of this study have been published in peer reviewed journals (Appendix VI) making it available to the health professionals, and acknowledged all the participating county hospitals, all the investigators and the source of funding. The study findings have also been presented in scientific conferences to reach a wider audience. A comprehensive report on the outcome of the study has also been submitted as feedback to the managements of the Moi Teaching and Referral Hospital, and the 5 county referral hospitals that participated in the study.

CHAPTER FOUR

RESULTS

4.1 Socio-demographic Characteristics of the Newborns with Surgical Conditions referred to the Moi Teaching and Referral Hospital

A total of 126 newborns with surgical conditions, referred from the county hospitals, were enrolled into the study, 63 into the intervention group (Group A) and 63 into the control group (Group B).

The median age at admission was 99 hours (IQR = 77,128), which was approximately 4.1 days, for the newborns in Group A; and 112 hours (IQR = 75,137), which was approximately 4.6 days, for the newborns in Group B. Their Male: Female ratio was 1.1:1 for Group A, and 1:1 for Group B. The majority (88.9% in Group A, and 92.1% in Group B) were delivered in health facilities. Table 4.1 shows the socio-demographic characteristics of the newborns by Group.

Table 4.1: Socio-demographic Characteristics of the Newborns.

Variable	Group A (n=63)	Group B (n=63)	Test Statistic	p-value
Age at admission (Hours)			0.312[1]	
Median (IQR)	99 (77,128)	112 (75,137)		.755
Birth Weight (Grams)			0.342[1]	
Median (IQR)	2695 (2160,3100)	2700 (2300,3300)		.732
Weight at admission (Grams)			0.161[1]	
Median (IQR)	2600 (2100,3000)	2630 (2150,3100)		.872
Sex			0.127[2]	
Male (%)	33 (52.4)	31 (49.2)		
Female (%)	30 (47.6)	32 (50.8)		.722
Gestational age (Weeks)			2.154[2]	
Preterm (<37), (%)	28 (44.4)	20 (31.7)		
Term (≥37), (%)	35 (55.6)	43 (68.3)		.142
Place of Birth			0.368[3]	
Home (%)	7 (11.1)	5 (7.9)		
Health Facility (%)	56 (88.9)	58 (92.1)		.544
Birth Order			0.141[2]	
1 (%)	27 (42.9)	30 (47.6)		
> 1 (%)	36 (57.1)	33 (52.4)		.708

Note. 1. Wilcoxon Rank Sum Test **(Z) 2.** Chi-Square Test **(χ^2) 3.** Fisher's Exact Test

4.2 Characteristics of Mothers of Newborns with Surgical Conditions referred to the Moi Teaching and Referral Hospital

4.2.1 Socio-demographic characteristics of Mothers of Newborns with Surgical Conditions referred to Moi Teaching and Referral Hospital

The maternal socio-demographic characteristics were similar in the two groups, with the median maternal age of 23 years (IQR = 20, 28) for Group A and 23 years (IQR = 19, 29) for Group B. The majority of the mothers in each group had formal education, but were unemployed (Table 4.2).

Table 4.2: Maternal Socio-demographic Characteristics.

Variable	Group A	Group B	Test Statistic	p-value
Maternal Age (Years)	n=63	n=63	0.213[1]	
Median (IQR)	23 (20, 28)	23 (19, 29)		.832
Maternal Level of Education	n=63	n=63	8.698[3]	
Non-formal (%)	7 (11.1)	1 (1.6)		
Primary (%)	27 (42.9)	24 (38.1)		**.034***
Secondary (%)	23 (36.5)	23 (36.5)		
Tertiary (%)	6 (9.5)	15 (23.8)		
Maternal Occupation	n=63	n=63	2.450[2]	
No Employment (%)	43 (68.3)	37 (58.8)		
Self-Employment (%)	14 (22.2)	14 (22.2)		.294
Formal Employment (%)	6 (9.5)	12 (19.0)		

Note. 1. Wilcoxon Rank Sum Test **(Z) 2.** Chi-Square Test **(χ^2) 3.** Fisher's Exact Test *****Statistically Significant p-value

4.2.2 Clinical Characteristics of the Mothers of Newborns with Surgical Conditions referred to the Moi Teaching and Referral Hospital

Twenty (31.7%) mothers in Group A and 26 (41.3%) in Group B did not seek antenatal care during pregnancy. A significantly high number (39.7%) of mothers in group A had antenatal ultrasound scans done, and the antenatal ultrasound detected congenital anomalies in 9 (36.0%) mothers in Group A and 1 (7.1%) mother in Group B. The majority of the newborns referred to MTRH with surgical conditions were delivered via normal vaginal delivery, by skilled birth attendants. The maternal clinical characteristics were largely similar in both groups (Table 4.3).

Table 4.3: Clinical Characteristics of the Mothers of Newborns with Surgical Conditions Referred to the Moi Teaching and Referral Hospital.

Variable	Group A	Group B	Test Statistic	p-value
Antenatal Care Visits	n=63	n=63	1.233[2]	
None (%)	20 (31.8)	26 (41.3)		
<3 (%)	29 (46.0)	25 (39.7)		
≥3 (%)	14 (22.2)	12 (19.0)		.540
Antenatal Ultrasound Scan	n=63	n=63	4.258[2]	
Yes (%)	25 (39.7)	14 (22.2)		
No (%)	38 (60.3)	49 (77.8)		**.033***
Trimester of Ultrasound Scan	n=25	n=14	4.203[3]	
1st (%)	2 (8.0)	3 (21.4)		
2nd (%)	14 (56.0)	7 (50.0)		
3rd (%)	9 (36.0)	4 (28.6)		.122
Congenital Anomaly Detected	n=25	n=14	3.271[3]	
Yes (%)	9 (36.0)	1 (7.1)		
No (%)	16 (64.0)	13 (92.9)		**.041***
Mode of Delivery	n=63	n=63	0.321[3]	
Normal vaginal delivery (%)	55 (87.3)	57 (90.5)		
Caesarean Section (%)	8 (12.7)	6 (9.5)		.571
Personnel Conducting Delivery	n=63	n=63	0.772[3]	
Non-skilled Birth Attendant (%) (TBA, family or neighbor)	7 (11.1)	5 (7.9)		
Skilled Birth Attendant (%) (doctor, nurse or nurse-midwife)	56 (88.9)	58 (92.1)		.380

Note. 2. Chi-Square Test **(χ^2) 3.** Fisher's Exact Test ***Statistically Significant p-value

4.3 Spectrum of Surgical Conditions Seen in Newborns Referred to the Moi Teaching and Referral Hospital

The majority (96.8%) of the newborns who were referred to MTRH had congenital anomalies. The most common surgical conditions in both groups were gastroschisis (27.0% in Group A, 19.1% in Group B), hydrocephalus (14.3% in Group A, 22.2% in Group B), Hirschsprung's disease (7.9% in Group A, 20.6% in Group B and ARM (17.5% in Group A, 11.1% in Group B). Figure 4.1 shows the distribution of the surgical conditions seen in newborns referred to MTRH by group.

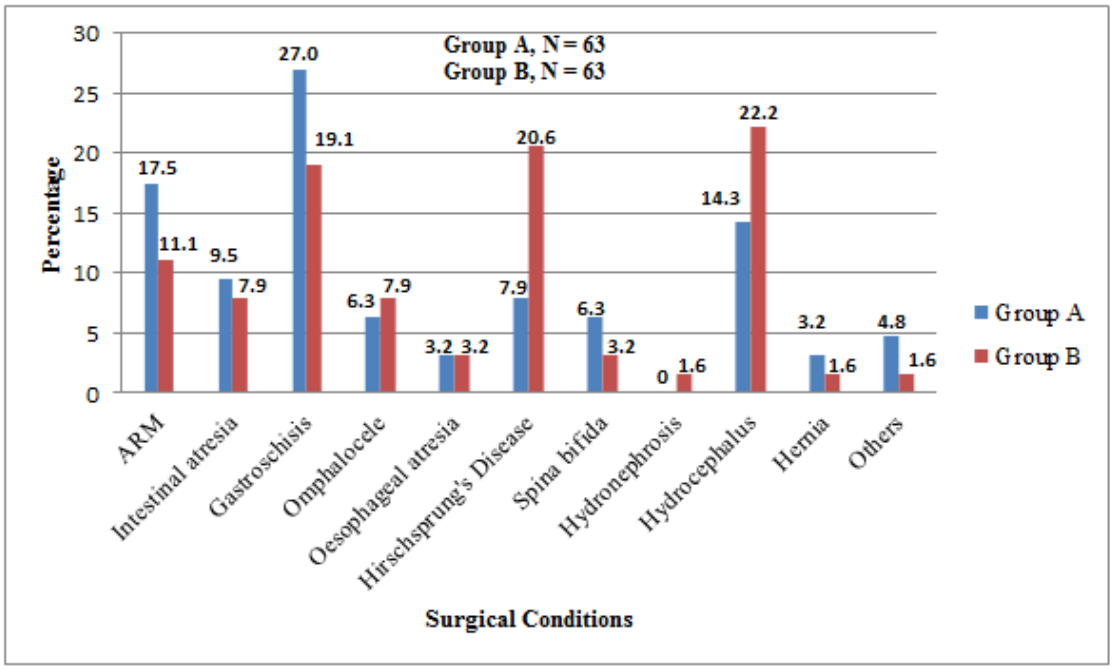

Figure 4.1: Spectrum of Surgical Conditions Seen in the Newborns Referred to MTRH.

4.4 Referral and Transport Characteristics of Newborns with Surgical Conditions

4.4.1 Pre-transport stabilization

Pre-transport stabilization was done for more newborns referred and transported from the hospitals in Group A, as compared to those referred from the hospitals in Group B. Ninety-six point eight percent (96.8%) of the newborns in Group A were adequately warmed prior to transport compared to 63.5% of the newborns in Group B. Ninety-six point seven percent (96.7%) of the newborns in Group A were positioned appropriately prior to and during transport compared to 31.7% of the newborns in group B, and only 3.2% of the newborns in Group B were given oxygen prior to transport compared to 66.7% of the newborns in Group A. The differences in the elements of pre-transport stabilization of the newborns referred from hospitals in Group A and those referred from the hospitals in Group B were statistically

significant (p-value < .05). Table 4.4 shows distribution of the newborns according to their characteristics on pre-transport stabilization by group.

Table 4.4: Distribution of the Newborns According to their Characteristics on Pre-referral and Pre-Transport Stabilization.

Variable	Group A n=63	Group B n=63	Test Statistic	p-value
Warmed the baby			22.009[3]	
Yes (%)	61 (96.8)	40 (63.5)		
No (%)	2 (3.2)	23 (36.5)		**< .001***
Given 10% Dextrose			29.196[2]	
Yes (%)	42 (66.7)	12 (19.0)		
No (%)	21 (33.3)	51 (81.0)		**< .001***
Given Oxygen			55.876[3]	
Yes (%)	42 (66.7)	2 (3.2)		
No (%)	21 (33.3)	61 (96.8)		**< .001***
Given IV Fluids			27.388[2]	
Yes (%)	51 (81.0)	22 (34.9)		
No (%)	12 (19.0)	41 (65.1)		**< .001***
Baby positioned appropriately			56.591[3]	
Yes (%)	59 (93.7)	20 (31.7)		
No (%)	4 (6.3)	43 (68.3)		**< .001***

Note. 2. Chi-Square Test **(χ^2) 3.** Fisher's Exact Test ***** Statistically Significant p-value

4.4.2 Referral and transport characteristics

In the majority (98.4% in Group A, 84.1% in Group B) of the referred newborns, MTRH was contacted prior to commencement of the referral and transport process, and the main mode of communication was written (95.2% in Group A, 92.1% in Group B). The majority of the newborns were transported using government-run road ambulances, and were escorted by trained medical personnel. The median duration of transfer was 2.8 (IQR=2.0, 4.0) hours for the newborns referred from the hospitals in Group A, and 4.0 (IQR=2.5, 6.0) hours for those referred from the hospitals in Group B. The elements of referral and transport that showed statistically significance differences between the two groups of newborns were: contact with MTRH prior to referral, mode of communication on referral and duration of transport. Table 4.5 shows the distribution of newborns according to their referral and transport characteristics by group.

Table 4.5: Distribution of the Newborns According to their Referral and Transport Characteristics.

Variable	Group A (n=63)	Group B (n=63)	Test Statistic	p-value
MTRH Contacted prior to Referral			8.068[3]	
Yes (%)	62 (98.4)	53 (84.1)		
No (%)	1 (1.6)	10 (15.9)		**.005***
Mode of Communication on Referral			9.797[3]	
Written (%)	60 (95.2)	53 (84.1)		
Verbal (%)	2 (3.2)	0 (0.0)		
None (%)	1 (1.6)	10 (15.9)		**.007***
Mode of Transportation			1.874[3]	
Road Ambulance (%)	62 (98.4)	59 (93.7)		
Public Motor Vehicle (%)	1 (1.6)	4 (6.3)		.171
Escort During Transport			2.800[3]	
Trained Medical Personnel (%)	62 (98.4)	58 (92.1)		
Parent/Guardian (%)	1 (1.6)	5 (7.9)		.104
Time to start of transfer, from time of decision to transfer (Duration of Pre-Transport Preparation) (Hours)			1.444[1]	
Median (IQR)	2.5 (1.3, 5.5)	2.8 (1.5, 9.2)		.222
Time to admission, from time of start of transfer (Duration of Transport) (Hours)	2.8 (2.0, 4.0)	4.0 (2.5, 6.0)	2.913[1]	**.004***
Median (IQR)				

Note. 1. Wilcoxon Rank Sum Test **(Z) 3.** Fisher's Exact Test *****Statistically Significant p-value

4.4.3 Care during transport

During transport, the majority (87.1%) of the newborns in Group A, who had naso-gastric tubes, had appropriate care of their tubes, with tube aspirations being done at intervals of between 30 minutes and 1 hour. None of the newborns in Group B had their naso-gastric tubes aspirated at intervals of less than 1 hour. The main methods of keeping the newborns warm during transport were *Kangaroo Mother Care* and use of polythene bag for the newborns referred from the hospitals in Group A; and use of cotton wool for the newborns referred from the hospitals in Group B. Intravenous fluid infusion was maintained during transport in 52 (85.0%) newborns in Group A, and 13 (20.6%) newborns in Group B. The referring hospitals sent specimens together with the patients in 13 (20.6) newborns in Group A, and none (0%) in Group B. Adverse events during transport were recorded in 6 (9.5%) newborns referred from the hospitals in Group A, and 25 (39.7%) newborns referred

from the hospitals in Group B. The differences in the characteristics of care during transport between newborns in Group A, and those in Group B were statistically significant (p-values < .05). Table 4.6 shows the distribution of newborns according to their characteristics on care during transport by group.

Table 4.6: Distribution of the Newborns According to their Characteristics on Care during Transport.

Variable	Group A	Group B	Test Statistic	p-value
Naso-gastric Tube Aspiration every:	n=39	n=8	48.814[3]	
30 Minutes (%)	1 (2.6)	0 (0.0)		
30 Minutes – 1 Hour (%)	34 (87.1)	0 (0.0)		
>1 Hour (%)	4 (10.3)	8 (100)		**< .001***
Method Used to Keep Baby Warm	n=63	n=63		
Kangaroo-Mother-Care (Skin-to-Skin) (%)	25 (39.7)	10 (15.9)		
Use of Polythene Bag (%)	15 (23.8)	5 (7.9)		
Use of Clothing (%)	14 (22.2)	5 (7.9)		
Use of Aluminium Foil (%)	7 (11.1)	1 (1.6)		
Use of Cotton Wool (%)	4 (6.3)	55 (87.3)		
Use of Infant Incubator (%)	3 (4.8)	0 (0.0)		
Baby Given Oxygen	n=63	n=63	13.049[3]	
Yes (%)	42 (66.7)	3 (4.8)		
No (%)	21 (33.3)	60 (95.2)		**.001***
Baby Given IV Fluids	n=63	n=63	18.801[2]	
Yes (%)	52 (82.5)	13 (20.6)		
No (%)	11 (17.5)	50 (79.4)		**< .001***
Medical Documents Sent from Referring	n=63	n=63	18.801[3]	
Hospital	13 (20.6)	1 (1.6)		
Consent for Surgery (%)	47 (74.6)	51 (80.9)		
Referral Note (%)	2 (3.2)	3 (4.8)		
Radiology Report (%)	1 (1.6)	8 (12.7)		**< .001***
None (%)				
Specimens Sent from Referring Hospital	n=63	n=63	14.496[3]	
None (%)	50 (79.4)	63 (100)		
Blood (%)	13 (20.6)	0 (0.0)		**< .001***
Adverse Events Reported During Transport	n=63	n=63	17.261[3]	
Airway Blocked (%)	0 (0.0)	1 (1.6)		
O_2 Supply Exhausted (%)	2 (3.2)	2 (3.2)		
Clinical Deterioration (%)	4 (6.3)	22 (34.9)		
None (%)	57 (90.5)	38 (60.3)		**.001***

Note. 2. Chi-Square Test **(χ^2) 3**. Fisher's Exact Test, ***Statistically Significant p-value

4.5 Outcomes of Newborns Referred to the Moi Teaching and Referral Hospital with Surgical Conditions

4.5.1 Primary Outcomes - Clinical Status of the Newborns at Admission

Thirty-point-two percent (30.2%) of the newborns referred from the hospitals in Group A had hypothermia compared to 88.9% of those referred from the hospitals in

Group B. Delay in capillary refill, which denotes dehydration, was recorded in 4.8% of the newborns referred from the hospitals in Group A and 52.4% of the newborns referred from the hospitals in Group B. There was a statistically significant (p-value < .05) difference in the clinical status of the newborns at admission, between those that were referred from hospitals in Group A and those that were referred from the hospitals in Group B. Table 4.7 shows the distribution of the newborns according to the parameters indicating their clinical status at admission by group.

Table 4.7: Distribution of Newborns According to Parameters Indicating their Clinical Status at Admission.

Variable	Group A (n/%)	Group B (n/%)	Test Statistic	p-value
Body Temperature (^{0}C)	n=63	n=63	51.294[2]	
32 - 36.4	19 (30.2)	56 (88.9)		
36.5 - 37.5	44 (69.8)	7 (11.1)		**< .001***
Capillary Refill Time (Seconds)	n=63	n=63	35.000[3]	
< 3	60 (95.2)	30 (47.6)		
≥ 3	3 (4.8)	33 (52.4)		**< .001***
Random Blood Sugar (Mmol/L)	n=63	n=63	29.461[3]	
< 2.5	1 (1.6)	26 (41.3)		
≥ 2.5	62 (98.4)	37 (58.7)		**< .001***
Respiratory Rate (Breaths/Minute)	n=63	n=63	6.690[3]	
30 – 60	59 (93.7)	53 (84.1)		
> 60	4 (6.3)	10 (15.9)		**.010***
Oxygen Saturation (S_PO_2)	n=63	n=63	45.853[2]	
< 90	13 (20.6)	51 (81.0)		
≥ 90	50 (79.4)	12 (19.0)		**< .001***
Immediate Resuscitation Done	n=9	n=48	40.367[3]	
Airway blocked – re-established	0 (0.0)	5 (10.4)		
Breathing ceased – assisted	3 (33.3)	12 (25.0)		
Collapse of circulation – supported	2 (22.2)	13 (27.1)		
Others	4 (44.5)	18 (37.5)		**<.001***

Note. 2. Chi-Square Test **(χ^2) 3.** Fisher's Exact Test ***** Statistically Significant p-value

4.5.2 Secondary Outcomes of Newborns Referred to the Moi Teaching and Referral Hospital with Surgical Conditions

The overall all-cause in-hospital mortality rate of the newborns referred to MTRH with surgical conditions was 15.9%. All-cause in-hospital mortality rate for the newborns referred from the hospitals in Group A was 3.2%, while that for those referred from the hospitals in Group B was 28.6%. The median time-to-death from

time of admission was 23 (IQR=11, 35) days in Group A, and 11 (IQR=4, 27) days in Group B. The differences in the variables that measured secondary outcomes between the two groups were statistically significant (p-values < .05). Table 4.8 shows the distribution of the newborns according to their secondary outcomes by group, and Figure 4.2 is Kaplan-Meier curve for time-to-death from time of admission.

Table 4.8: Distribution of Newborns According to their Secondary Outcomes.

Variable	Group A	Group B	Test Statistic	p-value
Outcome	n=63	n=63	15.210[3]	
Discharged Home (%)	61 (96.8)	45 (71.4)		
Died (All-cause in-hospital mortality) (%)	2 (3.2)	18 (28.6)		**< .001***
Duration of Hospital Stay (Days)	n=61	n=45	2.850[1]	
Median (IQR)	11 (8,17)	18 (9,28)		**.004***
Time-to-Death, from Admission (Days)	n=2	n=18	0.821[1]	
Median (IQR)	23 (11,35)	11 (4,27)		.412

Note. 1. Wilcoxon Rank Sum Test **(Z)2.** Chi-Square Test **(χ^2) 3.** Fisher's Exact Test ***** Statistically Significant p-value

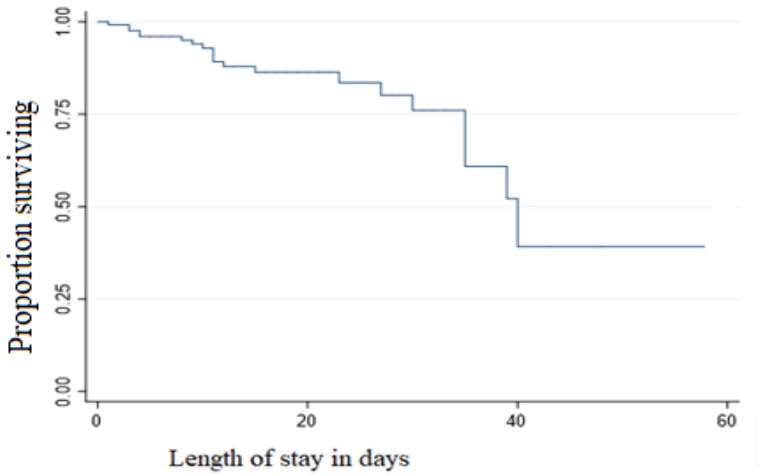

Figure 4.2: Kaplan-Meier Curve for Time-to-Death, from Time of Admission.

4.6 Predictors of Mortality in Newborns Referred to the Moi Teaching and Referral Hospital with Surgical Conditions

Some socio-demographic, referral, transport, and clinical characteristics were associated with time-to-death from admission. On further multivariate analysis using Final Model Cox Regression, the factors that showed statistically significant association with time-to-death from time of admission included the newborn's weight at admission, and the respiratory rate ($P < .05$). The weight at admission of < 1500 g was used as a standard because it had highest hazard of neonatal mortality. The final Cox model showed strong evidence that those newborns whose weights at admission was ≥ 2500 g had 10 times less hazard of mortality (HR: 0.118; 95%CI:0.016-0.888). Similarly, the respiratory rate of 30-60 breaths per minute was used as a standard because it had the lowest hazard of mortality. The evidence showed that the newborns whose respiratory rates were > 60 breaths per minute had 3.2 times higher hazard of mortality (HR: 3.221; 95%CI:1.078-9.626). Table 4.9 shows multivariate Cox regression analysis of factors associated with the newborns' time-to-death from time of admission (predictors of neonatal mortality).

Table 4.9: Factors associated with Time-to-Death from Time of Admission.

Variable	Hazard Ratio	95% CI	p-value
Sex			
Male	1.000 (Reference)		
Female	0.564	0.175 – 1.818	.338
Age (Days)	1.001	0.988 – 1.014	.892
Weight at Admission (grams)			
< 1500	1.000 (Reference)		
1500 – 2499	0.151	0.021 – 1.090	.061
≥ 2500	0.118	0.016 – 0.888	**.038***
Mode of Delivery			
Normal Vaginal Delivery	1.000 (Reference)		
Caesarean Section	1.621	0.306 – 8.589	.570
Duration of Transport (Hours)	1.003	0.982 – 1.024	.803
Capillary Refill Time (Seconds)			
< 3	1.000(Reference)		
≥ 3	2.220	0.672 – 7.340	.191
Random Blood Sugar (Mmol/L)			
< 2.5	1.000 (Reference)		
>2.5	0.831	0.247 – 2.793	.765
Respiratory Rate (Breaths/Minute)			
30 – 60	1.000 (Reference)		
>60	3.221	1.078 – 9.626	**.036***
Oxygen Saturation (S_PO_2) (%)			
< 90	1.000 (reference)		
≥ 90	1.109	0.155 – 7.922	.918

Note. * Statistically significant p-value

4.7 Effect of a Structured SOP for Transport on Outcomes of Newborns Referred to the Moi Teaching and Referral Hospital with Surgical Conditions

4.7.1 Effect on Primary Outcomes – Clinical Status of the Newborns at Admission

Adverse outcomes on all the parameters used to measure the clinical status of the newborns at admission were noted more in the newborns referred from the county hospitals in the control group. Overall, the need for immediate cardio-pulmonary resuscitation was recorded in 57 (45.2%) newborns, 9 (14.3%) in Group A and 48 (76.2%) in Group B. The differences in the clinical status of the newborns in the two groups were statistically significant (P<.05).

4.7.2 Effect on Secondary Outcomes

Overall, the all-cause in-hospital mortality rate was 15.9%, 2 (3.2%) newborns in the intervention group (Group A) and 18 (28.6%) newborns in the control group (Group B) died. The differences in the all-cause in-hospital mortality rates and the median durations of hospital stay in the two groups were statistically significant, further providing evidence that the introduction of the structured SOP for transport of newborns with surgical conditions at the referring county hospitals improved their outcomes at the MTRH.

CHAPTER FIVE

DISCUSSION

5.1 Introduction

This was a cluster-randomized-controlled trial that aimed at assessing the effect of a structured Standard Operating Procedure (SOP) for transport of newborns with surgical conditions, on their outcomes at the Moi Teaching and Referral Hospital (MTRH), Eldoret. The structured SOP was adopted from the WHO guidelines on transfer and referral of sick neonates (WHO, 2003), and customized to include locally innovative improvisations.

5.2 Socio-demographic Characteristics of the Newborns with Surgical Conditions

Socio-demographic characteristics of the newborns are of great significance, as several studies have linked various socio-demographic, clinical, referral, and transport characteristics of newborns referred and transported to tertiary-level hospitals for specialized care, to their treatment outcomes. Narang *et al* (2013), Aggarwal *et al* (2015) and Sachan *et al* (2016) reported an inverse relationship between mortality rates of newborns referred to tertiary-level hospitals; and their gestational age, birth weight and delivery conducted by unskilled birth attendant.

The socio-demographic characteristics of the newborns with surgical conditions referred to and treated at the MTRH, from the county hospitals in both the intervention group (Group A) and the control group (Group B) were similar. The median age at admission was approximately 4.1 days for Group A, and 4.6 days in Group B. This however suggests a delay in accessing neonatal surgical care, which could be explained by the 3-delay model that characterizes barriers to health care-seeking. This model that comprises the delay in deciding to seek care (delay 1), delay in reaching the health care facility (delay 2), and delay in receiving quality care once at the health facility, was initially developed for use in analyzing maternal deaths (Thaddeus & Maine, 1994). It was later validated and found to be useful in analyzing

perinatal deaths in L/MICs (Mbaruku *et al*, 2009; Waiswa *et al*, 2010). In this study, there was a delay in accessing neonatal surgical care despite the majority (88.9% in Group A, 92.1% in Group B) of the newborns being born in health facilities. Studies conducted in middle-income countries (MICs) reported lower median ages at admission (Goldsmit *et al*, 2012; Abdulraheem *et al*, 2016), further suggesting socio-economic status as an important determinant of delay in seeking care.

The distribution of the newborns by gender was similar in both groups, with an almost equal male to female ratio. Many of the congenital anomalies that formed the majority of the surgical conditions found in this study have an even gender distribution.

The median birth weight of 2695g in Group A, and 2700g in Group B, were similar to those found in other studies (Upadhyay *et al*, 2013; Punitha *et al*, 2016). The median weight at admission of 2600g in the newborns referred from the county hospitals in the intervention group, and 2700g in the newborns referred from the county hospitals in the control group denote a median physiological weight loss of between 3.0% to 3.5%, which is normal.

The majority (55.6% in Group A and 68.3% in Group B) of the newborns transported to MTRH with surgical conditions were term, a finding that was similar to other studies in the L/MICs (Goldsmit *et al*, 2012; Abdulraheem *et al*, 2016). Studies done in India reported varying proportions of term newborns that ranged from 40.0% to 78.5% (Sachan *et al*, 2016; Upadhyay *et al*, 2013; Punitha *et al*, 2016; Rathod *et al*, 2016).

5.3 Characteristics of the Mothers of Newborns with Surgical Conditions referred to MTRH

On the place of delivery, the study found that only 11.1% of the newborns in Group A, and 7.9% of the newborns in Group B, were delivered at home. This is comparable to those reported in other similar studies, which range between 10.5% and 24.0% (Waiswa *et al*, 2010; Upadhyay *et al*, 2013; Sachan *et al*, 2016; Abdulraheem *et al*, 2016). This could perhaps be the fruits of the global efforts in

formulation and implementation of strategies aimed at increasing health-facility deliveries (Butrick *et al*, 2014). Demographic and Health Surveys (DHS) in Sub-Saharan Africa and Asia have indicated that more than 75% of women in both regions combined now deliver in health facilities (Montagu *et al*, 2017). In this study, 88.9% of newborns in Group A, and 92.1% of those in Group B, were delivered in health facilities, compared to 66.1% overall health facility deliveries in Kenya (Mbugua & MacQuarrie, 2018), and the 56.9% reported in a similar study in Nigeria (Abdulraheem *et al*, 2016). The high proportion of health-facility deliveries reported in this study could also suggest that the surgical conditions that these newborns had may have caused pregnancy-related complications that perhaps necessitated health-facility delivery.

The study further reported a young median maternal age of 23 years in both groups. This could be explained by the spectrum of the surgical conditions that was observed in the newborns. Young maternal age has been associated with congenital anomalies such as gastroschisis and neural tube defects (Saula & Kuremu, 2015; Kuremu *et al*, 2017).

Despite the fact that the majority of the mothers (88.9% in Group A and 98.4% in Group B) had formal education, the majority (68.3% in Group A and 58.8% in Group B) were unemployed. A further 22.2% in both groups were self-employed. Low socio-economic status has previously been found to be a major contributor to the first and second levels of delays in the 3-delays model, which leads to high neonatal mortality (Waiswa *et al*, 2010).

In this study, 43 (68.3%) mothers in Group A and 37 (58.7%) mothers in Group B had some antenatal care, but only 14 (22.2%) mothers in Group A and 12 (19.0%) mothers in Group B had the recommended optimal antenatal visits during pregnancy. Gitonga (2017) found maternal age, level of education and occupation to be major determinants of the uptake of focused antenatal care. Similarly, the maternal age below 20 years was associated with least uptake, and women in formal employment had higher uptake of focused antenatal care.

During these antenatal visits, antenatal ultrasound scans were done in 25 (39.7%) mothers in Group A and 14 (22.6%) mothers in Group B, and congenital anomalies were only detected in 9 (36.0%) mothers in Group A and 1 (7.1%) mother in Group B. Goldsmit *et al* (2012) reported similar findings in a study done in Argentina. Onyambu and Tharamba (2018) reported a much lower detection rate of 3%, of congenital fetal anomalies on routine antenatal ultrasound screening of low-risk pregnancy. Evidence-based policies developed by WHO have suggested that antenatal ultrasound scans done in early pregnancy may increase the detection rate of congenital anomalies (WHO, 2016). Hence, the concurrent finding in this study that the majority of the antenatal ultrasound scans were done in the 1st and the 2nd trimesters (64% in Group A and 71.4% in Group B), and this could perhaps explain the apparently higher detection rate of congenital anomalies as compared to similar studies in other L/MICs (Goldsmit *et al*, 2012; Onyambu & Tharamba, 2018).

The majority (87.3% in Group A and 90.5% in Group B) of the newborns with surgical conditions were born via normal vaginal delivery, which were conducted majorly by skilled birth attendants (88.9% in Group A and 92.1% in Group B). This is in conformity with the finding that the majority of the newborns were delivered in health facilities, which are obviously manned by skilled birth attendants. Upadhyay *et al* (2013) and Sachan *et al* (2016) reported similar findings in studies done in India. Despite this, the newborns still had a significant delay in accessing surgical care at the MTRH.

5.4 Spectrum of the Surgical Conditions seen in Newborns referred to MTRH

The majority (95.2% in Group A and 98.4% in Group B) of the neonatal surgical conditions were congenital anomalies, with the leading anomalies being gastroschisis (27.0% in Group A and 19.1% in Group B), hydrocephalus (14.3% in Group A and 22.2% in Group B), Hirschsprung's disease (7.9% in Group A and 20.6% in Group B), and ARM (17.5% in Group A and 11.1% in Group B). Ikol *et al* (2019) reported a similar spectrum in a study on the outcomes of neonatal surgery at the MTRH. Ekenze *et al* (2016) reported that 2.6 million children are born with congenital anomalies in sub-Saharan Africa, many of which are only amenable to surgery

during the neonatal period. Hospital-based studies in Africa have reported incidences of congenital anomalies at 1.5% in Egypt and 2.5% in East Africa (Muga *et al*, 2009; Ndibazza *et al*, 2011; Shawky & Sadik, 2011).

The findings in this study further conform to the WHO estimates that approximately 10% of all neonatal deaths in sub-Saharan Africa and southern Asia are due to congenital anomalies (Paul & Singh, 2004). Whereas ARM has previously been reported to be the most prevalent congenital anomaly in African children (Moore *et al*, 2008), and in Egypt (Chirdan *et al*, 2012), gastroschisis still remains the most prevalent congenital anomaly in MTRH. Opara *et al* (2014) reported similar findings in a retrospective study done in Nigeria. The spectrum of surgical conditions reported in this study conforms to the other concurrent finding of a relatively young median maternal age, a characteristic that is often associated with gastroschisis and neural tube defects. However, the spectrum of the surgical conditions in newborns referred from the county hospitals in the intervention group (Group A) had more acute conditions (ARM, intestinal atresia, and gastroschisis) compared to that of newborns referred from the county hospitals in the control group (Group B). This could perhaps be due to the fact that the intervention (training of the clinicians and subsequent introduction of the structured SOP) may have sensitized the clinicians to promptly refer and transport more acutely ill newborns with surgical conditions. On the contrary, more acutely ill newborns in the county hospitals in the control group could have succumbed to their surgical illness before referral.

5.5 Referral and Transport Characteristics of Newborns with Surgical Conditions

The intervention in the county hospitals in Group A had a positive effect on pre-transport stabilization of newborns with surgical conditions, with more newborns referred from the county hospitals in the intervention group receiving pre-transport stabilization. Aggarwal *et al* (2015) underscored the importance of stabilization before transport of referred newborns. Contrary to the findings in this study, Buch *et al* (2012) in a similar study in India reported that pre-referral treatment was given only to a paltry 23.5% of their referred newborns.

This study further demonstrated the positive effect of the introduction of a structured SOP for transport of newborns with surgical conditions on their referral and transport characteristics. In the majority (98.4% in Group A and 84.1% in Group B) of the referred newborns, MTRH was contacted prior to commencement of the referral and transport process. This could perhaps be indicating the effect of the referral strategies that were initiated by the Ministry of Health in 2014 (Kenyan Ministry of Health, 2014). However, this characteristic showed a statistically significant difference between those newborns referred from the county hospitals in Group A, and those referred from the county hospitals in Group B. The main mode of communication on referral of the newborns in both groups was written (95.2% in Group A and 84.1% in Group B). This was in contrast to the finding by Butt *et al* (2008) in a study done in Pakistan, in which they reported that only 11.1% of the referred newborns had referral letters. Their study concluded that maintaining good standards in medical note-keeping and referral documentation is important in planning further patient management and counseling parents on their newborns' prognosis. Mutlu and Aslan (2011) in a study done in Turkey found that 71% of the referred neonates had referral notes, Buch *et al* (2012) in a study done in India reported a paltry 41.9% of referred newborns that had referral letters, which is in contrast to the findings in this study.

This study further showed that the majority (98.4% in Group A and 93.7% in Group B) of the newborns with surgical conditions, who were referred to MTRH, were transported by road ambulances. The ushering in of the devolved system of governance in Kenya following the enactment of a new constitution in 2010 enabled many county governments to procure fleets of road ambulances as part of equipping their county health systems. Prior to this, Barker *et al* (2014) reported that the number of road ambulances per hospital in Kenya was at 0.06 – 3.63. This could perhaps explain this finding, which is similar to that of a study in India (Punitha *et al*, 2016). In the contrary, a study done in Nigeria reported the use of road ambulances at a paltry 4% (Abdulraheem *et al*, 2016), and a study done in India reported the use of road ambulance at 26.8% (Buch *et al*, 2012). However, there was no statistically significant difference in this characteristic, between the newborns referred from the

county hospitals in the intervention group and those referred from the county hospitals in the control group.

The majority (98.4% in Group A and 92.1% in Group B) of the newborns were accorded escort by trained medical personnel during transport, which was appropriate. In the contrary, Buch *et al* (2012) in a study done in India found that only 11.4% of the referred newborns were accompanied by skilled attendants. Aggarwal *et al* (2015) further noted that survival rates were higher when trained medical personnel accompanied the newborns during transport.

There was no statistically significant difference in the median duration of pre-transport preparation of the newborns referred from the county hospitals in both groups (median of 2.5 hours in Group A, and 2.8 hours in Group B). However, the median duration of transport was longer for the newborns referred from the county hospitals in the control group (median of 2.8 hours in Group A, and 4.0 hours in Group B). Ashokcoomar and Naidoo (2016) reported similar findings, with a mean time-to-complete inter-healthcare facility transfer of 3 hours, 49 min, in a study done in South Africa. In their study, inadequate pre-transport preparation and lack of dedicated transport teams are important determinants of survival of transported surgical newborns. Waiswa *et al* (2010) and Upadhyay *et al* (2013) used the three-delay-model to demonstrate that transport delays do contribute significantly to neonatal mortality. Mori *et al* (2007) reported similar findings in Japan in which they found that transported newborns with long duration of transport had 85% higher hazard of neonatal death. In this study, the difference in the median duration of transport of newborns referred and transported from the two groups of county hospitals was statistically significant.

Care of the newborn during transport is vital in mitigating the risks of adverse events (Pan, 2017). In this study, the majority of the newborns with surgical conditions referred from the county hospitals in the intervention group (Group A) had care during transport. The majority (87.1) of the newborns in Group A, who had naso-gastric tubes, had appropriate care of their tubes, with tube aspirations being done at intervals of between 30 minutes and 1 hour. On the contrary, none of the newborns

referred from the county hospitals in the control group (Group B) had their naso-gastric tubes aspirated at intervals of less than 1 hour. Proper management of the naso-gastric tube during transport is key in preventing vomiting and aspiration of the gastro-intestinal secretions into the airway hence minimizing the occurrence of adverse events.

The main methods of keeping the newborns warm during transport were *Kangaroo-Mother-Care* and use of polythene bag wraps for the newborns referred from the county hospitals in Group A; and use of cotton wool wraps for the newborns referred from the county hospitals in Group B. Maintaining the newborn's core temperature at 36.5^0C-37.5^0C minimizes energy consumption and improves survival (Karlsen, 2001). The use of aluminium foil wraps to keep the newborns warm during transport was noted in 11.1% of the newborns in Group A, and 1.6% in those in Group B. Similarly, the use of infant incubators was noted in a paltry 4.8% of the newborns in Group A, and none in Group B. A similar study done in Nigeria reported use of infant incubator at a mere 0.7% and that *Kangaroo-Mother-Care* was not used to keep the newborns warm during transport (Abdulraheem *et al*, 2016).

This further shows that innovative improvised methods of maintaining warmth during transport that included the *Kangaroo-Mother-Care*, use of polythene bag wraps, and use of aluminium foil wraps were used more by the county hospitals where the intervention was done. Furthermore, the use of infant incubators was very low, perhaps owing to their unavailability at the county hospitals. Joshi *et al* (2010) in a study done in India demonstrated that effective thermal control can be achieved using cheap and easily fabricated neonatal carriers. This innovative technology could be vital in improving newborn survival particularly in resource-limited settings.

In this study, 42 (66.7%) newborns transported from the county hospitals in Group A had oxygen supplementation compared to 3 (4.8%) newborns transported from the county hospitals in Group B. Intra-venous access and intravenous fluid infusion were maintained in the majority (85.0%) of the newborns referred from the county hospitals in the intervention group (Group A), compared to 20.6% of those referred from the county hospitals in the control group (Group B). The proportion of the

newborns that had their blood specimens sent during transport was 20.6% in Group A, and none (0%) in Group B. This further indicates that the intervention may have had a positive effect on this element of newborn care. However, there is still need to emphasize the importance of sending specimens collected from the newborns and/or their parents during transport.

The findings on this pillar of care could perhaps explain the concomitant findings on the adverse events that occurred during transport. The adverse events were recorded in 6 (9.5%) newborns referred and transported from the county hospitals in the intervention group (Group A), and in 25 (39.7%) newborns referred from the county hospitals in the control group (Group B). The main adverse event observed in this study was clinical deterioration, which was noted in 22 (34.9%) newborns referred from the county hospitals in the control group, and 4 (6.3%) newborns referred from the county hospitals in intervention group. A similar study done in Argentina reported that 57% of their transported newborns had clinical deterioration, a proportion which is much higher than those found in this study (Goldsmit *et al*, 2012). This study further demonstrated statistically significance differences in the proportions of newborns given care during transport, further indicating the positive effect of the introduction of the SOP in the county hospitals in Group A.

5.6 The Outcomes of Newborns with Surgical Conditions

In this study, the measure of primary outcomes following the intervention in the county hospitals in Group A was the clinical status of the newborns at their admission to MTRH. Hypothermia, hypoperfusion, hypoglycaemia and hypoxia have been shown to be associated with high mortality in transported newborns (Pan, 2017). Studies have shown that proper pre-transport stabilization and adequate care during transport are important factors in decreasing the incidences of clinical deterioration, adverse events, and neonatal mortality (Kumar *et al*, 2011).

At admission to MTRH, 88.9% of the newborns referred from hospitals in Group B and 30.2% of the newborns referred from hospitals in Group A had hypothermia. Goldsmit *et al* (2012) and Sachan *et al* (2016) reported findings on hypothermia that

were similar to those found in the newborns referred from the county hospitals in the intervention group. However, the incidences of hypothermia found in this study were in contrast to those reported in other previous studies (Sehgal *et al*, 2001; Narang *et al*, 2013; Aggarwal *et al*, 2015). Moreover, the findings in this study could perhaps be explained by the concurrent findings on the care of the newborns during transport, in which the majority (71.4%) of newborns referred from the county hospitals in the intervention group (Group A) were kept warm using effective methods (*Kangaroo-Mother-Care*, use of polythene bag wraps, use of aluminium foil wraps, use of infant incubator), compared to 25.4% of those referred from the county hospitals in the control group (Group B).

The majority (52.4%) of the newborns referred from the county hospitals in the control group had hypoperfusion (Capillary Refill Time ≥ 3 seconds). Hypoglycaemia (Random Blood Sugar < 2.5 Mmol/L) was reported in 26 (41.3%) newborns referred from the county hospitals in the control group, and in only 1 (1.6%) newborn referred from the county hospitals in the intervention group. Whereas the incidence of hypoglycaemia in the newborns referred from the county hospitals in the control group was much higher than that in of the newborns referred from the county hospitals in the intervention group, the incidence of hypoglycaemia in newborns referred from the county hospitals in the intervention group was comparable to those reported in previous studies (Narang *et al*, 2013; Aggarwal *et al*, 2015; Sachan *et al*, 2016). Similarly, these findings seem to concur with those on pre-transport stabilization and care during transport, in which adequate care was given more to newborns referred from the county hospitals in Group A than to those referred from the county hospitals in Group B.

Hypoxia (SP02 < 90%) was found in 51 (81.0%) newborns referred from the county hospitals in the control group, and 13 (20.6%) newborns referred from the county hospitals in intervention group, which were comparable to those reported by Sachan *et al* (2016) in a study done in India. Need for immediate cardio-respiratory resuscitation was noted in 48 (76.2%) newborns referred from the county hospitals in the control group, as opposed to 9 (14.3%) newborns referred from the county hospitals in the intervention group. Overall, 45.2% of the referred newborns had need

for immediate cardio-respiratory resuscitation, which was lower than that found in a similar study in Argentina (Goldsmit *et al*, 2012).

The incidences of hypothermia, hypoperfusion, hypoglycaemia, and hypoxia were significantly higher in newborns transported from the county hospitals in the control group (Group B) than in those transported from the county hospitals in the intervention group (Group A), further demonstrating the positive effect of introducing a structured SOP for transport of newborns with surgical conditions in the hospitals in Group A. Martínez *et al* (2011) in a before-and-after (quasi-experimental) study in Mexico found that more transported newborns had normal body temperature, normal range of blood sugar, more infant incubator use and normal oxygen saturation following training on the *S.T.A.B.L.E.* program. Similar findings were earlier reported by Spector *et al* (2009) in a study done in Panama.

The overall all-cause in-hospital mortality rate for the transported newborns with surgical conditions was 15.9%, which was similar to that reported by Goldsmit *et al* (2012): 17.5%, Sachan *et al* (2016): 18.3%, and Aggarwal *et al* (2015): 20%; but much lower than those reported by Buch *et al* (2012): 32.2%, Dalal *et al* (2013): 23.7%, Narang *et al* (2013): 36% and Sehgal *et al* (2001): 36%. However, the all-cause in-hospital mortality rate for the newborns referred and transported from the county hospitals in the intervention group was 3.2%, compared to the 28.6% for those referred from the county hospitals in the control group, a difference that was statistically significant ($P < .05$). Although this difference in the all-cause in-hospital mortality rate could be easily attributed to the intervention in this study, individualized surgical treatment that are specific to each surgical condition were probable confounders.

While the median duration of hospital stay was significantly longer ($P < .05$) for the newborns referred from the county hospitals in the control group than for those referred from the county hospitals in the intervention group, the median time-to-death from time-of-admission was longer for the newborns referred from the county hospitals in the latter group. This perhaps could indicate better survival of newborns

with surgical conditions following the introduction of the structured SOP for newborn transport.

5.7 Predictors of Mortality in Newborns with Surgical Conditions

The factors that were significantly associated with time-to-death, from time-of-admission were the newborn's weight at admission and the newborn's respiratory rate. This study showed that the transported newborns with surgical conditions, whose weight-at-admission was ≥ 2500g, had 10 times less hazard to neonatal mortality compared to those whose weight-at-admission was < 1500g (HR:0.118; 95%CI: 0.016-0.888; P < .05). The transported newborns who had tachypnea (Respiratory rate > 60 breaths per minute) at admission, had 3 times more hazard to neonatal mortality compared to those who had normal respiratory rate (HR: 3.221; 95%CI: 1.078-9.626; P < .05). Similar findings were reported in previous studies (Buch *et al*, 2012; Rao *et al*, 2015; Sachan *et al*, 2016). The newborn' age and gender were not significant predictors of all-cause in-hospital neonatal mortality.

Contrary to the findings in previous similar studies, the long duration of transport, delayed Capillary-Refill-Time, low Random-Blood-Sugar, and low Oxygen Saturation were not significantly associated with higher hazard of neonatal mortality. Mori *et al* (2007) found long duration of transport to be a significant predictor of neonatal mortality. Sachan *et al* (2016) found deliveries conducted by unskilled birth attendants, birth weight < 1000g, duration of transport > 1 hour and low oxygen saturation (S_P0_2 < 90%) to be significant predictors of mortality in transported newborns. Similarly, Buch *et al* (2012) reported prematurity < 32 weeks, hypothermia, Capillary-Refill-Time ≥ 3 seconds, and respiratory distress as significant predictors of mortality in transported newborns. These studies however analyzed data from larger study samples.

5.8 Effect of a Structured SOP for Transport on Outcomes of Newborns Referred to the Moi Teaching and Referral Hospital with Surgical Conditions

The study results showed statistically significant differences (P < .05) in the parameters that indicated the clinical status of the newborns at admission. The study

provided strong evidence that the introduction of the SOP for transport of newborns with surgical conditions had a positive effect on both their primary and secondary outcomes at MTRH.

Similar educational programs on newborn transport have previously been shown to improve their outcomes at the tertiary-level hospitals. Kumar *et al* (2011) noted significant improvement in the clinical status of the newborns at admission following an intervention on pre-transport stabilization by a specialized neonatal transport service. Spector *et al* (2009) in Panama, and Martínez *et al* (2011) in Mexíco, further demonstrated improvements in the outcomes of transported newborns at the tertiary-level hospitals that directly resulted from the implementation of neonatal provider educational programs - *Sugar and Safe Care, Temperature, Airway, Blood, Lab work, and Emotional support* (S.T.A.B.L.E.) and newborn transport guidelines. In India, Ezhumalai (2020) reported a significant improvement in the quality of referral letters, and a decrease in the proportion of newborns seen at triage with physiological decompensation, following a referral education module.

Overall, the findings in this study have made a significant contribution to the existing body of knowledge on transport of newborns with surgical conditions. Nonetheless, the results need to be interpreted in the light of the study limitations.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

The study findings indicate that:

1. a). The main surgical conditions seen in the newborns referred and transported to the MTRH were congenital anomalies.

   b). The referral and transport characteristics of the newborns with surgical conditions referred to and treated at the MTRH were enhanced by the structured SOP for newborn transport.

2. Overall, the outcomes of the newborns with surgical conditions referred to and treated at MTRH were good; nonetheless, the structured SOP for transport of newborns significantly decreased the proportions of the newborns presenting with physiological decompensation at admission.

3. Weight-at-admission < 2500g and tachypnea were significant predictors of neonatal mortality in the newborns with surgical conditions referred to and treated at the MTRH.

4. The introduction of a structured SOP for transport of newborns with surgical conditions at the county hospitals, significantly improved their outcomes at the MTRH.

5. Overall, the referred newborns with surgical conditions had delay in accessing neonatal surgical care, and the majority of their mothers had sub-optimal antenatal care during pregnancy despite the apparently high health-facility delivery.

6.2 Recommendations

This study therefore, recommends as follows:

1. To the MTRH, to escalate the introduction and use of the structured SOP for transport of newborns with surgical conditions, to all county referral hospitals that refer and transport newborns to MTRH for surgical care.
2. To the newborn transport teams, emergency care teams, and the neonatologists at the county referral hospitals/MTRH, to be more vigilant and offer extra care when transporting and receiving newborns with surgical conditions, and low birth weight/tachypnoea.
3. To the other tertiary-level hospitals and the health services departments of all county governments, to study and adopt the use the structured SOP for transport of newborns with surgical conditions, an intervention that is context-appropriate, implementable and scalable.
4. To the MOH, Kenya, to consolidate the initial gains achieved by this study by instituting a more sustained multifaceted outreach program with a continuous feedback mechanism at a policy level.
5. To the MOH, Kenya, to do a systematic audit of perinatal surgical morbidity and mortality using the 3-delay model that would perhaps unravel the real cause of delay in accessing neonatal surgical care despite the high health-facility delivery and readily available government-run road ambulance services at the county referral hospitals.

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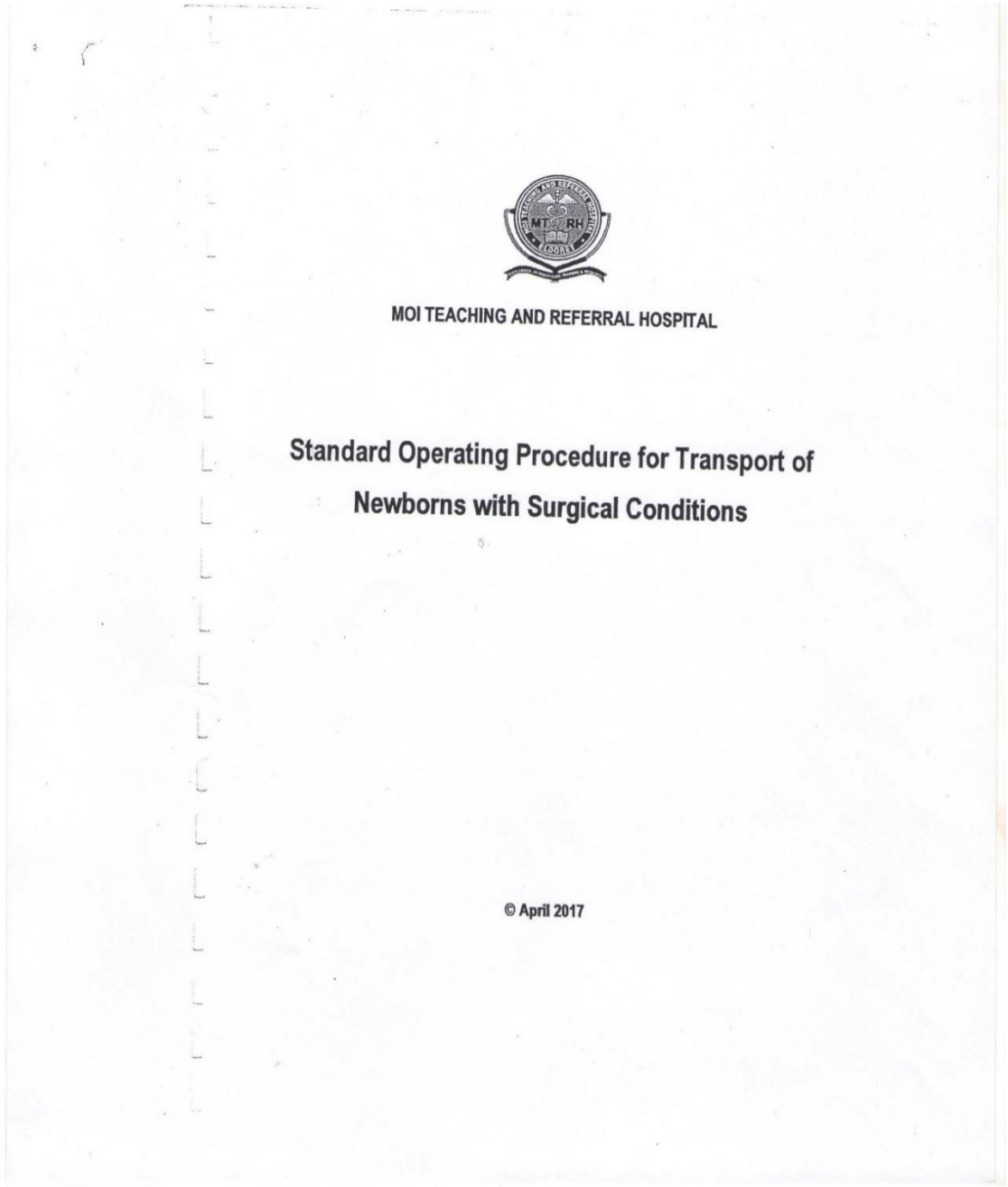
APPENDICES

Appendix I: A structured Standard Operating Procedure for Transport of Newborns with Surgical Conditions



MOI TEACHING AND REFERRAL HOSPITAL

Standard Operating Procedure for Transport of Newborns with Surgical Conditions

© April 2017

Next Revision - on or before April 2019

ISO 9001:2008 Certified Hospital

MOI TEACHING AND REFERRAL HOSPITAL

Standard Operating Procedure for Transport of Newborns with Surgical Conditions

Developed by : Dr. P. W. Saula Sign: ..... Date..... 07.06.2017

Designation : Consultant, Paediatric Surgery

Reviewed by : Department of Paediatric Surgery MTRH

Approved by : Dr. Wilson K. Aruasa Sign: ..... Date..... 07/06/2017

Designation : Chief Executive Officer

April 2017

Preamble

The burden that maternal and neonatal ill health poses on the development of individuals, communities and societies has attracted the attention of world leaders who had to adopt specific goals and targets to reduce maternal and childhood-infant mortality as part of the Millennium Declaration and later Sustainable Development Goals.

With the realization that many conditions that result in perinatal deaths can be prevented or treated without sophisticated and expensive technology, education of clinicians on simple but critical interventions for the newborn during the first days of life became necessary. A guide to achieve this was then developed by the WHO in collaboration with UNFPA, UNICEF and World Bank with a common understanding of the key elements in reducing newborn deaths. The aspects that deal with the newborns were further reviewed and endorsed by the International Pediatric Association.

Moi Teaching and Referral Hospital is the second largest national referral hospital in Kenya and serves a population of 20 million, mainly in the larger western, North Rift and South Rift regions of Kenya. It also receives patients referred from the eastern part of Uganda and South Sudan for specialized care. The department of Paediatric Surgery has therefore adopted and domesticated this Standard Operating Procedure for Transport of Newborns with Surgical Conditions to further enrich hospital's referral policy in line with its strategic plan.

This protocol will henceforth guide the referral and transport of all newborns with surgical conditions from all county and sub-county referral hospitals that wish to refer these patients to our Newborn Unit for specialized care, with the view to streamlining service delivery and improving child survival.

Dr. Peter W. Saula

Department of Paediatric Surgery

FOREWORD

The Hospital Management is keen on implementing a functional referral system and as such has created an enabling environment for staff in Counties to refer patients to Moi Teaching and Referral Hospital (MTRH). Similarly, we have made arrangements for downward referral system to enable patients recuperate from their facilities. This will help in decongesting our facility thereby leaving room for other deserving cases to be attended to.

To complement the aforementioned, MTRH has developed and domesticated Standard Operating Procedures (SOPs) to guide referrals for Paediatric Surgery for Transport of Newborns with Surgical conditions.

With this document in place, all referring facilities will be expected to fully adhere to this protocol.

On our part we promise that we will deliver unapparelled specialized services to all our clientele and the counties must also commit to full adherence of the stipulated guidelines covered in this SOPs.

Finally, it is my expectation and that of the Hospital Board that this SOPs and guidelines herein shall guide the referral process and will ensure its implementation to the letter.

MOI TEACHING & REFERRAL HOSPITAL
APPROVED
07 JUN 2017
SIGN ..... DOP:

07/06/2017

DR. WILSON K. ARUASA

CHIEF EXECUTIVE OFFICER

Circulation List

Chief Executive Officer

DDCS

DDFA

DNS

Accident and Emergency Department

Sick Child Clinic, Shoe4Africa Children's Hospital

Operating Theatres, Shoe4Africa Children's Hospital

Newborn Unit, Mother & Baby Hospital

Head, Department of Paediatric Surgery

Newborn Units & Labour Wards, all county referral and sub-county hospitals

Table of Contents

Definition:

- Transfer of newborns with surgical conditions from the hospital of birth/level IV – V (sub-county or county hospital) to a tertiary level hospital (Moi Teaching and Referral Hospital) for ongoing intensive care or surgical care, and/or back from the tertiary level hospital to hospital of birth/level III – V hospital.

Indications:

Newborns requiring:

- Surgical care or review.
- Ambulatory surgical procedures.
- Diagnostic procedures (CT-Scan, MRI- Scan, Contrast studies).
- Return transfer for ongoing care.

Principles:

- Transport of newborns involves pre-transport intensive care level resuscitation and stabilization, and continuing intra-transport care to ensure the baby arrives in a stable state.
- Organized neonatal transport teams bring the intensive care environment to critically ill newborns before and during inter-hospital or intra-hospital transport.
- The basis of safe and timely transport is proper communication and coordination between the referring and receiving hospital to ensure adequate pre-transport stabilization and continuing intra-transport care.
- There is rare need for haste.
- There must be a balance between anticipated clinical complications that may arise due to delay in definitive care and the benefits of further stabilization.

Procedure:

1. Retrieval Process

a) Communication

i. Referring (County or Sub-County) hospital

- Make the decision to transfer together with the parents.
- Provide clear clinical details, interventions and medications to the transport team.
- Document advice given / received.
- Prepare a copy of the baby's clinical notes, investigations and transfer letter.
- Obtain parental consent for transfer and/or consent for surgery.
- Obtain sample of mother's blood (if required).

ii. Receiving (Referral) hospital

- Call and ensure consultant paediatric surgeon/NICU manager agree to accept referral.

MTRH Referral Coordination Desk = **0701 790 434**

- Provide clinical details to the consultant paediatric surgeon/NICU manager.
- Consultant surgeon/NICU manager to provide clear instructions of the initial management before departure.

b) Newborn Transport Service (If available)

- Careful consideration be made on the **mode of transport** – the best mode of transport would be "In-Utero" if ante-natal diagnosis is made.

- Post-natal transfer, the advantages of road and air transport must be carefully considered for each baby.
- Inform the newborn transfer service (if available) in time to organize transport.
- The newborn transfer service will ensure appropriate staff and equipment are available for transport.

c) Handling of the parent(s)/ guardian(s)

- Constantly update the parent(s)/ guardian(s) with the plan of care.
- Ensure that they are aware that transport is in the baby's best interest and warrants the added risks.
- Determine the method of feeding.
- Show baby to the parent(s)/ guardian(s) before departure, if feasible take a photograph of the baby.
- Ensure that the mother is transferred nearer to the baby as soon as possible.
- Give them the receiving hospital's contact information.

2. Pre-transport Stabilization

- Transport of the newborn causes significant stress on the baby; hence they can easily deteriorate during the journey.
- The presence of hypothermia, hypotension and metabolic acidosis has a significant negative impact on the eventual patient outcome.
- It is also almost impossible to do any significant procedures well during the actual transport. Therefore, stabilization pre-transport is critical to ensure a good patient outcome.
- The principles of initial stabilization of the neonate follow the widely recognized ABC's of resuscitation.
    - Airway
    - Breathing
    - Circulation

- Drugs
- Documentation & Specimens
- Environment/ {Equipment}
- Fluids – Electrolytes/ Glucose
- Gastric decompression

a) Airway Management

- Establish a patent airway.
- Evaluate the need for oxygen, frequent suction (Oesophageal atresia) or an artificial airway (potential splinting of diaphragm).
- Security of the airway – the endotracheal tubes (ETT) must be secure to prevent intra-transport dislodgement.
- Do a chest X-ray to check the position of the ETT.

b) Breathing

- The need for intra-transport ventilation has to be carefully assessed. The newborn requires FiO_2 60% to maintain adequate oxygenation.
- Maintain the ABG – $PaCO_2$ >60mmHg to prevent tachypnoea and expected respiratory fatigue.
- Assess for possibility of recurrent apnoeic episodes and expected increased abdominal/bowel distension during air transport.
- If there is a possibility that the child may require to be ventilated during the transfer, it is safer to electively intubate and ventilate before setting off.
- However, there may be certain conditions where it may be preferable not to ventilate if possible, e.g. tracheo-oesophageal fistula. If in doubt, the receiving surgeon should be consulted. If manual ventilation is to be performed throughout the journey, due consideration must be taken about staff fatigue and possible erratic nature of ventilation.

c) Circulation

i. Assessment:

- Heart rate and perfusion (Capillary refill) are good indicators of the hydration status of the baby. The blood pressure in a neonate drops just before the baby decompensates.
- The urine output should be a minimum of 1-2 mls/kg /hr. The baby can be catheterized or the nappies weighed (1g = 1 ml urine).
- A reliable intravenous access (at least 2 cannulae) must be ensured before setting off.
- If the child is dehydrated, the child must be rehydrated before setting off.

ii. Fluid Therapy

- **Resuscitation Fluid:** Normal Saline or Fresh Frozen Plasma or Blood; at a rate of 10 – 20 mls/kg given as boluses over up to 2 hours according to the clinical status.
- **Ongoing losses:** Hartmann's solution, Fresh Frozen plasma or Blood; used to correct ongoing measured (e.g. orogastric) or third space losses as required. The perfusion and heart rates are reliable indicators of the hydration.
- **Maintenance Fluid:** In the surgical neonate, the recommended solution is ½ Saline + 10% D/W, at a rate of 60 mls/kg on Day 1 of birth, 90 mls/kg on Day 2, 120 mls/kg on Day 3, and 150 mls/kg on Day 4 onwards. Watch out for hyponatraemia and hypoglycemia.
- **Ensure Normal Blood Sugar:** Check the blood sugar hourly. If blood sugar is less than 2.5 mmol/L, give boluses of 10% dextrose at half hourly interval until the blood sugar normalizes.

iii. Drugs

- Antibiotics – Most sick neonates will require antibiotics.
- Analgesia/ Sedation – especially if the baby has peritonitis or is intubated.
- Inotropes.
- Vitamin K.

- Sodium bicarbonate.

d) Documentation & Specimens

- History including antenatal and birth history/ Physical Findings/ Diagnosis.
- Previous and current management.
- Previous operative and histopathology notes, if any.
- Input/output charts.
- Results of laboratory and radiological investigations.
- Consent – informed and signed by parents especially if high risk and parents are not escorting the baby.
- Parents' contact addresses and telephone numbers, if not escorting the baby.
- Mother's blood – about 5-10 mls for cross match, if the mother cannot escort the child.
- Any other samples taken from the baby prior to transfer.

e) Warmth

- Optimal temperature for the neonate (axilla) – 36.5 – 37.0 C
- If the body temperature is < 36.50, re-warm the baby in the incubator or using a room heater, until the body temperature normalizes.
- Maintain warmth by:
    - Keeping the baby in a transport incubator if available or
    - Kangaroo Mother Care if mother is well or
    - Wrapping body and the limbs of the baby in aluminum foil, cling film, polythene paper bag or cotton wool, exposing the face to avoid suffocation.
    - Care of the exposed membranes in abdominal wall defects.

    - Monitor and document the baby's body temperature before and after stabilization, on arrival at the referral hospital and throughout the transport process.
- Warm the intravenous fluids.

f) Equipment

Check all equipment for their completeness and function before leaving the hospital.

- Monitors- Cardio - respiratory monitor/ Pulse oximeter for transport would be ideal. However, if unavailable or if affected by vibration, perfusion, a pre-cordial stethoscope and a finger on the pulse will be adequate.
- Syringe and/or infusion pumps with adequately charged batteries.
- Intubation and ventilation equipment and endotracheal tubes of varying sizes.
- Oxygen tanks – ensure adequacy for the whole journey.
- Suction apparatus and catheters.
- Anticipated medication and water for dilution and injection.
- Intravenous fluids and infusion sets.
- Pre-draw fluids/ medication into syringes if required during the journey.

g) Gastric Decompression

- An orogastric tube will be required in nearly all surgical neonates especially if the baby has intestinal obstruction, congenital diaphragmatic hernia or abdominal wall defects.
- The oral route is preferred as a larger bore tube can be inserted without compromising the nasal passages (neonates are obligatory nasal breathers). However, the orogastric tube can easily dislodge and the position needs to be checked regularly.
- Hourly aspiration and free flow of the gastric contents is recommended.

3. Care Immediately Before Departure

a) Preparation for transport begins as soon as decision made to transfer baby.

- Check vital signs and condition of the baby.
- Check the completeness and function of equipment.
- Re-communicate with receiving doctor about the current status and the expected time of arrival.
- Ensure X-rays are sent with baby
- Check and ensure all tubes and lines are very well securely taped.
- Clamp the underwater seal drains or change to Heimlich flutter valve if available.
- Ensure there are TWO reliable IV access sites.
- Prepare extra fluid boluses for babies with gastroschisis, neonatal intestinal obstruction or neonatal sepsis.

b) Packaging, moving and other issues

- Minimize handling of the baby on transit.
- While moving baby into transport incubator ensure smooth transfer and minimize heat loss.
- If the transport team is adequately staffed, identify staff responsible for:
    - Transferring baby from incubator to transport incubator/ambulance.
    - Caring for the infusion lines & other tubes.
    - Monitoring the vital signs.

c) Monitoring

- Monitor temperature half hourly during stabilization process and throughout the transport.
- Check blood glucose hourly.

4. Care during Transport

a) Escort:

- Ideally, there should be a specialized neonatal transport team. If not, the escort should be a medical doctor with/without a trained nurse.
- A minimum of 2 escorts will be required for the ventilated/critically ill baby. The team should be familiar with resuscitation and care of a neonate.
- They should also be able to handle critical incidents.
- The team members should preferably not be prone to travel sickness.
- Safety of the team must be given utmost priority. Insurance, life jackets and survival equipment should be made available for the escort team and parents.

b) Monitoring:

- Regular (half hourly) monitoring of the vital signs, oxygenation and perfusion of the baby should be performed.

c) Fluids:

- Intravenous fluids must be given to the sick newborn to prevent dehydration and acidosis during the transport. Boluses need to be given as necessary depending on the assessment of the perfusion and heart rate of the child.
- If the baby is catheterized, the urine output can be monitored and ensure the urine output is > 1 ml per Kg per hour.
- The orogastric tube should be aspirated half hourly.

d) **Temperature Regulation:**

- A regular (half hourly) check on the baby's temperature should be made.
- Warmth should be maintained in a functioning transport incubator or by wrapping the limbs and the body of the baby in aluminum foil / polythene bag/cotton wool.
- If condition of the baby is not critical and the mother is stable, then Kangaroo Mother Care may be an alternative.
- Wet clothes should be changed as required especially in the child with abdominal wall defects. Disposable diapers and one way nappy liners can be very useful here.

e) **Critical Incidents:**

- Preoperative preparation is to minimize the critical incidents as these can cause loss of life and stress to the transport team.
- These include:
    - Airway – Blocked /dislodged endotracheal tube.
    - Oxygen Supply – exhausted.
    - Loss of IV Access.
    - Deterioration in patient's condition.
    - Loss of life or injury to patient /parent/co-worker.

5. Arrival at the Receiving (Referral) Hospital

- Reassess and document the vital signs of the baby.
- Hand over care to the medical and nursing staff of the referral hospital.
- Hand over transport and referring documents, radiological investigations and specimens to the receiving team.

6. Special Surgical Conditions

a) Oesophageal Atresia with /without Tracheo-oesophageal fistula

These babies have a risk of aspiration of saliva/feeds as well as reflux of the gastric contents through the distal fistula, hence:

- Evaluate for other anomalies e.g. cardiac, pneumonia, and intestinal atresia.
- Keep the newborn Nil by Mouth – **DO NOT FEED** the baby.
- Suction of the upper oesophageal pouch – a ***Replogle*** (sump suction) tube should be inserted and continuous low pressure suction done if possible. If no Replogle tube, insert an ordinary stiff oro-gastric tube (Fr 8) and intermittently aspirate every 15 – 30 minutes.
- Suction of the oro-pharynx is done throughout the journey to prevent aspiration pneumonia.
- Mechanical ventilation should be done only if absolutely necessary. If there is a tracheo-oesophageal fistula, unintended intubation of the fistula may occur leading to insufflation of the GI tract and possible gastric perforation more so if there is a distal bowel atresia.
- Warmth – ensure that the baby is kept warm.
- Fluids – resuscitation and maintenance fluids be administered as required.
- Position - Lie the baby on the left lateral or prone to minimize aspiration of the saliva and reflux.
- Monitor vital signs half hourly.

b) Abdominal Wall Defects

- **Omphalocele, Gastroschisis and Bladder Extrophy** are the common abdominal wall defects.
- Fluid loss, infection, malnutrition, hypothermia and trauma to the exposed viscera are important considerations in these babies.
    - Evaluate the baby for associated syndromes and cardiac anomalies (more commonly in babies with omphalocele.

- **Fluids:** Intravenous fluids are essential as the losses are tremendous especially from the exposed bowel. Give **boluses** (10-20 mls/kg) of normal saline/Hartmann's solution frequently to keep up with the ongoing losses. A **maintenance** drip of ½ Saline + 10% D/W at 60 – 90 mls/kg (Day 1 of life) should also be given. The baby may need to be catheterized to monitor the urine output (> 1 ml/Kg/hr).
- **Hypoglycemia** can occur in about 50% of babies with Beckwith-Wiedermann's Syndrome.
- **Orogastric/Nasogastric tube:** Gastric decompression is essential here and a Size 6 or 8 Fr tube is inserted and aspirated hourly.
- **Warmth:** Particular attention must be paid to temperature control because of the increased exposed surface area and the fluid exudation causing evaporation and the baby to be wet and cold. Wrapping the baby's limbs with aluminum foil or polythene bag will help.
- **Care of the exposed membranes:** The bowel/membranes should be wrapped with a clean plastic film (Cling film or polythene bag) without compressing, twisting and kinking the bowel. ***Please do not use "warm, saline soaked gauze or cotton wool" directly on the bowel as the gauze will get cold and stick to the bowel / membranes.*** Disposable diapers or cloth nappies changed frequently will help the keep the child dry.
- **Position:** The baby should be placed in the right lateral position to prevent tension and kinking of the bowel.

c) Neonatal Intestinal Obstruction

- May be functional e.g. **Hirschsprung's disease** or mechanical e.g. **intestinal atresia, small gut volvulus & ano-rectal malformations**. Fluid loss with dehydration, diaphragm splinting and aspiration of intestinal contents are important considerations.
  - Evaluate the baby for associated syndromes and cardiac anomalies.
  - Keep the newborn Nil by Mouth – **DO NOT FEED** the baby.
  - **Fluids:** Intravenous fluid administration here crucial. Boluses - 10-20 mls/kg Hartmann's solution/normal saline to **correct dehydration**, **maintenance fluid** - ½ Saline + 10% D/W - and **replace** the measured ongoing losses.
  - **Orogastric or Nasogastric tube:** Gastric decompression is essential here and a Size 6 or 8 Fr tube is inserted and aspirated half hourly. Document amount & type of aspirate.

- **X-rays:** Babygram, lateral abdominal X-Rays.
- **Warmth:** Baby must be kept warm.
- **Monitoring** – vital signs and urine output.
- Do **NOT** insert any instrument (tube or thermometer) into the anus.
- **Position:** Nurse in lateral or prone position.
- **Air transport:** Must be avoided unless using pressurized air cabin.

d) Necrotizing Enterocolitis

- Evaluation – These babies are usually premature and septic with severe metabolic acidosis, coagulopathy and thrombocytopenia. There may be an associated perforation of the bowel or gangrenous bowel, initiating the referral to the surgeon.
- **Mechanical ventilation:** Most of the babies may require intubation and ventilation before setting out especially if they have acidosis.
- **Fluids:** Aggressive correction of the dehydration, acidosis and coagulopathy should be done before transporting the baby.
- **Orogastric/Nasogastric tube:** Fr 8, aspirated hourly.
- Nil by Mouth – **DO NOT FEED** the baby.
- **Drugs:** Will require antibiotics and possibly inotropic support that needs to be continued during the journey.
- Check clotting and consider administration of FFP/extra Vitamin K.
- **Peritoneal Drain:** If there is a perforation of the bowel, insertion of a peritoneal drain with/without lavage with normal saline or dialysate solution should be considered. This can help to improve the ventilation as well as the acidosis.

e) Congenital Diaphragmatic Hernia

- Evaluate for associated anomalies and persistent pulmonary hypertension of the newborn (PPHN).
- **Ventilation:** Intubation and ventilation may be required pre-transport. Ventilation with a mask should be avoided and low ventilatory pressures used. A contralateral pneumothorax or PPHN

need to be considered if the child deteriorates. If the baby is unstable or on high ventilatory settings, the baby should not be transported.

- Frequent consultation with a paediatric surgeon will be helpful to decide when to transport the baby.
- If a chest tube has been inserted, it should not be clamped during the journey.
- **Orogastric or NasogastricTube:** Gastric decompression is essential here and a Size 6 or 8 Fr tube is inserted, aspirated hourly.
- **Fluids:** Caution required as both dehydration and fluid overload can precipitate PPHN.
- **Monitoring:**
    - Warmth: Keep the baby warm.
    - Consent - High risk.
    - Position: Lie baby lateral with the affected side down to optimize ventilation.
    - Mode of Transport: Avoid air transport.

f) Pneumothorax / pneumomediastinum

- Pneumothorax that is not under tension does not require drainage.
- Keep oxygen saturations high (PaO_2 > 90%).
- Tension pneumothorax requires drainage.
- If pneumomediastinum present, place infant in ambient oxygen concentration of 100% to enhance absorption of gas collection.

g) Choanal atresia

- Provide oropharyngeal airway.
- Do not feed for at least 2 hr before transfer.
- Observe breathing pattern during transfer.

h) *Pierre Robin Syndrome*

- If the newborn is in respiratory distress, insert oropharyngeal or nasopharyngeal airway.
- Discuss endotracheal intubation with referring or receiving consultant before any attempt is made; expect to seek help from an experienced anesthesiologist.
- Airway patency can be improved by nursing and transferring, in prone position.

i) *Neural tube defects (meningocele, myelomeningocele, encephalocele)*

- If sac ruptured, apply sterile dressing.
- Nurse in prone position to prevent pressure on lesion.
- Cover the lesion with cling film to prevent stool contamination.
- IV antibiotics: Amoxicillin and Gentamicin if available.

7. Organized Newborn Transport Service (if/where available)

- Mother may accompany only if baby stable and at discretion of NTS transport team.
- In the ambulance:
    - Secure the transport incubator, power mains or battery supply, oxygen and air supply.
    - Minimize handling of the baby: if any handling required, stop ambulance in a safe place.
    - Avoid hypothermia by minimizing interference.
    - Monitor: Heart rate, respiratory rate, blood pressure and temperature continuously; and record readings every 30 minutes.
    - Document type and volume of infusions, if central access used, ensure umbilical stump visible and observe for any bleeding.
    - Monitor peripheral IV site/s for any leakage and patency.
    - Ensure any peripheral arterial line site visible.

- At the receiving unit at the referral hospital:

- When moving baby from transport incubator to the incubator, identify the nurse responsible for: transferring baby from transport incubator to incubator, taking care of infusion lines & other tubes, and opening and closing incubator doors.
- Hand over care to medical and nursing staff.
- Photocopy, if possible, all transport and referring documents and give to receiving team.
- **DO NOT** leave receiving unit until this has been done as you are asking them to be responsible for the ongoing care of baby.
- Hand over X-rays & specimens to the receiving team.
- When baby settled, check and document the vital signs ± blood gases & blood glucose.
- Inform referring centre and parents of safe arrival of baby.
- Complete documentation and provide receiving unit with photocopy before you depart.
- **Do NOT** leave the baby at a unit without all necessary documentation.

8. Pre-departure checklist

Patient Status	Documents & Specimens
• **Airway** is secured and patent (must do post intubation chest X-ray before departure to make sure ET tube is at correct position). • **Venous access** is adequate and patent (at least 2 IV lines). • **IV drip** is running well. • Patient is safely secured in **transport incubator** or trolley. • Vital signs are charted. • All **tubes** (Naso- or Oro-gastric drains) are functioning and secured. • **Stabilization** is complete (Hypotension, hypoxia, hypothermia and hypoglycemia adequately corrected). • **Warmth** (transport incubator, Kangaroo Mother Care, Aluminum Foil/Plastic bag/Cling Film wrap). • **Oxygen** is flowing (Mask, nasal prongs or ET tube). • **Escort** (Nurse/paramedic).	• Patient notes / referral letter. • X-rays, ultrasounds, other investigations. • Consent form. • Vital signs chart. • Input/output charts. • Maternal blood (for infant).
Medication	**Equipment**
• **Intravenous fluids:** normal saline, Hartmann's solution, 5% albumin, dextrose 10%. • **Inotropes:** dopamine, dobutamine, adrenaline. Sedative: morphine, midazolam. • **Blood product(s)** if indicated. • **Others:** atropine, sodium bicarbonate, sterile water for injection.	• Transport incubator (if available). • Airway and intubation equipment are all available and working (ET tubes Fr 2 - 5, laryngoscope, Magill forceps). • Batteries. • Manual resuscitation (Ambu) bags and masks of various sizes are available and functions properly. • Suction device functions properly. • Oxygen cylinders are full and a spare oxygen cylinder is available. • Oxygen tubing. • Infusion pumps are functioning properly. • Intravenous cannulae of various sizes. • Needles of various sizes. • Syringes and tubings of various sizes.

	• Suture material of various sizes. • Adhesive tape, scissors, gloves, gauze, swabs (alcohol and dry). • Stethoscope. • Thermometer. • Nasogastric tubes of various sizes. • Pulse oximeter (if available) functions properly with set alarm limits. • Cardiac monitor if indicated. • Chest clamps (if an underwater chest drain is present).

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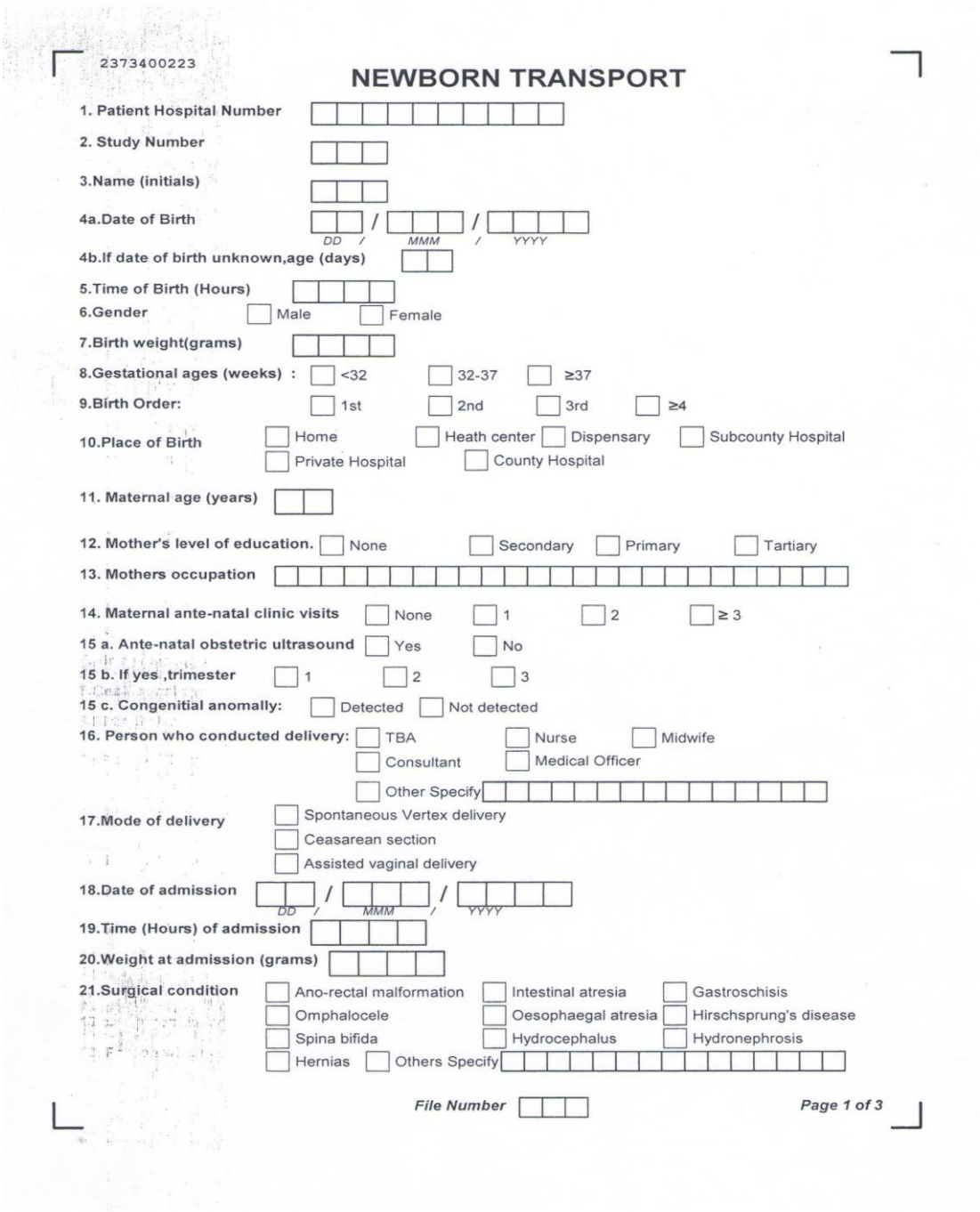
Appendix II: Data Collection Tool



2373400223

NEWBORN TRANSPORT

1. Patient Hospital Number
2. Study Number
3. Name (initials)
4a. Date of Birth (DD / MMM / YYYY)
4b. If date of birth unknown, age (days)
5. Time of Birth (Hours)
6. Gender ☐ Male ☐ Female
7. Birth weight(grams)
8. Gestational ages (weeks) : ☐ <32 ☐ 32-37 ☐ ≥37
9. Birth Order: ☐ 1st ☐ 2nd ☐ 3rd ☐ ≥4
10. Place of Birth ☐ Home ☐ Heath center ☐ Dispensary ☐ Subcounty Hospital ☐ Private Hospital ☐ County Hospital
11. Maternal age (years)
12. Mother's level of education. ☐ None ☐ Secondary ☐ Primary ☐ Tartiary
13. Mothers occupation
14. Maternal ante-natal clinic visits ☐ None ☐ 1 ☐ 2 ☐ ≥ 3
15 a. Ante-natal obstetric ultrasound ☐ Yes ☐ No
15 b. If yes ,trimester ☐ 1 ☐ 2 ☐ 3
15 c. Congenitial anomally: ☐ Detected ☐ Not detected
16. Person who conducted delivery: ☐ TBA ☐ Nurse ☐ Midwife ☐ Consultant ☐ Medical Officer ☐ Other Specify
17. Mode of delivery ☐ Spontaneous Vertex delivery ☐ Ceasarean section ☐ Assisted vaginal delivery
18. Date of admission (DD / MMM / YYYY)
19. Time (Hours) of admission
20. Weight at admission (grams)
21. Surgical condition ☐ Ano-rectal malformation ☐ Intestinal atresia ☐ Gastroschisis ☐ Omphalocele ☐ Oesophaegal atresia ☐ Hirschsprung's disease ☐ Spina bifida ☐ Hydrocephalus ☐ Hydronephrosis ☐ Hernias ☐ Others Specify

File Number ☐☐☐ *Page 1 of 3*

1549400227

22.Mode of transport ☐ Ambulance ☐ Private vehicle ☐ Public transport
☐ Motorcycle
☐ Others Specify

23.Date of decision to refer DD / MMM / YYYY

24.Time of decision to refer(Hours)

25.Date of the start of transfer DD / MMM / YYYY

26.Time of the start of transfer(Hours

27.MTRH contacted before transfer ☐ Yes ☐ No

28.Communication on referal

☐ Written ☐ Verbal ☐ None

b.Reason

29.Pre-transport stabilization

a. Warmed the baby ☐ Yes ☐ No

b. Given 10% dextrose ☐ Yes ☐ No

c. Given IVFluids/Blood ☐ Yes ☐ No

d. Given oxygen ☐ Yes ☐ No

e. Baby positioned appropriately ☐ Yes ☐ No

f. Specific treatment for the surgical condition

☐ Nasogastric tube ☐ vitamin K ☐ IV line
☐ Defect covered with polythene bag
☐ Others (Spcify)

30. Care during transport

a. Nasogastric tube aspiration every:

☐ 30 Minutes ☐ 30 Minutes to 1 hour
☐ ≥ 1 hour ☐ None

b. Method used to keep baby warm

☐ skin to skin (KMC) ☐ Polythene bag ☐ Clothing
☐ Alluminuim foil ☐ Cotton Wool ☐ Incubator
☐ None ☐ Others (Specify)

c. Baby given oxygen ☐ Yes ☐ No

d. If yes ,by ☐ Nasal Prongs ☐ Facial Mask
☐ Others

e. Baby on IV fluids ☐ Yes ☐ No

f. Documentation ☐ Consent for surgery ☐ Refferal Note ☐ Radiology report
☐ Laboratory Report ☐ Others

File Number

5512400221

g. **Who escorted the baby during transport**

☐ Doctor ☐ Nurse ☐ Clinical Officer ☐ Nurse Aid
☐ Relative ☐ Others (Specify) ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

h. **Specimens sent from the referring hospital**

☐ None ☐ Blood ☐ Others (Specify) ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

i. **Critical incidents that occured during transport**

☐ Airway- blocked/dislodged endotracheal tube ☐ O2 supply exhausted
☐ Death of the newborn ☐ Deterioration in new born's condition
☐ Injury to newborn/parent/co-worker ☐ None

31. **Assessment of clinical condition at admission**

a.**Forehead skin temperature** ☐ 32.0 °c ☐ 32.0 to 35.9 °c ☐ 36.0 to 36.4 °c
☐ 36.5 to 37.5 °c ☐ > 37.5 °c

b.**Capillary Refill time** ☐ < 3 seconds ☐ ≥ 3 seconds

c.**Random Blood sugar** ☐ <2.5MM0l/L ☐ 2.5-6.9MM0l/L ☐ >6.9MM0l/L

d.**Respiratory rate (breaths per minute)** ☐ <30 ☐ 30-60 ☐ >60

e.**Oxygen saturation (spo2)** ☐ <85% ☐ 85-90% ☐ >90%

f.**Did the baby undergo immediate resuscitation at admission**

☐ Yes ☐ No

g.**If yes** ☐ Airway blocked-re-established ☐ Breathing ceased -assisted ☐ Support for circulation given
☐ Others (specify) ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

32.**Overall outcome**

a.**Final disposition** ☐ Discharged home ☐ Died ☐ Transfered
☐ Abandoned ☐ Left against medical advice

b.**Date of final disposition** ☐☐ / ☐☐☐ / ☐☐☐☐ (DD / MMM / YYYY)

c.**Timeof final disposition(Hours)** ☐☐☐☐

Filled By ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ **Signature** ☐☐☐☐
Date filled ☐☐ / ☐☐☐ / ☐☐☐☐ (DD / MMM / YYYY)

Checked By ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ **Signature** ☐☐☐☐
Date checked ☐☐ / ☐☐☐ / ☐☐☐☐ (DD / MMM / YYYY)

File Number ☐☐☐

Appendix III: Consent Form

I. Consent form – English

Consent will only be given by the parent or legal guardian of the patient. The consent form is in English and Kiswahili, however this will be translated to a language that the parent/guardian understands in cases where he/she does not comprehend either of the two languages. The research assistant or an individual appointed by the investigator or research assistant will be the translator.

Study number: ……..

MTRH/MU – IREC Approval Number 0001861.

Study title: Outcomes of Newborns with Surgical Conditions at Moi Teaching and Referral Hospital: The Context of a structured Standard Operating Procedure for Newborn Transport

Principal investigator: Peter W. Saula

TM 410 – 0741/2016

Background information

We are conducting a research to find out the effect of introducing a standard procedure of transporting newborns with conditions that require surgery on their outcome. As it is now, there is no standard operating procedure for these very ill newborns in Kenya. Your participation in this study therefore will go a long way in contributing to the formulation of newborn transport policy by the national and county governments that will improve the health of these babies in future. This study will not interfere with the treatment of your baby and your participation in the study is purely voluntary. Should you opt not to participate in the study, your baby will still

receive fair treatment like any other patient. Before participating, you are requested to go through the form and understand the aim and purpose of the study. You are free to ask questions and clarifications where necessary before proceeding to consent to the study.

Purpose of study

The study will be looking at the outcomes of neonates with surgical conditions who have been referred from the county hospitals for specialized care, the manner in which they were referred and transported to MTRH, and whether this could have some influence on their outcome.

Procedure

After you understand what will be done and consent to the study, your baby will be recruited to participate in the study. You will be allowed to ask questions or clarifications where you are not sure and you will be at will to withdraw from the study when deemed necessary without any consequences as pertaining to the care of your child.

Once you give consent, your baby will be enrolled into the study and a research assistant will ask you questions pertaining to the condition of the baby. He/she will examine your baby and make observations using a thermometer and pulse oximeter; and record all the relevant findings on a data sheet. Further information pertaining to your baby will be obtained from the doctor's records. A blood sample will be collected from the heel of your baby's foot to test for blood sugar. This procedure may cause some pain but does not endanger the life of the baby.

Confidentiality

The information collected is confidential and will not include any information that will identify you and your baby directly. Any identification numbers are purely for purposes of record keeping and to allow us to work with the information gathered.

Benefits

There will be no direct benefit to the participants or incentives given. We are NOT going to pay you for participating in this study and we will NOT ask you to pay for blood sugar test. This study will NOT interfere in any way with the treatment of your baby.

Risks

The procedure of taking a blood sample for measuring the blood sugar of your baby may cause some pain but does not endanger the life of the baby. There will be no other direct risks involved to the participants for participating in this study.

Will to withdraw

You will be at will to withdraw from the study at any given time with no consequences in relation to the standards of care and management given to your baby. Should you opt to withdraw your child from the study, he/she will still receive care at the unit as required without discrimination.

Person to contact

In case of complaints or any further questions regarding the study, please contact the principle investigator through the following address.

Peter W. Saula

Moi Teaching and Referral Hospital

P.O. Box 3 – 30100 ELDORET

Mobile: 0722 771 963

Email: saulapw@yahoo.com

Institutional review board

This study has been approved by the Institutional Research and Ethics Committee (IREC) of Moi University/Moi Teaching and Referral Hospital. Contact IREC if you have questions regarding your child's right as a participant, and also if you have complaints or concerns which you do not feel you can discuss with the investigator. Contact IREC using the address; The Chairman IREC, Moi Teaching and Referral Hospital, PO BOX 3, Eldoret, Kenya. Tel. 33471/2/3

INFORMED CONSENT

By signing this consent form, I confirm I have read the information in this consent form and have had the opportunity to ask questions. I will be given a signed copy of this consent form. I hereby voluntarily agree to take part in this study.

Name of Caregiver…….…… Signature/Mark…….. Date…….

Name of Investigator…….……Signature……Date……

Thank you.

II. Consent Form – Kiswahili

Fomu ya idhinisho

Idhini ya kushiriki katika utafiti

Nambari ya siri……

Nambari ya MTRH/MU – IREC ni 0001861.

Anwani: matukio yanayojiri kwa wana wachanga wanao safiri kwa mnajili ya kupata huduma za upasuaji katika hospitali ya rufaa na mafunzo ya moi.

Mtafiti mkuu: Peter W. Saula

TM 410 – 0741/2016

Utangulizi

Unaombwa kushiriki katika utafiti huu. Kabla ya kutoa uamuzi ni muhimu kuelewa lengo la utafiti na yatakayo jumulishwa. Soma habari ifuatayo kwa uangalifu na uulize iwapo kuna chochote huelewi au unahitaji ufafanuzi zaidi. Tafadhali tafakari zaidi kabla ya kutoa uamuzi iwapo wataka kuhusika katika utafiti. Lengo la utafiti huu ni kuangazia jinsi usafirishaji ya watoto wachanga ambao wanahitaji huduma wa upasuaji katika hospitali ya rufaa ya Eldoret, yanavyo dhiri matokeo ya matibabu. Pia tutaangalia magonjwa haya yanafanya watoto kulazwa kwa muda mgani kwenye hospitali na matokeo yao kulingana na ugonjwa zingine mbali ambayo watoto hawa hutibiwa. Uchunguzi wetu ni wa utafiti japo tunadhamiria kuwa habari tutakayoipata itasaidia kujulisha hospitali na watungaji wa sera kwa madhumuni ya kuangaza kiwango cha uenezaji wa afya bora.

Namna utafiti utakaofanywa

Ukisha soma fomu idhinisho na kuelewa, utaombwa kujaza na kutia sahihi au muhuri kwenye fomu hii. Mtoto wako atachaguliwa kwenye utafiti huu kulingana na maelekezo ya kushiriki. Fomu ya maswali kuhusu wewe na mwanao kulingana na jinsi ya kusafiri, dalili za ugojwa wakati wanapolazwa katika wadi ya watoto wachanga itajazwa na ugonjwa ule kuangaliwa na yale yatakayo tukia kujazwa kwenye fomu. Hauta lazimishwa kushiriki utafiti huu na yale matibabu ambayo mtoto wako atapokea yatakuwa sawa na wengine wote watakao shiriki au kutoshiriki utafiti huu.

Usiri

Utafiti huu utatekelezwa kulingana na sheria za nchi ya Kenya na utaratibu unaohifadhi haki za binadamu katika maswala ya utafiti. Habari kuhusu afya ya mwanao, kodi zote na habari zote zitakazopatikana zitahifadhiwa kisiri na habari kuhusu afya ya mwanao haitatumiwa bila idhini. Ni mtafitii mkuu na msaidizi wake tu watakao kuwa na habari hizi. Njia zote za kupata habari zitatambuliwa kwa nambari au kuficha uhalisia ili kuhifadhi habari inayoweza kutumiwa kumtambulisha mwanao. Matokeo ya utafiti huu yanaweza kuchapishwa hakuna majina au habari za kukutambulisha zitakazotolewa.

Faida

Hakutakuwepo na faida ya moja kwa moja itakayomfahidi mwanao kwa kuhusika katika utafiti huu. Faida inayotarajiwa ni kuhimarisha viwango vya afya ya watoto kutokana na mapendekezo ya utafiti huu na kuboresha hali ya afya. Na pia hutalipia gharama ya motto kupimwa sukari kwenye damu kwa mnajili ya utafiti huu. Kushiriki kwa utafiti huu ni kwa hiari bali hakuna malipo yoyote utakaopewa.

Madhara

Isipokuwa uchungu wakati motto anapodungwa kwa mnajili wa kupima kiwango cha sukari kwenye damu, hakuna madhara mengine yoyote yatakayohusishwa mwanao katika utafiti huu. Utafiti utakuwa wa kisiri. Mtoto atapata matibabu ya ugonjwa wake kulingana na matokeo au sera zinazokubaliwa na hakuna mpangilio mwingine au utafiti utakao fanywa kwa mtoto wako kwa kushiriki utafiti huu.

Njia mbadala

Una uhuru wa kuamua mwanao asihusike katika utafiti huu. Kwa kufanya hivi hakutakuwa na madhara yoyote kwa mwanao au kunyimya matibabu yoyote kwa kuamua kutoshiriki utafiti huu.

Mawasiliano

Iwapo una swali lolote, malalamishi au jambo lisilokuridhisha kuhusiana na utafiti huu, mjulishe mtafiti mkuu kutoka Chuo kikuu cha Moi, Kitivo cha utabibu, idara ya Afya ya watoto:

Peter W. Saula

Nambari ya simu 0722771963

Barua pepe saulapw@yahoo.com

Idhinisho kutoka kwa bodi

Utafiti huu umekubaliwa na kamati ya chuo ya utafiti na maadili (IREC) ya chuo kikuu cha Moi na hospitati ya mafunzo na Rufaa ya Moi Eldoret. Julisha idara hii ukiwa na swali kuhusu haki ya mtoto wako kuhusishwa katika utafiti au kama una

malalamishi au ujumbe unaonelea huwezi kujadiliana na mtafiti kupitia kwa anwani hii:

Mwenyekiti kamati ya chuo ya utafiti na maadili (IREC) ya chuo kikuu cha Moi na hospitali ya mafunzo na Rufaa ya Moi Eldoret, S.L.P. 3, ELDORET, Kenya Nambari ya simu: 33471/2/3

IDHINI:

Kwa kutia sahihi fomu hii, ninadhibitisha kwamba nimesoma habari iliyomo na nimekuwa na fursa ya kuuliza maswali. Nitapewa nakala iliyotiwa sahihi ya fomu hii. Nina hiari kukubali kuhusika katika utafiti huu.

MAJINA YA MZAZI…….Sahihi/Alama…….……..Tarehe……...

MAJINA YA MTAFITI……..Sahihi/Alama…….……..Tarehe……...

Ahsante.

Appendix IV Letters of Approval

I. Formal Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

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

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

Reference: IREC/2017/30
Approval Number: 0001861

9th May, 2017

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
09 MAY 2017
APPROVED
P. O. Box 4606-30100 ELDORET

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

Dear Dr. Saula,

RE: FORMAL APPROVAL

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

"Effect of a Structured Standard Operating Procedure for Transport of Newborns with Surgical Conditions".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1861*** on 9th May, 2016. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 8th May, 2018. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

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

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

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

II. Continuing Approval 1

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

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

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2017/30
Approval Number: 0001861

9th May, 2018

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

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
09 MAY 2018
APPROVED
P. O. Box 4606 - 30100 ELDORET

Dear Dr. Saula,

RE: CONTINUING APPROVAL

The Institutional Research and Ethics Committee has reviewed your request for continuing approval to your study titled:-

"Effect of a Structured Standard Operating Procedure for Transport of Newborns with Surgical Conditions".

Your proposal has been granted a Continuing Approval with effect from 9th May, 2018. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 8th May, 2019. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

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

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

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

III. Continuing Approval 2

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

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

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

Reference: IREC/2017/30
Approval Number: 0001861

9th May, 2019

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
09 MAY 2019
APPROVED
P. O. Box 4606 - 30100 ELDORET

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

Dear Dr. Saula,

RE: CONTINUING APPROVAL

The Institutional Research and Ethics Committee has reviewed your request for continuing approval to your study titled:-

"Effect of a Structured Standard Operating Procedure for Transport of Newborns with Surgical Conditions".

Your proposal has been granted a Continuing Approval with effect from 9th May, 2019. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 8th May, 2020. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

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

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

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

IV. Continuing Approval 3

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

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

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

Reference: IREC/2017/30
Approval Number: 0001861

9th May, 2020

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

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
09 MAY 2020
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Dr. Saula,

RE: CONTINUING APPROVAL

The Institutional Research and Ethics Committee has reviewed your request for continuing approval to your study titled:-

"Effect of a Structured Standard Operating Procedure for Transport of Newborns with Surgical Conditions".

Your proposal has been granted a Continuing Approval with effect from 9th May, 2020. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 8th May, 2021. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

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

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

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

V. Permission to conduct research

MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke
P. O. Box 3
ELDORET

Ref: ELD/MTRH/R&P/10/2/V. II/2010

15th May, 2017

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

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

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

"Effect of a Structured Standard Operating Procedure for Transport of Newborns with Surgical Conditions".

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

DR. WILSON K. ARUASA
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

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

Appendix V: WHO Guidelines for Transfer of Sick Neonates

Preamble

The burden that maternal and neonatal ill health poses on the development of individuals, communities and societies has attracted the attention of world leaders who had to adopt specific goals and targets to reduce maternal and childhood-infant mortality as part of the Millennium Declaration and later Sustainable Development Goals. With the realization that many conditions that result in perinatal deaths can be prevented or treated without sophisticated and expensive technology, education of clinicians on simple but critical interventions for the newborn during the first days of life became necessary. A guide to achieve this was then developed by the WHO in collaboration with UNFPA, UNICEF and World Bank with a common understanding of the key elements in reducing newborn deaths. The aspects that deal with the newborns were further reviewed and endorsed by the International Pediatric Association.

Section 2 – C-63 of the guide that sets the standards on the transfer and referral of sick neonates was adopted and domesticated for use in this study.

- If the baby needs to be transferred to a tertiary hospital or specialized centre, or brought from a more peripheral facility or to a different service within the same facility (e.g. from the delivery room to the newborn special care unit), ensure a safe and timely transfer. It is important to prepare the baby for transfer, communicate with the receiving or sending facility, and provide care during transfer.
- Pre-transport preparation and stabilization:
    - Explain to the family the reason for transfer of the baby.
    - Obtain informed consent for any anticipated procedures, if applicable.
    - Prepare the baby for transfer:

- Ensure that the baby's condition is stable before transfer by correcting hypothermia, hypotension, hypovolaemia, hypoglycaemia, hypoxia and anaemia.
- Give necessary treatment before transfer (e.g. treat low blood glucose), if possible;
- Keep the baby Nil by Mouth.
- Insert appropriate size Nasogastric Tube (6-F or 8-F) and connect to a 10 or 20 cc Syringe for suction every after half an hour.
- Ensure that the IV line, if present, is in place and secured and that the micro-dropper is filled with fluid.

• Gather essential equipment, supplies, drugs, and fluid (Table C-13).
• Have a health care provider (with experience in establishing and maintaining IV lines, resuscitating a baby, and giving drugs) accompany the baby, if possible.
• Ensure that the vehicle has adequate lighting and insulation to keep the baby warm or to prevent overheating.
• Ask a relative to accompany the baby and mother, if possible.

- Suggested equipment, supplies, drugs, and fluids for transfer of a sick baby

TABLE C-13

Equipment	Supplies	Drugs and Fluids
Resuscitation bag and mask	IV infusion set	Any drug (e.g. antibiotics) the baby is receiving if a dose is anticipated during the trip
Suction apparatus	Butterfly set or cannula	IV Fluids
Oxygen cylinder with flow meter and a head box, nasal prongs, nasal catheter, or face mask	Antiseptic solution and cotton-wool ball	
Stethoscope	Syringes and needles (various sizes and types)	
Thermometer	Adhesive tape	
Blanket	Gloves	
Source of warmth	Napkins (diapers)	
Gastric tubes (6-F or 8-F)	Torch and extra batteries and bulb	

- Communication

a) If receiving the transferred baby, request a referral form (Fig. A-3) with the baby's essential information.

b) At discharge or following the death of the baby, send a detailed note or feedback to the referring facility.

c) If referring a baby to another facility:

- Contact the receiving facility in advance, if possible, so they can be prepared.

- Confirm that the facility is able to admit the baby.

- Give an estimated time of arrival.

- Fill out the referral form and send it with the baby (Figure A-3).

- If the mother is accompanying the baby, inform the facility to ensure that she will have a place to stay with the baby.

- Care during transfer

a) Warmth

• Keep the baby in skin-to-skin contact with the mother or a relative (Kangaroo Mother Care). If skin-to-skin contact is not possible, wrap the baby in a polythene bag or aluminum foil and then keep the baby covered.

- If transferring the baby during cold weather, use a warming device. Keep the baby dressed and covered and check the temperature setting and measure the baby's temperature every hour;
- If a warming device is not available, place the baby in a box with warm water bottles and cover the bottles with a cloth to ensure that they are secured so that they do not directly touch the baby's skin; when the water becomes cold, refill the bottles with warm water or remove them from the box.
- If transferring the baby during hot weather, ensure that the baby does not become overheated.

b) Ensure that the baby receives IV fluids:

- Carefully monitor the rate to ensure that the baby receives the correct volume of fluid.
- Inspect the infusion site every hour, look for redness and swelling around the insertion site of the cannula, which indicate that the cannula is not in the vein and fluid is leaking into the subcutaneous tissue. If redness or swelling is seen at any time, stop the infusion, remove the needle, and establish a new IV line in a different vein.
- Check the volume of fluid infused and compare to the prescribed volume.
- Record all the findings.

c) If the baby is receiving oxygen, check the oxygen flow and tubing every 15 minutes.

    - Assess the baby's respiratory rate every 15 minutes. If the baby is not breathing at all, is gasping, or has a respiratory rate less than 20 breaths per minute, resuscitate the baby using a bag and mask.

d) Nasogastric tube must be suctioned every 30 minutes to prevent the baby vomiting and aspirating the gastro-intestinal secretion into the respiratory tract.

e) Stop the vehicle, if necessary, to manage problems.

Appendix VI: Publications

East African Medical Journal Vol. 95 No. 10 October 2018
CHARACTERISTICS OF NEWBORNS WITH SURGICAL CONDITIONS, REFERRED TO AND SEEN AT A TERTIARY LEVEL HOSPITAL IN WESTERN KENYA

Peter Saula, School of Medicine, Moi University, P.O. Box 4606, 30100, Eldoret, Kenya. Yeri Kombe, Centre for Public Health Research, KEMRI P.O. Box 54,840, 00200, Nairobi, Kenya. Gideon Kikuvi, School of Public Health, Jomo Kenyatta University of Agriculture and Technology, P.O. Box 62,000, 00200, Nairobi, Kenya.

Corresponding author: Peter W. Saula, School of Medicine, Moi University, P.O. Box 4606, 30100, Eldoret. Email: saulapw@yahoo.com.

CHARACTERISTICS OF NEWBORNS WITH SURGICAL CONDITIONS, REFERRED TO AND SEEN AT A TERTIARY-LEVEL HOSPITAL IN WESTERN KENYA

P. W. Saula, Y. I. Kombe and G. M. Kikuvi

ABSTRACT

Background: World over, neonatal mortality contributes significantly to the under-five mortality rate, and 10% of neonatal deaths in low and middle-income countries (LMICs) are due to surgical conditions. The majority of surgical conditions are congenital malformations that are only amenable to surgical treatment in the neonatal period. In Kenya, specialized neonatal surgical care is only available in the two tertiary level hospitals in Eldoret and Nairobi. Since the majority of newborns with surgical conditions are born or seek initial care in the lower level health facilities, appropriate referral and transport to the tertiary-level hospitals determines the overall outcome of their treatment. Moreover, socio-demographic and clinical characteristics of newborns with surgical conditions are important determinants of the outcome of their care at the tertiary-level hospital.
Study Objective: To describe the socio-demographic; clinical; and referral and transport characteristics of the newborns with surgical conditions, who were referred to and seen at Moi Teaching and Referral Hospital (MTRH).
Study design: A hospital-based cross-sectional study was done on all newborns with surgical conditions referred, transported to and seen at the Newborn Unit.
Study Setting: Moi Teaching and Referral Hospital, Eldoret, Kenya.
Main Outcomes: Socio-demographic; clinical; and referral and transport characteristics of the newborns who met the inclusion criteria.
Results: One-hundred and twenty-six newborns who met the inclusion criteria were recruited into the study between February 2018 and January 2019. The median age of the newborns at admission was 4.4 days (106.5 hours), and only 26 (20.6%) of their mothers had optimal antenatal care during pregnancy. The level of education and the occupation of their mothers had a significant association with the uptake of antenatal care during pregnancy (p-value = 0.000). The

majority had congenital anomalies that were mainly gastroschisis (23.0%), hydrocephalus (18.3%), ano-rectal malformations (ARM) (14.3%) and Hirschsprung's disease (14.3%). Most (96.0%) of the newborns were transported to MTRH using road ambulance, and 95.2% were escorted by trained medical personnel during transport.
Conclusions: Congenital anomalies were the major surgical conditions seen in the newborns referred and transported to MTRH, and gastroschisis was the leading condition. The newborns had delay in accessing neonatal surgical care; and the majority of their mothers had poor antenatal care during pregnancy, despite the apparent high health-facility delivery.

INTRODUCTION

Maternal and neonatal health is an important public health issue both nationally and globally as enshrined in the World Health Organization (WHO)'s fourth Millennium Development Goal[1]. Neonatal mortality accounts for between 35% and 50% of the under-five mortality rates in low- and middle-income countries (LMICs), mainly in Asia and Africa[2]. Moreover, 9% of global disease burden is attributed to congenital malformations[3]. In sub-Saharan Africa, 2.6 million children are born with congenital malformations[4]. Many of these malformations are only amenable to surgery in the neonatal period, which in Kenya is only feasible in the two tertiary level hospitals in Eldoret and Nairobi. Many of these newborns are born and/or seek initial care in health facilities that have no capacity to treat their conditions hence, the need for appropriate referral and transport[5].

Previous hospital-based studies have indicated that improper referral and inter-facility transport of newborns with surgical conditions contribute significantly to the overall neonatal mortality[6,7,8]. These deaths are often attributed to a three-delay model, the delay in recognition of the severity of the illness, the delay in seeking and accessing care, and the delay in the provision of care once at the health facility[9]. This 3-delay model was developed by *Thadeus and Maine* while exploring the causes of maternal deaths, and initially comprised the delay in deciding to seek care (delay 1), the delay in reaching the health care facility (delay 2), and delay in receiving quality care once at the health care facility (delay 3)[10]. The model has been explored in analyzing perinatal deaths in LMICs and found to be useful[11,12].

Several studies have linked various characteristics of newborns referred to tertiary level hospitals for specialized care, and the outcomes of their treatment. Sachan *et al*, Narang *et al* and Aggarwal *et al* reported an inverse relationship between mortality of referred newborns, and their gestational age, birthweight and delivery conducted by unskilled birth attendant[13,14,15].

Whereas the exact contribution of neonatal referral and transport characteristics to neonatal mortality is unknown, a few studies have reported mortality rates of 25 – 35% in sick newborns transported to tertiary level hospitals[16]. Currently, there is limited research, particularly in resource limited settings like Kenya, which focuses on appropriate transport of newborns with surgical conditions.

This study laid focus on the delay in seeking and accessing newborn surgical care, and sought to describe the socio-demographic; clinical; and referral and transport characteristics of the newborns with surgical conditions that were referred, transported to, and seen at Moi Teaching and Referral Hospital (MTRH), for specialized surgical care.

MATERIALS AND METHODS

Study design and Study Population: This was a descriptive cross-sectional study that was nested in a wider quasi-experimental study design. The study population was all newborns with surgical conditions referred to and seen at the Newborn Unit of the Moi Teaching and Referral Hospital (MTRH).

Study Setting: The study was conducted in the Newborn Unit of the MTRH, which is located in Uasin Gishu County in the North Rift Region of western Kenya. Moi Teaching and Referral Hospital, the second tertiary-level hospital in Kenya, serves the greater western Kenya, with an approximate population of 16.2 million. Its Newborn Unit receives referrals from over 20 county referral hospitals in the region, and approximately 30% of the referred newborns seek surgical care[17].

Variables: The variables were socio-demographic; clinical; and referral and transport characteristics.

Sampling, Data Collection, and Data Analysis: All newborns with surgical conditions, referred from 10 selected county referral hospitals during the study period (February 2018 – January 2019) were recruited into the study. The 10 hospitals were selected, out of 20 county referral hospitals that refer newborns with surgical conditions to MTRH, by random cluster sampling. A pre-tested data collection tool was used to record data on the study variables. Data were collected by review of medical records, and interviews of the transport teams which were done immediately after the newborns were handed over to the Newborn Unit. Data was entered into STATA version 11 and analyzed using descriptive statistics. Fisher's Exact Test was used to test associations between study variables and $P < 0.05$ was considered statistically significant.

Ethical Considerations: The study protocol was fully explained to the parents/guardians and the transport teams; and informed consent was obtained. Ethical approval was sought from and granted by Moi University-MTRH Institutional Research Ethics Committee.

RESULTS

One hundred and twenty-six (126) newborns, with surgical conditions, were recruited into the study during the study period (February 2018 to January 2019).

Socio-demographic characteristics of the newborns with surgical conditions. The median age at admission was 106.5 hours, (IQR = 77,133), which was approximately 4.4 days. Their median birth weight was 2700g (IQR = 2200, 3200), and the Male to Female ratio was 1:1. The median maternal age was 23 years and the majority (93.7%) of their mothers had formal education. (See Table 1).

Table 1
Socio-demographic Characteristics of the Newborns

Variable	
Age at admission (Hours)	N = 126
Median (IQR)	106.5 (77, 133)
Birth Weight (Grams)	N = 126
Median (IQR)	2700 (2200, 3200)
Weight at admission (Grams)	N = 126
Median (IQR)	2617.5 (2140, 3020)
Maternal Age (Years)	N = 126
Median (IQR)	23 (20,28)
Maternal Level of Education	N = 126
Non-formal (%)	8 (6.3)
Primary (%)	47 (37.3)
Secondary (%)	50 (39.7)
Tertiary (%)	21 (16.7)
Maternal Occupation	N = 126
No Employment (%)	80 (63.5)
Self-Employment (%)	28 (22.2)
Formal Employment (%)	18 (14.3)

Clinical Characteristics of the newborns with surgical conditions: Forty-Six (36.5%) mothers of the recruited newborns did not seek antenatal care during pregnancy. Of the 80 (63.5%) who sought antenatal care, only 26 (20.6) had > 3 antenatal visits. Thirty-Nine (30.9%) mothers had antenatal ultrasound scans done during the antenatal visits that only detected congenital anomalies in 9 (23.1%). The majority (90.5%) of the newborns referred with surgical conditions were born in health facilities, by normal vaginal delivery (88.9%). Eighty-nine-point seven percent of the deliveries were assisted by skilled birth attendants (See Table 2).

Table 2
Clinical Characteristics of the Newborns

Variable	
Gestational Age (Weeks)	N = 126
Preterm (< 37), (%)	48 (38.1)
Term (≥ 37) (%)	78 (61.9)
Antenatal Care Visits	N = 126
None (%)	46 (36.5)
< 3 (%)	54 (42.9)
≥ 3 (%)	26 (20.6)
Antenatal Ultrasound Scan	N = 80
Yes (%)	39 (48.8)
No (%)	41 (51.2)
Trimester of Ultrasound Scan	N = 39
1st (%)	5 (12.8)
2nd (%)	21 (53.8)
3rd (%)	13 (33.3)
Congenital anomaly detected	N = 39
Yes (%)	9 (23.1)
No (%)	30 (76.9)
Place of Birth	N = 126
Home (%)	12 (9.5)
Private hospital (with Skilled Birth Attendant) (%)	9 (7.1)
Dispensary (%)	23 (18.3)
Health Centre (%)	7 (5.6)
Sub-County hospital (%)	34 (27.0)
County hospital (%)	41 (32.5)
Mode of delivery	N = 126
Normal vaginal delivery (%)	112 (88.9)
Caesarean Section (%)	14 (11.1)
Personnel Conducting Delivery	N = 126
Non-Skilled Birth Attendant (%) (TBA, family or neighbor)	12 (9.5)
Skilled Birth Attendant (%) (doctor, nurse or nurse-midwife)	114 (90.5)

Spectrum of surgical conditions seen in newborns referred to MTRH: The majority of the newborns who were referred and transported to MTRH had congenital anomalies (See Figure 1). The top 4 surgical conditions were gastroschisis (23.0%), hydrocephalus (18.3%), ano-rectal malformations (ARM) (14.3%) and Hirschsprung's disease (14.3%).

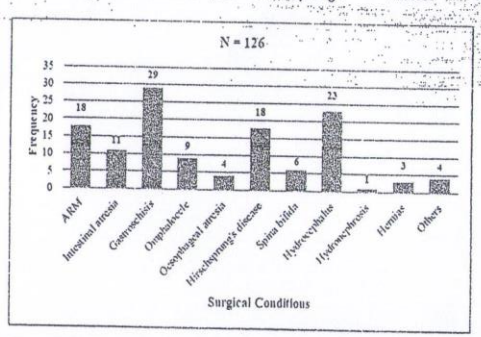


Figure 1: Spectrum of surgical conditions of newborns referred to and seen at MTRH.

Referral and Transport characteristics of the newborns with surgical conditions: Most (96.0%) of the newborns were transported to MTRH using road ambulance, and 95.2% were escorted by trained medical personnel during transport (See Table 3).

Table 3
Referral and Transport Characteristics of the Newborns

Variable	
Mode of Transportation	N = 126
Road Ambulance (%)	121 (96.0)
Public Motor Vehicle (%)	5 (4.0)
MTRH Contacted before Referral	N = 126
Yes (%)	115 (91.3)
No (%)	11 (8.7)
Mode of Communication on Referral	N = 126
Written (%)	113 (89.7)
Verbal (%)	2 (1.6)
None (%)	11(8.7)
Escort during Transport	N = 126
Trained Medical Personnel (%)	120 (95.2)
Parent/Guardian (%)	6 (4.8)

Association between socio-demographic and clinical characteristics of the newborns with surgical conditions. The level of education and the occupation of the mothers had a statistically significant association with their antenatal clinic visits during pregnancy (p-value = 0.001). (See Table 4)

Table 4

Association between Socio-demographic and Clinical Characteristics of Newborns

Variable	Antenatal Care Visits Frequency (%)			p-value
	None	<3	≥3	
Maternal Level of Education	N = 126			
Non-formal	8 (100)	0 (0.0)	0 (0.0)	
Primary	19 (40.4)	23 (48.9)	5 (10.6)	
Secondary	16 (32.0)	22 (44.0)	12 (24.0)	0.001*
Tertiary	3 (14.3)	9 (42.9)	9 (42.9)	
Maternal Occupation	N = 126			
No Employment	40 (50.0)	30 (37.5)	10 (12.5)	
Self-Employment	6 (21.4)	18 (64.3)	4 (14.3)	0.001*
Formal Employment	0 (0.0)	6 (33.3)	12 (66.7)	

Fisher's Exact Test *statistically significant*

DISCUSSION

In this audit, which was nested within a quasi-experimental study that attempts to determine the effect of introducing a structured standard operating procedure for transport of newborns with surgical conditions in western Kenya, we describe the socio-demographic; clinical; and referral and transport characteristics of the newborns with surgical conditions, who were referred and transported to a tertiary-level hospital for specialized surgical care. These characteristics often determine the newborns' treatment outcomes at the tertiary-level hospital. Improper transport of the newborns during referral has been found to be a major contributor to neonatal mortality usually at the second level of the 3-delay model[11,12].

The median age at admission of 106.5 hours (4.4 days) suggests a delay in accessing neonatal surgical care. Barriers to care-seeking as characterized by the 3-delay model could explain this delay. This model that comprises the delay in deciding to seek care (delay 1), delay in reaching the health care facility (delay 2), and delay in receiving quality care once at the health care facility (delay 3), has been found to be useful in analyzing perinatal deaths in LMICs[11,12]. In this study, there is delay in accessing neonatal surgical care despite the majority (90.5%) of the newborns being born in health facilities. Studies done in Middle-Income-Countries (MICs) reported lower median ages at admission[18,19], further suggesting socio-economic status as an important determinant of delay to seek care. The median birth weight of 2700g was similar to those found in other studies[20,21].

The majority (61.9%) of the newborns transported to MTRH with surgical conditions were term, a finding that was similar to other studies in LMICs. Studies done in India reported varied proportions of

term newborns that ranged from 40.0% to 78.5%[13,20,21,22]. This may further suggest that congenital anomalies that form a large proportion of surgical conditions of the referred newborns is often associated with preterm deliveries.

On the place of delivery, we found that only 9.5% were delivered at home, which was comparable to that reported in other studies, that ranges between 10.5% and 24.0%[12,13,19,20]. This could perhaps be part of the fruits of the global efforts in formulation and implementation of strategies that increase deliveries in health facility[23]. Demographic and Health Surveys (DHS) in Sub-Saharan Africa and Asia have shown that more than 75% of women combined in both regions now deliver in health facilities[24]. In this study, 90.5% of the newborns were delivered in health facilities compared to the 66.1% overall health facility deliveries in Kenya[25], and the 56.9% that was reported in a similar study in Nigeria[19]. The high proportion of health facility deliveries found in this study could perhaps suggest that most of the mothers may have had pregnancy complications that necessitated health facility delivery.

The study further reports a young median maternal age that may perhaps be related to the spectrum of neonatal surgical conditions. The majority (98.8%) of the neonatal surgical conditions were congenital anomalies, with the leading anomalies being gastroschisis, neural tube defects, anorectal malformations and Hirschsprung's disease. Ikol *et al* reported a similar spectrum in a study on the outcomes of neonatal surgery[17]. Young maternal age has been reported to have an association with gastroschisis and neural tube defects[26,27]. Despite the fact that the majority (93.7%) of the mothers had formal education, 63.5% were unemployed and a further 22.2% were self-employed. Low socio-economic status contributes to the first and second levels of delays in the 3-delays model that leads to high neonatal mortality[12].

In this study, 80 (63.5%) mothers had some antenatal care, but only 26 (20.6%) had the recommended optimal antenatal visits during pregnancy. However, there was a statistically significant association between maternal level of education and occupation; and antenatal care visits during pregnancy. These findings were similar to those by Gitonga *et al*, who found maternal age, level of education and occupation to be the major determinants of uptake of focused antenatal care[28]. Similarly, they noted that maternal age below 20 years was associated with least uptake, and that women with formal employment had higher uptake.

During these antenatal visits, antenatal ultrasound scan was done in 39 (48.8%) mothers, and congenital anomalies were only detected in 9 (23.1%). Goldsmit *et al* reported similar findings in Argentina[18]. Onyambu *et al* reported the detection of congenital fetal anomalies on routine antenatal ultrasound screening of low-risk pregnancy, at a rate of 3%[29]. Evidence-based policies developed by the WHO have suggested that early antenatal ultrasound scans may increase the detection of congenital anomalies[30]. In view of the WHO's recommendation of routine early (< 24 weeks) antenatal ultrasound in pregnancy, the finding that the majority of the antenatal ultrasound scans were done in the 1st trimester (12.8%) and 2nd trimester (53.8%) is pivotal, and could perhaps explain the apparently higher detection rate of congenital anomalies on antenatal ultrasound.

We further report that the majority (88.9%) of the newborns with surgical conditions were born via normal vaginal delivery, which were conducted majorly (90.5%) by skilled birth attendants. This further conforms to the

finding that the majority of the newborns were delivered in health facilities, which are obviously manned by skilled birth attendants. Sachan *et al* and Upadhyay *et al* had similar findings in studies done in India[13,20].

The majority (96.0%) of the newborns with surgical conditions, who were referred to MTRH, were transported by road ambulance. The ushering in of devolved system of government in Kenya following the enactment of the new constitution in 2010 enabled many counties to procure road ambulances as part of equipping their county health systems. Prior to this, Mwai *et al* reported that the number of road ambulances per hospital in Kenya was at 0.06 – 3.63[21]. This could perhaps explain the finding in this study, that is similar to that reported is a study done in India[20]. In the contrary, a study done in Nigeria reported the use hospital ambulances at a paltry 4%[19].

This study further demonstrated that prior to the referral and transport of newborns with surgical conditions, appropriate communication was made in the majority (89.7%) of the cases, perhaps indicating the effect of referral strategies that were initiated by the Ministry of Health in 2014[22]. Only 6 (4.8%) newborns had inappropriate escort during transport. This was contrary to a similar study in India that reported that appropriated communication to the referral hospital prior to referral was done in 28% of the newborns, and a further 55.7% had inappropriate escort during referral and transport[20].

CONCLUSION AND RECOMMENDATION

Congenital anomalies were the major surgical conditions seen in the newborns referred and transported to MTRH, and gastroschisis was the leading condition. The newborns had delay in accessing neonatal surgical care, and the majority of their mothers had poor antenatal care during pregnancy, despite the apparent high health-facility delivery. The majority of the newborns had appropriate mode of transportation and adequate pre-referral communication from the referring health facility.

We recommend a systematic analysis of perinatal surgical morbidity and mortality using a simple 3-delay methodology that would perhaps determine the causes of delay in access to neonatal surgical care despite the majority of the newborns with surgical conditions being born in health facilities, and used the road ambulance as their main mode of transportation.

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East African Medical Journal Vol. 95 No. 11 November 2018

ASSESSMENT OF CLINICIANS' KNOWLEDGE AND PRACTICES ON SAFE TRANSPORT OF NEWBORNS WITH SURGICAL CONDITIONS IN WESTERN KENYA.

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ASSESSMENT OF CLINICIANS' KNOWLEDGE AND PRACTICES ON SAFE TRANSPORT OF NEWBORNS WITH SURGICAL CONDITIONS IN WESTERN KENYA

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ABSTRACT

Background: Neonatal ill health poses a great burden on the development of individuals, communities and societies, hence the adoption of specific goals and targets to reduce infant mortality worldwide. Many of the conditions that result in perinatal deaths can be prevented or treated without sophisticated and expensive technology. Subsequently, the World Health Organization (WHO) continues to advance education of clinicians on simple but critical interventions for the newborn during the first days of life, and the role of safe transport of newborns with surgical conditions during their referral to a tertiary-level hospital for specialized surgical care is pivotal.

Objective: To assess the clinicians' knowledge and practices on safe transport of newborns with surgical conditions.

Setting: Newborn Units/Labour Wards of five county referral hospitals in Western Kenya, which refer newborns with surgical conditions to Moi Teaching and Referral Hospital (MTRH).

Materials and Methods: This was a cross-sectional descriptive study that was conducted on clinicians working in the Newborn Units/Labour Wards of 5 county referral hospitals. Interviewer-administered questionnaires were administered to assess their knowledge and practices on referral and safe transport of newborns with surgical conditions. Data on demographic characteristics, the clinicians' knowledge on and practices of the principles of transporting newborns with surgical conditions, was analyzed.

Results: Fifty clinicians, 10 from each of the 5 county referral hospitals were recruited into the study. Their mean age was 32.8 ± 8.6 years, and the majority (34.0%) were nurses. Overall, the clinicians' knowledge on safe transport of newborns with surgical conditions was poor, with a median score of 50.0% (IQR=25.0, 87.5). There was no association between the clinicians' knowledge scores on the principles of newborn transport, and the length of time that they had worked in their respective Newborn Units/Labour Wards (p=0.042). On practices, only 11 (22.0%) clinicians had participated in the procedure of transporting newborns.

Conclusions: The clinicians' knowledge on, and practices of, safe transport of newborns with surgical conditions were poor.

INTRODUCTION

Neonatal mortality, defined as deaths occurring within the first 28 days of life, accounts for over 40% of deaths in children under the age of 5 globally[1]. Reports by the World Health Organization (WHO) indicate the leading causes of neonatal mortality as prematurity, birth asphyxia, birth trauma, neonatal infections and congenital anomalies[2]. However, the burden of surgical disease in the newborn remains a silent but significant contributor to these deaths[3].

The majority of births in the low- and middle-income countries (LMICs) occur in rural settings, often at home or in rural health centres[4]. These health facilities have minimal equipment and are often manned by health providers with limited formal training. Therefore, newborns with surgical conditions, born at home or in these health facilities, are often in need of referral and transport to a facility with a higher level of care. In North-Rift and Western regions of Kenya, specialized neonatal surgical care is only available at the MTRH, Eldoret.

Many neonatal deaths could be avoided or morbidity minimized if the ability to safely transfer a newborn with a surgical condition to a health facility with a higher level of care could be enhanced, and organized transport service, that would provide close to same level of newborn monitoring and quality of care during transport as that in advanced care facility, is therefore a key concept[5].

This study laid the groundwork for the implementation of a structured Standard Operating Procedure for transporting newborns with surgical conditions in 5 county referral hospitals that transfer newborns to the MTRH. The study aimed at establishing the knowledge and practices of the clinicians, who provide the initial care to these newborns, on safe transport of newborns with surgical conditions.

MATERIALS AND METHODS

Study Design and Study Population. This was a cross-sectional descriptive study that laid the ground for a subsequent wider quasi-experimental study. The study population was all clinicians who were working in the Newborn Units/Labour Wards and providing initial care to the newborns with surgical conditions in the county referral hospitals before referring them to MTRH for specialized surgical care.

Study Setting. The study was conducted in the Newborn Units/Labour Wards of 5 county referral hospitals in western Kenya.

Study Variables. The variables included the socio-demographic characteristics of the clinicians, as well as their knowledge and practices on safe transport of newborns with surgical conditions.

Sampling, Data Collection, and Data Analysis. The 5 county referral hospitals were selected by simple random sampling from the over 20 county referral hospitals that refer newborns to MTRH. Approximately 30% of the referred newborns seek surgical care[6]. Subsequently, 50 clinicians (10 from each county referral hospital) were selected by purposive sampling and included into the study during the study period (December 2017 – May 2018). Clinicians who were working in the Newborn Units/Labour Wards of the selected county referral hospitals were given a pretest using interviewer-administered questionnaires that were derived from a validated *Basic Knowledge Assessment Tool (BKAT)* to assess their knowledge and practices on transport of newborns with surgical conditions prior to the training sessions that aimed the introduction of a structured operating procedure for transport of newborns. Scores on the clinicians' knowledge and practices were determined on Likert-type scales. Data from the interviews were entered into STATA version 11 and analyzed using descriptive statistics.

Ethical Considerations. Ethical approval was sought and granted by Moi University-MTRH Institutional Research Ethics Committee.

RESULTS

A total of 50 participants, 10 from each of the 5 county referral hospitals were interviewed.

Socio-demographic characteristics of the clinicians: The participants were aged between 19 and 57 years, with a mean age of 32.8 ± 8.6 years with a M:F ratio of 1.1:1. Most (34.0%) of the participants were nurses and only 2 (4.0%) participants were consultant paediatricians. The length of time that the participants had worked in the Newborn Unit/Labour Ward ranged from 4 months to 168 months (14 years), with a median of 36 months (Inter-Quartile Range, IQR=13,60). Table 1 shows the socio-demographic characteristics of the clinicians.

Table 1

Socio-demographic Characteristics of the Clinicians

Variable	Frequency (%)
Gender	N=50
Males	26 (52.0)
Females	24 (48.0)
Cadre	N=50
Paramedic	5 (10.0)
Nurse	17 (34.0)
Clinical Officer	11 (22.0)
Medical Officer-Intern	7 (14.0)
Medical Officer	8 (16.0)
Consultant	2 (4.0)

Clinicians' knowledge on safe transport of newborns with surgical conditions: The majority (96.0%) of the participants agreed that newborns with surgical conditions need special considerations during their transport, both intra- and inter-facility. Overall, the clinicians' median knowledge score on safe transport of newborns with surgical conditions was 50.0% (IQR=25.0, 87.5). Only 2 (4.0%) participants correctly stated all the 8 principles of newborn transport. Appropriate escort for the newborn was the most (96.0) known principle, while sending specimens with the newborns was the least (22.0%). Table 2 shows the principles of newborn transport that were correctly mentioned by the clinicians.

Table 2

Principles of Newborn Transport as correctly mentioned by the Clinicians

Principle	Frequency (N=50)	Percentage (100)
Tubes	26	52.0
Warmth	34	68.0
Oxygen	40	80.0
Pre-Transport Stabilization	16	32.0
IV access/Fluids	23	46.0
Documentation	20	40.0
Appropriate Escort	48	**96.0**
Specimens	11	**22.0**

On assessment of clinicians' knowledge on the specific elements of principles of transport of newborns with surgical conditions, the importance of using oro-/naso-gastric tubes was mostly (30.0%) known by the medical officers. The importance of keeping the baby warm and administering oxygen during transport was mostly (29.4% and 30.0% respectively) known by the nurses. Pre-transport stabilization of newborn and gaining IV access and maintaining the baby on a drip was mostly (43.7% and 34.8% respectively) known by the medical officers. The importance of ensuring appropriate escort during transport was mainly (33.3%) known among the nurses, while that of sending relevant medical documents and specimens with the newborn during transfer was mainly known by the medical officers (30.0% and 36.4%) respectively). Table 3 shows the distribution of the participants' knowledge on principles of newborn transport by cadre.

Table 3

Distribution of the Participants' Knowledge on Principles of Newborn Transport by Cadre

Cadre	Principle of Newborn Transport							
	Tubes N=26	Warmth N=34	Oxygen N=40	Pre-Transport Stabilization N=16	IV access N=23	Documentation N=20	Escorts N=48	Specimens N=11
Paramedic (%)	0 (0.0)	2 (5.9)	3 (7.5)	0 (0.0)	0 (0.0)	0 (0.0)	5 (10.4)	0 (0.0)
Nurse (%)	7 (26.9)	10 (29.4)	12 (30.0)	1 (6.3)	7 (30.4)	6 (30.0)	16 (33.3)	1 (9.1)
Clinical Officer (%)	2 (7.7)	5 (14.7)	8 (20.0)	0 (0.0)	0 (0.0)	1 (5.0)	10 (20.8)	0 (0.0)
Medical Officer-Intern (%)	7 (26.9)	7 (20.6)	7 (17.5)	6 (37.5)	6 (26.1)	6 (30.0)	7 (14.6)	4 (36.4)
Medical Officer (%)	8 (30.8)	8 (23.5)	8 (20.0)	7 (43.7)	8 (34.8)	5 (25.0)	8 (16.7)	4 (36.4)
Consultant (%)	2 (7.7)	2 (5.9)	2 (5.0)	2 (12.5)	2 (8.7)	2 (10.0)	2 (4.2)	2 18.1)

All the cadres of clinicians had the most knowledge on the importance of according the newborns with surgical conditions an appropriate escort. The paramedics and clinical officers had no knowledge on the importance of sending specimens with the newborn during transport. On calculating the knowledge level of each cadre on all the principles of newborn transport, the consultants' scored the highest at 100% while the paramedics scored the lowest at 25.0%. There was no association between the clinicians' knowledge scores on the principles of newborn transport, and the length of time that they had worked in their respective Newborn Units/Labour Wards (p=0.042). Table 4 shows the clinicians' knowledge level on each element of the principles of newborn transport by cadre.

Table 4

Clinicians' knowledge level on each element of principles of newborn transport by cadre

Principle of Newborn Transport	Cadre N=50					
	Paramedics (n=5)	Nurses (n=17)	Clinical Officers (n=11)	Medical Officers-Intern (n=7)	Medical Officers (n=8)	Consultants (n=2)
Escort (%)	(5) 100	(16) 94.1	(10) 90.9	(7) 100	(8) 100	(2) 100
Oxygen (%)	(3) 60.0	(12) 70.6	(8) 72.7	(7) 100	(8) 100	(2) 100
Warmth (%)	(2) 40.0	(10) 58.8	(5) 45.5	(7) 100	(8) 100	(2) 100
Tubes (%)	(0) 0.0	(7) 41.2	(2) 18.2	(7) 100	(8) 100	(2) 100
IV access (%)	(0) 0.0	(7) 41.2	(0) 0.0	(6) 85.7	(8) 100	(2) 100
Documentation (%)	(0) 0.0	(6) 35.3	(1) 9.1	(6) 85.7	(5) 62.5	(2) 100
Pre-Transport Stabilization (%)	(0) 0.0	(1) 5.9	(0) 0.0	(6) 85.7	(7) 87.5	(2) 100
Specimen (%)	(0) 0.0	(1) 5.9	(0) 0.0	(4) 57.1	(4) 50.0	(2) 100
Overall Knowledge Score (%)	**25.0**	**44.1**	**29.5**	**89.3**	**87.5**	**100**

On the assessment of the clinicians' knowledge on the procedure of transporting newborns with surgical conditions, 28 (56.0%) stated correctly the need to involve the parents in the transport procedure. Thirty-three (66.0%) clinicians correctly stated that the basis of safe and timely transport was proper communication and coordination between referring and receiving hospitals. None (0%) stated that there is rare need for haste during the transport procedure, and 18 (36.0%) stated correctly that the condition of the newborn dictates the choice of the mode of transport. Table 5 shows the responses of the participants to various questions pertaining to their understanding of certain aspects of newborn transport.

Table 5

Responses of the participants their knowledge on newborn transport

Variable	Category	Frequency (%)
Safe newborn transport determines their overall survival at the receiving hospital.	Disagree	11 (22.0)
	Agree	25 (50.0)
	Strongly agree	14 (28.0)
Proper communication between referring and receiving hospitals is vital.	Disagree	17 (34.0)
	Agree	26 (52.0)
	Strongly agree	7 (14.0)
Should parents/guardians be informed about the transport of their newborn?	Yes	28 (56.0)
	No	22 (44.0)
Does the surgical condition dictate the choice of the mode of transport?	Yes	18 (36.0)
	No	32 (64.0)

Forty-three (86.0%) participants felt that safe transport of newborns with surgical conditions would improve the newborns' surgical outcome. When asked whether organized transport for newborns with surgical conditions should be incorporated into the county healthcare system, 42 (84.0%) agreed or strongly agreed.

On escort of the newborns during transport, 28 (56.0%) participants said they would escort the newborns with surgical conditions during transport. Of the 22 (44.0%) that would not escort the newborns, 8 (36.4%) opined that the newborns are too difficult to handle, while 14 (63.6%) felt that they were too busy to offer escort to the newborns during transport. Forty-four (88.0%) participants mentioned lack of supplies and equipment needed for newborn transport, and 38 (76.0%) mentioned lack of newborn transport protocols, as the great impediments to organized safe transport of newborns with surgical conditions. Table 6 shows distribution of clinicians' reasons as impediments to safe newborn transport by cadre.

Table 6

Distribution of clinicians' reasons as impediments to safe transport of newborn with surgical conditions by cadre

Variable	Cadre						
	Paramedics (n=5)	Nurses (n=17)	Clinical Officers (n=11)	Medical Officers -Intern (n=7)	Medical Officers (n=8)	Consultants (n=2)	TOTAL (N=50)
Lack of Supplies/Equipment (%)	5 (100)	15 (88.2)	10 (90.9)	6 (85.7)	6 (75.0)	2 (100)	44 (88.0)
Improper Coordination/Communication (%)	2 (40.0)	3 (17.6)	1 (9.1)	5 (71.4)	7 (87.5)	2 (100)	20 (40.0)
Lack of Newborn Transport Protocol (%)	4 (80.0)	10 (58.8)	10 (90.1)	5 (71.4)	7 (87.5)	2 (100)	38 (76.0)

Clinicians' practices of transport of newborns with surgical conditions: With regard to past and current practices, only 11 (22.0%) clinicians had participated in transport of newborns with surgical conditions in the past 5 years, with 6 (54.5%) participating ≥ 3 times, 3 (27.3%) participating 2 times, and 2 (18.2%) participating only once. None of the clinical officers and medical officers-intern had ever participated in transport of newborns with surgical conditions. Table 7 shows the distribution of the clinicians who have ever participated in transport of newborns with surgical conditions.

Table 7

Distribution of Clinicians who have ever participated in Transport of Newborns with Surgical Conditions by cadre

Variable	Frequency (%) n=11
Paramedics	5 (45.5)
Nurses	4 (36.3)
Clinical Officers	0 (0.0)
Medical Officers-Intern	0 (0.0)
Medical Officers	1 (9.1)
Consultants	1 (9.1)

Of the 11 (22.0%) that participated in the transport procedure that included escorting the newborns during transport, 6 (54.5%) stated that they had a bad experience, with 5 (45.5%) stating that the transport team and equipment were hastily assembled, 1 (9.1) stated that the clinical condition of the baby deteriorated while on transit, and 4 (36.4)

stated that the babies died while on transit. Only 1 (9.1%) participant who had a good experience stated that the transport process was well organized with transport team being informed well in advance.

The most observed elements by the clinicians who participated in newborn transport were; escort by trained medical personnel (100%) and maintaining the baby on oxygen (100%). None (0.0%) of the clinicians observed the principles of documentation and delivery of specimens. Table 8 shows the distribution of the clinicians according to the specific elements of principles of newborn transport that were practiced during newborn transport, by cadre.

Table 8

Distribution of Clinicians according to Specific Elements of Principles of Newborn Transport that were practiced, by cadre

Variable	Cadre				
	Paramedics (n=5)	Nurses (n=4)	Medical Officers (n=1)	Consultants (n=1)	TOTAL N=11
Inserted & managed oro-/naso-gastric tube	2 (40.0)	0 (0.0)	1 (100)	1(100)	4 (36.4)
Kept the baby warm	3 (60.0)	3 (75.0)	1 (100)	1 (100)	8 (72.7)
Gave baby oxygen	5 (100)	4 (100)	1 (100)	1 (100)	11 (100)
Ensured the baby was stable before transport	0 (0.0)	0 (0.0)	1 (100)	1 (100)	2 (18.2)
Inserted IV line & maintained the baby on a drip	2 (40.0)	1 (25.0)	0 (0.0)	1 (100)	4 (36.4)
Delivered medical documents including consent for surgery	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ensured the baby was escorted by trained medical personnel	5 (100)	4 (100)	1 (100)	1 (100)	11 (100)
Sent relevant specimens with the baby	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

On the availability of supplies and equipment during transport, the most available functional equipment in the ambulances were oxygen delivery equipment mentioned by 11 (100%) participants, and assorted items for IV fluid infusion as mentioned by 10 (90.9%) participants. None of the clinicians mentioned mechanical ventilator, infant transport incubator, infusion pumps or Non-Invasive Blood Pressure (NIBP) monitor.

DISCUSSION

This study, which was a pretest carried out to set the stage for the implementation of a structured standard operating procedure for transport of newborns with surgical conditions in western Kenya, found that the majority (96.0%) of the clinicians were in agreement that newborns with surgical conditions need special considerations during their referral and transport to a tertiary level hospital for specialized surgical care. With the realization that many conditions that result in perinatal deaths can be prevented or treated without sophisticated and expensive technology, the WHO advocated for education of clinicians on simple but critical interventions for the newborns. This resulted in the formulation of a guide that set the standards on referral and transfer of sick neonates, which was published in 2003[7]. Despite the existence of this guide, the clinicians' overall knowledge score was poor, with a median score of 50.0% (IQR=25.0, 87.5). Only 2 clinicians, the only consultant paediatricians who participated in this study, were aware of all the 8 principles of newborn transport. However, the knowledge on specific elements of the principles of newborn transport was mostly demonstrated by the nurses and the medical officers, who perhaps are the more critical cadres of clinicians, involved in referral of patients from the lower level health facilities to the tertiary level hospitals. The Ministry of Health in a survey done in 2013 reported that the referral procedures in the level 2 (dispensaries) and level 3 (health centres) health facilities were mainly done by nurses while those in level 4 (sub-county) and level 5 (county referral) hospitals were mainly done by medical officers[8].

This study highlighted the disparities in the average level of knowledge on all principles of newborn transport. Whereas the consultants had the highest score (100%), the paramedics who apparently are the most involved in transport of newborns with surgical conditions scored the lowest (25%). Furthermore, the paramedics and the clinical officers were not aware of the importance of pre-transport stabilization and sending specimens with the referred newborns during transport. This perhaps indicates a clear gap that could be addressed by further training and implementation of newborn transport protocols. Kumar *et al* reported that proper training of the transport team and adequate pre-transport stabilization of the newborns can decrease transport-related morbity[9]. The study further found no association between the clinicians' knowledge scores on the principles of newborn transport, and the length of time that they had worked in their respective Newborn Units/Labour Wards.

This study further highlighted disparities between the clinicians' knowledge and practices on transport of newborns with surgical conditions. Whereas the majority (86.0%) were of the opinion that safe transport of the newborns would improve the outcome of their surgical care at the tertiary hospital, only 11 (22%) had participated in the transport procedures of newborns with surgical conditions in the past 5 years. This further indicates need for training and mentorship program on newborn transport that would help decrease transport-related morbidity and mortality. Marítnez *et al* reported a significant improvement in neonatal survival following the implementation of a similar training course for medical and paramedical transport personnel[10]. Similarly, Spector *et al* reported improvement in the clinical status of

transported neonates following an implementation of a neonatal provider educational program[11].

The majority (84.0%) of the clinicians opined that organized referral and transport for newborns with surgical conditions should be incorporated into national and county healthcare system. Woodward *et al* in a study done in Hungary reported that a structured and specialized neonatal transport service can lead to decreased transport-related neonatal mortality[12]. This study further highlights the two major challenges that the clinicians' thought could impede safe newborn transport as lack of supplies/functional equipment and lack of structured protocol for referral and transport of newborns with surgical conditions. The clinicians who participated in the transport of the newborns reported using poorly equipped road ambulances that had only oxygen delivery equipment (100%) and assorted items for IV fluid infusion (90.9%). Transport incubators which are vital in ensuring that the newborns are transported in a thermo-neutral environment that maintain continuum of care was not reported by any clinician. Joshi *et al* demonstrated that cheap and easily fabricated cardboard neonatal carrier can be effective in thermal control when used to transport neonates for short distances[13]. The use of Kangaroo Mother Care (KMC), aluminium foil and polythene paper wraps during transport have equally been shown to be effective.

CONCLUSIONS

Overall, the clinicians' knowledge on safe transport of newborns with surgical conditions was poor, with a median score of 50.0% (IQR=25.0, 87.5). The cadres of clinicians that had poor scores on knowledge of specific principles of safe transport of newborns with surgical conditions were the paramedics, the nurses and the clinical officers. Most of the clinicians who participated in the procedures of transporting newborns with surgical conditions were the paramedics and the nurses.

RECOMMENDATIONS

The training of the clinicians on the structured Standard Operating Procedure for transporting newborns with surgical conditions should focus more on the paramedics and the nurses whom despite their poor knowledge were the main participants in the transport procedures of newborns with surgical conditions in the 5 county referral hospitals.

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