OUTCOMES OF NEONATES REQUIRING SURGICAL INTERVENTIONS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

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DECLARATION

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DEDICATION

I dedicate this thesis to my parents who have been my constant source of inspiration and who gave me the drive and discipline to tackle any task with enthusiasm and determination. Without their support this work would not have been made possible.

Special dedication goes to my husband Frederick for his material, financial, emotional and spiritual support. To my lovely daughters Trizzah and Kristel for their endless prayers, support and love throughout this process.

ABSTRACT

BACKGROUND: Neonatal surgical procedures are important in improving the outcomes of many diseases in neonates most of which are congenital anomalies. Timely intervention plays a major role in determining the success rates as well as improving outcomes. In order to be successful in managing neonates with surgical problems, a multidisciplinary approach is required with adequate medical supplies and resources availed in the right setting. Other co-morbid conditions including sepsis, respiratory distress and apnea have been found to affect outcomes. This study sought to find out the outcomes and factors influencing these outcomes in neonates with surgical conditions.

OBJECTIVE: To evaluate the outcomes (mortality and length of stay) of neonates with diseases that require surgical intervention at Moi Teaching and Referral Hospital.

METHODS: This was a prospective descriptive study carried out at Moi Teaching and Referral Hospital New Born Unit. A total of 124 neonates with conditions requiring surgical intervention were recruited into the study. Data was collected at the point when the decision was made for surgical intervention and recorded using a structured questionnaire. The spectrum of conditions and factors influencing outcomes were recorded until discharge or mortality and length of stay determined. Data analysis was done using STATA^R version 13 at 95% confidence interval. Data was presented in frequency tables, pie charts and graphs. Descriptive statistics was used for continuous variables. Logistic regression and Mann Whitney U test were also done. A p-value of less than 0.05 was considered statistically significant.

RESULTS: A total of 124 participants were recruited between February and November 2016. The number of males was 66(53.2%) with a male to female ratio of 1.1:1. The median age at admission to the newborn unit was 2 days (IQR 1,5). The leading neonatal surgical conditions were gastroschisis at 33(26.6%), neural tube defects 25(20.2%) and ARM 25(20.2%). The overall mortality rate was 31.5%(39). The number of neonates discharged home was 83(66.9%) with 2(1.6%) being referred to KNH. Majority of neonates 103(83.1%) came in as referrals from peripheral health facilities. Most neonates 74(59.7%) had a birth weight of 2.5-3.9kgs. Antenatal clinic attendance was protective of mortality (OR 0.126; 95% CI 0.025-0.6429; p= 0.013). Sepsis, respiratory distress and electrolyte imbalance were associated with increased odds of mortality at (OR 3.4; 95% CI 1.09-22.06; p=0.049), (OR 4.9; CI 0.91-11.61; p=0.001) and (OR 3.1; CI 1.21-31.60; p=0.029) respectively. The median length of hospital stay was 14.5 days with a range of 0-102 days. There was an association between time to initiation of feeds post operatively and length of stay p= 0.0071.

CONCLUSION The overall mortality was 31.5%. The length of hospital stay was long. Gastroschisis was the leading neonatal surgical condition. Sepsis and electrolyte imbalance were associated with mortality.

RECOMMENDATION Effective management of sepsis and electrolyte imbalance will improve on outcomes. Early initiation of appropriate feeding in the post-operative period.
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ACKNOWLEDGEMENT

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LIST OFABBREVIATIONS

ANC	Antenatal care
ARM	Anorectal Malformations
BBA	Born before arrival
CHAP	Child health and pediatrics
CNS	Central Nervous system
CPAP	Continuous Positive Airway Pressure
CSF	Cerebrospinal fluid
DALYs	Disability adjusted life years
EBM	Expressed breast milk
ELBW	Extremely low birth weight
ELC/S	Elective caesarian section
EMC/S	Emergency caesarian section
GA	General anesthesia
GBD	Global burden of disease
GIT	Gastrointestinal
GUT	Genitourinary
HIC	High income countries
HIV	Human Immunodeficiency Virus
IREC	Institutional Research and Ethics Committee
KDHS	Kenya Demographic Health Survey
LA	Local anesthesia
LBW	Low birth weight
LIC	Low income countries
LOS	Length of stay

MTRH	Moi Teaching and Referral Hospital
NBU	New Born Unit
NEC	Necrotizing Enterocolitis
NICU	Neonatal intensive care unit
RDS	Respiratory distress syndrome
RMBH	Riley Mother Baby Hospital
SOPs	Standard operating procedures.
SVD	Spontaneous vertex delivery
TPN	Total parenteral nutrition
VLBW	Very low birth weight
WHO	World Health Organization
3D	Three dimension

DEFINITION OF TERMS

1. Neonatal period   First 28 days of life

2. Surgical intervention   Procedure that will warrant a neonate being taken to theatre for surgery under anesthesia

3. Low birth weight   Weight at birth between 1500g and 2449g

4. Very low birth weight   Weight at birth between 1000g and 1499g

5. Extremely low birth weight   Weight at birth less than 1000g

6. Neonatal mortality   Death occurring within the first 28 days of life

7. Outcomes   The measures of outcomes will be mortality and length of hospital stay.

8. Length of stay   Time taken from admission to discharge or mortality.

9. Hypoglycemia   Random blood sugar <2.5mmol/l

CHAPTER ONE

INTRODUCTION

1.1 Background Information

Neonatal surgical procedures are important in improving the outcomes of many diseases most of which are congenital anomalies. Timely intervention plays a major role in determining better outcomes thus improving the quality of life and reducing disability. In order to be successful in managing neonates with surgical problems, a multidisciplinary approach is required. A number of specialists with both inter-departmental and intra-departmental approach of management have to be on board since management of these neonates includes nutrition, nursing care, pre- and post anesthetic care, imaging, as well as occupational and physical therapy among others. Some of the congenital anomalies may occur as syndromes like in duodenal atresia in neonates with Down syndrome who may also have cardiac anomalies and other complications hence stressing on multidisciplinary approach of management. Improper and delayed consultation between the various pediatric surgical disciplines and other departments or specialties has been reported in some centers as a cause of poor outcomes that results to an increase in morbidity and mortality (Okoro PE et al 2012).

Despite all surgical conditions accounting for 11% of the Global Burden of Disease (GBD) there is reported neglect in their management coupled with the fact that most of these conditions are surgically amenable (Chirdan LB et al 2012). Moreover it is not known how much burden is contributed by neonatal surgical cases to overall neonatal mortality. This is because a lot of focus has shifted to the management of the top 3 leading causes of neonatal mortality which are prematurity, sepsis and perinatal asphyxia and that surgical conditions have not been thought to be of significant public

health concern thus not so much focus has been put on neonatal surgical cases (WHO 2014). Congenital anomalies account for up-to 25.3-38.8million Disability Adjusted Life Years (DALYs) worldwide which goes to show the high disease burden of these conditions of which most can be surgically corrected (Murray CJL et al 2010; WHO 2008; KDHS 2013). They have been reported to rank 17 in terms of disease burden (Murray CJL et al 2010). Some conditions like cardiac defects, neural tube defects and cleft lip and palate cause 21million of disability adjusted life years (DALYs) however 12 million of these could be corrected surgically if outcomes in HICs could be realized in LIC (Higashi H et al 2013). Some studies done, for instance in Japan indicate a 5 fold increase in neonatal surgical cases over the last 50years with a reduction in mortality rates in developed units from 60% to 15% in conditions like esophageal atresia, diaphragmatic hernia, omphalocele and gastroschisis (Taguchi T et al 2014).

Most conditions (88.7%) that require surgical intervention in the neonatal period are congenital (Ugwu RO et al 2013). These may range from anterior abdominal wall defects like gastroschisis, omphalocele and bladder exstrophy to anorectal malformations (ARM), spinal defects, hydrocephalus, intestinal atresia with obstruction, Hirschsprung's disease, cystic hygromas and inguinal hernias among others. Most of these conditions occur as a result of defects in the process of fetal development known as embryogenesis. The most crucial period is usually the first trimester of pregnancy which is the first 12 weeks when organogenesis takes place.

Early diagnosis and identification especially during the ante-natal period with use of 3D ultrasonography to diagnose conditions like anterior abdominal wall defects has been shown to have better outcomes (Grigore M et al 2012; Shakya VC et al 2010; Ameh EA et al 2000; Abdur-Rahman LO et al 2011). Low rates of antenatal diagnosis

and sepsis during the care of these neonates have been shown to contribute significantly to mortality with only 1 of 7 cases of gastroschisis being diagnosed in the antenatal period in West Africa whereas there is up-to 69% of omphalocele and 88% of gastroschisis cases being diagnosed in High Income Countries (HICs) like Germany antenatally (Ameh EA et al 2000; Abdur-Rahman LO et al 2011; Henrich K et al 2007). In most developed countries over 60% of neonatal surgical cases are diagnosed antenatally (Henrich K et al 2007). This could be due to the routine anomaly prenatal ultrasound done in most developed countries between 18 to 20 weeks gestation. Prenatal repair has been shown to be possible with better outcomes for instance in repair of neural tube defect (Grivell RM et al 2014). Laparoscopic surgery for some neonatal surgical conditions like intestinal atresia and gut stenosis as well as early intervention in anterior abdominal wall defects like gastroschisis repair have been shown to have better outcomes than staged procedures practiced in most developing countries for anterior abdominal wall defects like gastroschisis (Li B et al 2012; Alshehri A et al 2013).

Sepsis control is important because it has been found to contribute greatly to mortality in the post-operative period with up-to 87.5% of neonates reported to have sepsis dying in some units with higher rates of mortality from sepsis in most units in the developing countries (Ugwu RO et al 2013; Shakya VC et al 2010; Sekabira J et al 2009; Ameh EA et al 2000; Mouafo Tambo et al 2011; Tarca E et al 2014). Simple measures like proper hand washing practices and good ward hygiene have been shown to greatly improve outcomes when it comes to infection control (WHO 2014).

Late presentation to hospital, with most neonates admitted as referrals from peripheral facilities and lack of adequate medical facilities and supplies have been associated with higher mortality rates especially in Sub-Saharan Africa and in most developing

countries (Shakya VC et al 2010; Tarca E et al 2013; Chirdan LB et al 2004, Kouame BD et al 2015, Chirdan LB et al 2010).

Post-operative care is important in determining good outcomes; most intestinal surgical operations are associated with complications and problems in feed advancement which necessitates use of Total Parenteral Nutrition (TPN) as well as admission to neonatal intensive care unit (NICU) and wound sepsis. The availability of TPN is reported to be low in most developing countries; as low as 36% in Low Income Countries (LICs) as opposed to 100% availability in HICs thus poor outcomes in centers lacking such facilities (Wright NJ et al 2015).

Meticulous care is required in the post-operative period ranging from effective analgesia, fluid management, wound care and proper aseptic technique in handling the neonates. Antibiotics use, ability to appropriately commence and advance feeds to attain required caloric intake for optimal growth and development and infection prevention and control have also been shown to improve outcomes in most settings. These are some of the factors shown to improve on outcomes according to WHO recommendations on safe surgeries. This study thus sort to look at some of these factors associated with the outcomes in these neonates.

1.2 Problem Statement

Given the diversity of surgically amenable neonatal surgical conditions seen at Moi Teaching and Referral Hospital, the variety and scarcity of settings and teams required to intervene, the variety of medical supplies required and the complications, it's important to look at factors that influence outcomes in these neonates. Globally it is not clear what the burden of neonatal surgical cases is to the overall mortality. According to WHO neonatal mortality contributes 41% of under five mortality with a reported neglect in the management of these cases (Chirdan LB et al 2012; WHO

2014). This is because a lot of focus is on the top three causes of neonatal mortality which are prematurity, sepsis and birth asphyxia since surgical conditions have not been recognized to be of significant public health concern thus there is paucity of data. In general surgical conditions account for 11% of the GBD and good progress has been reported if outcomes in HICs countries could be emulated in LICs (Chirdan LB et al 2012).

There is a reported global increase in neonatal surgical cases with neglect in their care despite the fact that most of them (88.7%) are congenital and that they can be surgically corrected in the neonatal period with reported good outcomes (Chirdan LB et al 2012; Ugwu RO et al 2013).

A study in Japan reported a 5-fold increase in neonatal surgical cases over the last 50 years prompting the need to address the changes in the patterns of these diseases (Taguchi T et al 2014). There is also an increase in specific neonatal surgical conditions for example, in a study done in Durban anterior abdominal wall defects like gastroschisis had increased from 6% to 15% over a 4-year period but with high mortality rates at 43% (Sekabira J et al 2009).

The mortality rates from these neonatal surgical cases however remains high in most developing countries like Nigeria at 48.2% and Cameroon at 43.1% (Ugwu RO et al 2013; Shakya VC et al 2010; Sekabira J et al 2009; Ameh EA et al 2000; Obu HA et al 2012), compared to some HICs like Germany reporting mortality rates of less than 25% since they are able to diagnose such conditions in-utero and intervene early (Henrich K et al 2007; Alshehri A et al 2013; Wright NJ et al 2015; Taguchi T et al 2014).

The mortality rates reported in a study in Kenya at Kenyatta National Hospital found a mortality of 33% with a mortality of 24% reported in a study done at MTRH in 2006 among these neonates (R. Tenge-Kuremu et al 2006; Ajanja Samson et al 2015).

The number of neonatal surgical cases has been on the rise from the monthly reports at MTRH over the years from as little as 3 cases per month in the early 2000s to 15-20 cases per month in 2016 (MTRH 2016).

Appropriate outcome appraisal is therefore becoming increasingly important as the numbers of neonates managed at MTRH are increasing. This study set out to find out the outcomes and factors contributing to these outcomes in neonates with surgical conditions at MTRH.

1.3 Justification

The mortality rates from neonatal surgical cases remain high in most developing countries (Ugwu RO et al 2013; Shakya VC et al 2010; Sekabira J et al 2009; Ameh EA et al 2000; Obu HA et al 2012). Most HICs have however reported reduced mortality despite an increase in these neonatal surgical cases (Wright NJ et al 2015; Taguchi T et al 2014). Good outcomes could be achieved in most developing countries if appropriate medical facilities, resources and medical supplies present in most HICs could be emulated in developing countries (Chirdan LB et al 2012; Wright NJ et al 2015). Kenya being a developing country, it is important to describe outcomes in the unit and in the region since nationally the last study at KNH in 2015 put the mortality at 33% (Ajanja Samson et al 2015) with no other similar studies reported in the country.

Despite the reported global increase in these neonatal surgical cases, there are limited studies in our setting. Majority of these neonatal surgical conditions are congenital (88.7%) in some studies and are reported to be surgically amenable with good outcomes (Ugwu RO et al 2013). Some of the common neonatal surgical conditions include anterior abdominal wall defects, anorectal malformations, neural tube defects and small gut atresias among others which can all be corrected surgically. There has been reported increase in these neonates at MTRH from the monthly reports over the recent years, there is no study that has been undertaken at the New Born Unit to look in to these changing patterns. The study done at the unit to look at neonatal surgical emergencies at MTRH more than 10years ago reported the mortality at 24% (R. Tenge-Kuremu et al 2006).

With the knowledge that congenital anomalies account for 88.7% of neonatal surgical cases and that most are surgically amenable, it will be important to find out the outcomes in these neonates at MTRH (Chirdan LB et al 2012; Ugwu RO et al 2013). Some of the factors reported to contribute to poor outcomes in most developing countries include late referrals to tertiary level facilities where this care is offered, overwhelming sepsis and late diagnosis (Ameh EA et al 2015; Arnold M et al 2010; P. Kuradusenge et al 2014).

The study aimed at describing the outcomes in these neonates and factors associated with these outcomes with the aim of providing the institution and other similar institutions within the region with information they can use to improve care of neonates requiring surgical interventions.

1.4 Research Question

What are the outcomes of neonates presenting with conditions that require surgical interventions in the neonatal period at the New Born Unit of MTRH?

1.5 Objectives

1.5.1 Broad Objective

To evaluate the outcomes of neonates with conditions or diseases that require surgical interventions in the neonatal period at the New Born Unit of Moi Teaching and Referral Hospital.

1.5.2 Specific Objectives

1. To describe the **spectrum** of surgical conditions in neonates requiring surgical interventions at the New Born Unit of MTRH.

2. To determine the **outcomes** of neonates who present with conditions requiring surgical interventions in the neonatal period at the New Born Unit of MTRH.

3. To evaluate the **factors which influence the outcomes** in neonates with conditions that require surgical interventions in the neonatal period at the New Born Unit of MTRH.

CHAPTER TWO

LITERATURE REVIEW

Surgical conditions account for 11% of the GBD although there is reported neglect in their management in most neonatal units (Chirdan LB et al 2012). Team work has been shown to be of great importance with a multidisciplinary approach showing good outcomes. Up to 95.7% of respondents in one study thought there was inadequate collaboration between pediatric surgery and other specialties leading to poor outcomes due to late diagnosis (Okoro PE et al 2012).

Some of the common conditions requiring surgical intervention in newborns include anorectal malformations, anterior abdominal wall defects, disorders of gastro intestinal tract with intestinal obstruction like duodenal and jejunoileal atresia, spinal defects, intussusception and Hirschsprung's disease among others. The number of neonatal surgical cases has increased 5-fold over the past 50years as seen in one study with a reduction in mortality rate in developed units from 60% to 15% like in esophageal atresia, diaphragmatic hernia, omphalocele and gastroschisis (Taguchi T et al 2014).

Neonatal or general intensive care units were found to be unavailable in several hospitals (51.4%) in West Africa with lack of apnea monitors in up-to 65% of hospitals (Okoye MT et al 2015). This was similar to findings in Sub-Saharan Africa where TPN availability and NICU in LICs was 36% and 19% respectively compared to 100% availability in HICs with associated mortality rates of greater than 75% in LICs compared to less than 25% in HICs (Wright NJ et al 2015). Up-to 12million cases of congenital defects are reported to be surgically amenable (Higashi H et al 2013). Most of these conditions could have good outcomes as reflected in most developed countries if medical facilities and resources could be availed in the right

settings in most developing countries (Higashi H et al 2013). These include diagnosis in the pre-natal period like in the use of 3D ultrasonography, early intervention and use of laparoscopic surgery in some procedures, availability of NICU services and provision of TPN especially for intestinal procedures like in resection and anastomosis where these neonates may require such facilities (Grigore M et al 2012). Most gastrointestinal anomalies like small gut atresia, intestinal perforations like Necrotizing Enterocolitis and gastroschisis usually require TPN support to optimize nutrition which lacks in most developing countries thus high mortality rates (Chirdan LB et al 2004; Nusinovich Y et al 2013; Stollman TH et al 2009; Okoye MT et al 2015; Bradnock TJ et al 2011).

Approach to management of some of these procedures has also been associated with different outcomes with staged closure in conditions like gastroschisis being associated with higher mortality rates compared to primary closure and prenatal repair for spina bifida being associated with reduction in shunt dependent hydrocephalus (Okoro PE et al 2012; Grivell RM et al 2014). Most developing countries have been shown to practice staged closure for most cases of gastroschisis due to late presentation to health facilities and this has been associated with poor outcomes, high mortality rates and prolonged length of hospital stay (Sekabira J et al 2009; Kouame BD et al 2015; Manson J et al 2012). Timing of intervention and approach to management also plays a role in outcomes like in the management of trachea-esophageal fistula where early intervention is associated with better outcomes and delay in management has been associated with complications especially aspiration pneumonia and subsequent septicemia (Pal K et al 2014). Laparoscopic surgery has also been shown to give better outcomes and could be safely accomplished in

neonates with intestinal atresia with better outcomes as opposed to open abdominal surgeries which are practiced more in most developing countries (Li B et al 2012).

Early prenatal diagnosis has been associated with reduced mortality and complications (Grigore M et al 2012; Henrich K et al 2007, Grivell RM et al 2014; Alshehri A et al 2013). Low rate of antenatal diagnosis in developing countries, (13.3%) in some centers have been associated with higher mortality rates compared to high rates of antenatal diagnosis reported in Germany with ability to diagnose 69% and 88% of omphalocele and gastroschisis cases respectively with better outcomes (Tarca E et al 2014; Henrich K et al 2007). Most anterior abdominal wall defects especially gastroschisis has been associated with poor outcomes especially in third world countries (Sekabira J et al 2009; Kouame BD et al 2015). The overall mortality from gastroschisis was 43% in Durban with the prevalence reported to have increased from 6% in 2003 to 15% in 2007 showing an upward trend (Sekabira J et al 2009). Higher mortality rates for gastroschisis have been reported with rates up to 100% in some centers with greatest mortality disparity in LICs compared to the high income countries which have reported mortalities of less than 25% (Kouame BD et al 2015; Badrinath R et al 2014). Better outcomes have been shown for gastroschisis in western units with mortality of 1% as compared to African centers at 23% with better prognosis from primary closure compared to staged closure with preformed silo (Manson J et al 2012). Most neonatal conditions can be picked in utero and timely intervention offered to improve outcomes. One of these modalities is the use of antenatal 3D ultrasonography that can help pick most anterior abdominal wall defects (Grigore M et al 2012). Neural tube defects, gastrointestinal anomalies especially small gut atresia and even renal or pulmonary anomalies can be picked by ultrasonography with presence of features like polyhydramnios and oligohydramnios.

In a study done in Malawi greater than 50% of children with congenital anomalies missed out on surgical intervention with clear advantage of survival if surgery was done due to late presentation to hospital (Kendig CE et al 2014).

There has been reduced incidence of complications in terms of post-operative bowel obstruction and sepsis for conditions in which early intervention has been done in intestinal atresia and gastroschisis (Alshehri A et al 2013). The post-surgical care is also important in terms of antibiotics use, feeds, infection prevention and meeting metabolic needs for optimal growth and development. It requires a multidisciplinary approach that includes nutritionists and intensive care specialties especially when it comes to neonatal intensive care to support ventilation and provision of TPN to attain adequate kilo calories per kilogram body weight daily for optimal growth and development. This is extremely important especially in conditions like perforated NEC and jejuno-ileal atresias which may lead to resection and anastomosis of the gut hence leading to complications like short gut syndrome and also in jejuno-ileal atresia with problems resulting in delayed commencement and advancement of feeds which leads to TPN use (Nusinovich Y et al 2013).

Better outcomes have been reported in centers where TPN and neonatal intensive care unit (NICU) are available showing the importance of such facilities in supportive care (Wright NJ et al 2015; Stollman TH et al 2009; Okoye MT et al 2015). Neonatal or general intensive care units were unavailable in 51.4% of hospitals in West Africa with lack of apnea monitors in 65% of the hospitals (Okoye MT et al 2015). Sepsis and multiple organ failure with low rate of antenatal diagnosis have been found to be a great contributor to mortality and some of the risk factors for severe post-operative complications include re-operation, sepsis and abdominal surgery (Tarca E et al 2014; Catre D et al 2013; Arnold M et al 2010; P. Kuradusenge et al 2014).

Overwhelming sepsis accounts for majority of mortality in Sub-Saharan Africa especially in intestinal surgeries like NEC as well as lack of delivery in hospitals with late presentation to seek medical attention contributing greatly to mortality (Ameh EA et al 2015; Arnold M et al 2010; P. Kuradusenge et al 2014). The other problems facing adequate delivery of pediatric surgical services in developing countries include poorly equipped facilities, shortage of manpower, late presentation to hospital, poverty and inadequate collaborations and consultations within departments (WHO 2014; Ameh EA et al 2000).

Neonatal intestinal obstruction and sepsis have been reported to carry the highest risk of mortality in several studies (Ugwu RO et al 2013; Shakya VC et al 2010; Sekabira J et al 2009; Mouafo Tambo et al 2011; Tarca E et al 2014; R. Tenge-Kuremu et al 2006; Ouedraogo I et al 2015). The overall mortality from neonatal intestinal obstruction in one study was 21.1% of these, 70% were due to complications from sepsis ((Ameh EA et al 2000). Mortality rates of 11.8% with sepsis contributing to 69.4% of the cases and up to 87.5% in some studies have been reported in cases of intestinal operations (Ugwu RO et al 2013). According to WHO good hand washing practices and good hygiene can greatly improve outcomes for neonates when it comes to infection control (WHO 2014).

Overall the mortality rate for congenital surgical conditions in developing countries remain high (Ugwu RO et al 2013; Bandre E et al 2010; Lukong CS et al 2011; Obu HA et al 2012) with up to 100% mortality reported for cases like gastroschisis (Ameh EA et al 2000; Kouame BD et al 2015; Badrinath R et al 2014) whereas mortality rate for gastroschisis in Western units was at 1% over a 1-month period compared to 23% in 3 African centers (Manson J et al 2012). Higher mortality rates in neonates with gastroschisis have also been attributed to staged closure which is practiced more in

developing countries due to late presentation to health facilities (Sekabira J et al 2009). This has been associated with poor prenatal diagnosis where only I of every 7 cases could be detected in the ante partum period in a tertiary hospital in Nigeria as opposed to 88% in developed centers like Germany (Abdur-Rahman LO et al 2011; Henrich K et al 2007). Outcomes of neonatal surgery in Sub-Saharan Africa have lagged behind contributing to the poor outcomes in most developing countries (Ameh EA et al 2015). This has been attributed to inadequate personnel with only 1 neurosurgeon per 10million people in East Africa and a generalized shortage of pediatric surgical specialties in West Africa (Sekabira J et al 2009; Okoye MT et al 2015). There is lack of pediatric surgeons in developing countries with less than 50% of hospitals having more than 2 pediatric surgeons (Okoye MT et al 2015).

Mortality has remained high from digestive tract disorders like duodenal and jejunal atresia as reported in a study done at Cameroon with mortality rate at 43.1% with inadequate dietary intake and sepsis as the common complications leading to mortality (Mouafo Tambo et al 2011). Jejunal atresia has been reported to have varied outcomes but with overall poor outcomes especially for type 111b and IV, from one study 28.5% mortality was reported from jejunal atresia with sepsis being the highest contributor to mortality at 87.5% (Shakya VC et al 2010).

Referrals from other facilities have also been shown to contribute greatly to mortality in most developing countries with rates of up to 44% in one study and late presentation to hospital being another factor contributing to mortality (Shakya VC et al 2010; R. Tenge-Kuremu et al 2006; P. Kuradusenge et al 2014). Late presentation to hospital and lack of adequate medical facilities as well as personnel has also been shown to contribute greatly to mortality (Shakya VC et al 2010).

In Nigeria the mortality rate for surgical conditions was 11.8% of all admissions, 88.7% accounted by congenital anomalies like intestinal obstruction, neural tube defects and anterior abdominal wall defects (Ugwu RO et al 2013). In a study done at Ouagadougou the overall mortality rate was 30.3% (Ugwu RO et al 2013; Ouedraogo I et al 2015). The overall mortality rate at KNH was at 33%, however at MTRH lower mortality rate at 24% was reported in neonates undergoing surgical emergencies with ARM being the most prevalent condition that required emergency neonatal surgery at 19.2% and 34% in both centers respectively (R. Tenge-Kuremu et al 2006). The study at MTRH was however done more than 10 years ago. At Kenyatta National hospital neonatal surgery contributed 30.13% of total workload in the pediatric surgical department with most of the neonates at 19.2% having anorectal malformations followed by anterior abdominal wall defects at 17.2%. The overall mortality from neonatal surgical cases was 33% which is still high compared to HICs with mortality of less than 25% (Wright NJ et al 2015; Ajanja Samson et al 2015).

In Kenya most expectant women present during labor at their first visit to a health facility hence showing the missed opportunities to identify such defects during pregnancy and intervening early (Njuguna et al; P. Kuradusenge et al 2014). Nutritional supplements like folic acid have been successfully used to prevent neural tube defects during the prenatal period by use of focused antenatal care thus reducing the morbidity from such surgical conditions. In a study at MTRH up to 62% of infants with anorectal malformations were delivered at home with an overall mortality of 31% and overwhelming sepsis contributing more to the overall mortality at 69.2% (P. Kuradusenge et al 2014).

This goes to show that alot needs to be done to evaluate factors that contribute to the poor outcomes in most developing countries with an aim to improve care especially

with the evidence that outcomes could be improved in most developing countries if the care seen in HICs could be emulated in low to middle income countries (Higashi H et al 2013).

CHAPTER THREE

METHODOLOGY

3.1 Study Design

A prospective descriptive study design was used.

3.2 Study Site

The study was carried out at the New Born Unit in Moi Teaching and Referral Hospital which is located in Eldoret town, about 300km from Nairobi, in Uasin Gishu County, Kenya.

The hospital is an 800-bed capacity tertiary hospital that also serves institutions around Eldoret. It also serves as a referral hospital for the Western part of Kenya, with a catchment population of about 15 million people - 33% of Kenyan population. The hospital provides various services ranging from primary to specialized care. The hospital also serves patients from neighboring countries like; Uganda, Sudan, South Sudan and Rwanda.

The hospital's New Born Unit is located in the Riley Mother and Baby Hospital wing, an extension of the hospital that was opened in 2009. The NBU is a 60-bed capacity unit with six functional incubators and has fifty baby cots with ability to provide basic neonatal services. The nurse to patient ratio at the unit is approximately 1:20. The new born unit at MTRH is where all neonates who present to the hospital and require admission are placed. It has an average occupancy of 75-150% at any given time depending on the number of neonates presenting at the unit.

The investigations that can be carried out in NBU include random blood sugar, calcium, electrolytes, complete blood count, CSF studies and blood cultures. The staff allocated to the unit includes 7 pediatricians, two of whom are neonatologist, 36

nurses, a nutritionist, pediatric resident doctors and clinical officer interns among others.

Under the devolved system, the Kenya Health Policy 2014-2030, health care facilities were organized into Level 1, 2, 3 and 4. Level 1 and 2 include community health services and primary care services like dispensaries whereas level 3 and 4 include County referral services and National referral services respectively. KNH and MTRH fall under the National referral services where this study was carried out. Neonates admitted in the NBU are either born in the hospital, referred from neighboring level I, II, and III health facilities or come directly from home. They are managed using the basic Pediatric protocol in Kenya which has been adopted from the WHO guidelines and also using the MTRH set protocols according to the needs and availability of resources in the facility.

The neonates who require surgical interventions are usually seen in the unit by resident doctors on call who then inform the various surgical disciplines involved who come to review the neonates and make decisions for surgical interventions. There are currently 2 pediatric surgeons, 5 neurosurgeons, 2 plastic surgeons, 2 urologists and 11 orthopedic surgeons who do reviews and ward rounds in the unit depending on the cases they are called to review and guide in the subsequent care of the neonates who are under the daily care of pediatricians and neonatologist in the unit. Neonates with Surgical conditions cared for in the unit range from 15-20 a month with the bulk of the cases being seen and managed by the 2 pediatric surgeons followed by the neurosurgeons and the other disciplines as the neonates with different surgical emergencies present to the unit.

3.3 Target Population

The target population comprised of neonates with surgical conditions who were admitted to the New Born Unit; delivered at MTRH, referred from other health facilities or those brought in as home deliveries requiring surgical intervention during the study period.

3.4 Study Population

This included neonates with conditions requiring surgical intervention in the neonatal period who had not undergone any surgical interventions at other health facilities prior to admission at the New Born Unit of MTRH.

3.5 Sample Size

Fisher's formula was used to determine the sample size

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

The p was the overall mortality rate from neonatal surgical cases reported to be 24% (R. Tenge-Kuremu et al 2006)

Z was at 1.96 having used a 95% confidence level

The e was my margin of error at 5%

Thus the sample size calculation was

$$n = \frac{1.96^2 \, 0.24(0.76)}{0.05^2}$$

n= 280

Adjusting to finite population: admission of neonates to the newborn unit requiring surgical intervention averages 17 babies monthly according to MTRH data (MTRH 2016) Thus following adjustment over a 9-month period;

N= 17 admissions*9 months (study period)

N= 153

$$nf = \underline{n0}$$

$$1 + \underline{no}$$

$$N$$

$$nf = \underline{280}$$

$$280/1 + 280/153$$

$$nf = 99$$

With 20% adjustment for missing data and non-response

$$nf = 99/80 \times 100$$

$$nf = 124$$

k^{th} number $153/124 = 1.2$

On calculating the kth number to determine the sampling frame it was 1.2 thus consecutive sampling was done.

The sample size was 124 neonates who presented with conditions requiring surgical interventions in the neonatal period during the study.

3.6 Eligibility Criteria

3.6.1 Inclusion Criteria

1) Neonates admitted to NBU at Moi Teaching and Referral with conditions requiring surgical intervention during the neonatal period.

3.6.2 Exclusion Criteria

1. Neonates who had undergone surgical procedures in other health facilities prior to admission at MTRH.

3.7 Study Procedure

Neonates admitted in the unit during the study period and who met the inclusion criteria were recruited. The recruitment was done by the principal investigator with

the help of the research assistant who was the nursing officer in charge in the unit once decision for surgery was made. For example, if a neonate presented with an anterior abdominal wall defect or a neural tube defect; the pediatric surgeon and neurosurgeon were informed respectively by the resident on call. This is because it is the resident on call who came into first contact with the neonates once they were admitted into the unit. The surgical specialist on board would then review the neonate and once a decision was made to operate on the neonates, they were recruited into the study once their parents or guardians gave their consent to participate in the study. The parents/guardians were taken through the consent form to make them understand the purpose of the study and those who accepted were given the written consent form to sign. The neonates whose parents consented to the study were then consecutively recruited as they presented to the newborn unit and as the indication for surgery was made until the sample size was reached.

A structured questionnaire was then administered focusing on various factors including; maternal age, marital status, place of delivery, and mode of delivery, ANC attendance and prenatal ultrasound scans and findings. Translation to Kiswahili was done without losing the meaning of the questions to the participants who did not understand English.

The neonates' information on birth weight, age at presentation, gender, diagnosis, type of surgery (elective or emergency) and length of hospital stay were recorded from the admission file notes of the neonates. The maternal demographic data, neonatal and maternal characteristics were entered in the data collection form on recruitment. (Appendix 11)

Any missing data was obtained by checking the maternal ANC attendance booklet.

The participants received standard newborn care based on the diagnosis made. Data was recorded and length of hospital stay determined to discharge or mortality.

3.8 Data Collection Instruments

A structured questionnaire was used to collect data on the various parameters that helped to determine the outcomes of neonates in whom surgery was indicated. The questionnaire was interviewer administered by the principal investigator with the help of the research assistant.

3.9 Data Analysis and Presentation

Data collected was entered in the computer data form with observation of strict confidentiality. Data coding was done on all the data collected during analysis. All the data was analyzed using STATA^R version 13 software at 95% confidence interval. Data was summarized in frequency tables. For continuous variables, descriptive statistics such as median and IQR were used. Frequency listings and percentages were used to describe categorical variables. A 95% confidence interval was computed to ascertain statistical significance with a p-value less than 0.05 considered statistically significant. Chi-square and fishers exact test were computed to test for associations. Logistic regression was done to check for independent associations between the dependent and independent variables to the outcomes of interest which was mortality. Mann Whitney U test and Kruskall Wallis H test which are non parametric tests used to compare 2 medians were used to check associations between categorical and numerical variables which was the length of stay.

3.10 Ethical Consideration

Ethical approval to conduct the study was sort from IREC as well as permission to perform the study at the Moi Teaching and Referral Hospital management.

Informed written consent was sort from the participants' parents or guardians. Parents or guardians were allowed to ask questions and any additional information about the study, its risks and benefits before consenting to the study.

Confidentiality was upheld. A unique coding system was used on the questionnaire to ensure confidentiality. The filled-up questionnaires were stored in lockable cabins with access to the information by the principal investigator only. De-identification was also done so that participants' clinical information remained confidential.

There was no preferential treatment to the participants recruited to the study in terms of the surgeon to do the procedure or any special considerations in terms of care during the study period. There were no direct benefits or any incentives offered for participation in this study other than the aim of improving health care in neonates requiring surgical interventions. The neonates' parents and guardians neither incurred additional costs to participate in the study nor underwent additional interventions other than those intended for their care during the study period.

There were no risks involved in participating in this study as the participants were not subjected to extra or additional procedures other than for those on the standard care of the neonates while undergoing their daily care for the conditions they were being managed for while in the unit.

Neonates whose parents or guardians did not consent to participate in the study received the same quality and standard of care as for those who gave their consent.

The parents or guardians were given the choice to willingly leave or withdraw from the study when they wished to. There was no coercion or use of incentives in order to be part of the study.

Data collected and analyzed from the study would be made available for use at MTRH and any other stakeholders to guide in decision and policy making. Data will also be presented in scientific conferences and published in journals once approved for dissemination of knowledge collected and to help guide and inform future research with the aim of improving the quality of health care.

CHAPTER FOUR

RESULTS

A total of 124 participants were included in the study which was carried out over a

period of 9 months from February to November 2016. There were 66(53.2%) males

and 58(46.8%) females with a male to female ratio of 1.1:1.

4.1 Maternal Characteristics

The most common maternal age range was 18-24 years at 72(58.1%) and the

majority of the mothers were married at 107(86.3%) as shown in Table 1.

Table 1: Maternal Demographics (n-124)

Variables	Frequency	Percentage
Age		
18-24 years	**72**	**58.1**
25-34 years	40	32.3
35-44 years	12	9.7
Marital status		
Single	16	12.9
Married	107	86.3
Separated	1	0.8

Majority of the participants' mothers attended ANC at 102(82.3%) with supplements

being issued to 84(82.4%). These included folic acid, iron and calcium supplements.

Of all the 102(82.3%) who received supplements, none of them received during the

crucial 1st trimester period of gestation or in the pre conceptual period with majority at

63(50.8%) receiving supplements between 16-24 weeks gestation during their first

ante natal clinic visit as shown on table 2.

Antenatal ultrasounds were done on only 5(4%) of the mothers during their routine

ANC visits. It is important to note that of the 4% who had ultrasound done, no

congenital anomaly was diagnosed from these ultrasounds done.

Table 2: Supplement use during pregnancy (n-122)

Variables		Frequency (n)	Percentage (%)
Supplements use	Yes	84	82.4
	No	18	17.6
Time supplements issued	<16 weeks	16	12.9
	16-24 weeks	63	50.8
	24-32 weeks	21	16.9
	>32 weeks	2	1.6
Type of supplements issued	Folic acid	83	98.8
	Iron supplements	83	98.8
	Calcium	1	0.01

Majority of the neonates 103(83%) were delivered in other peripheral health facilities

then referred to MTRH with only 9(7%) of the participants being delivered at MTRH.

There was a higher mortality among neonates who were brought in as referrals from

peripheral health facilities at 36(35.3%) compared to no mortality among neonates

who were delivered at MTRH where this study was done.

The rest were home deliveries as shown in Figure 1.
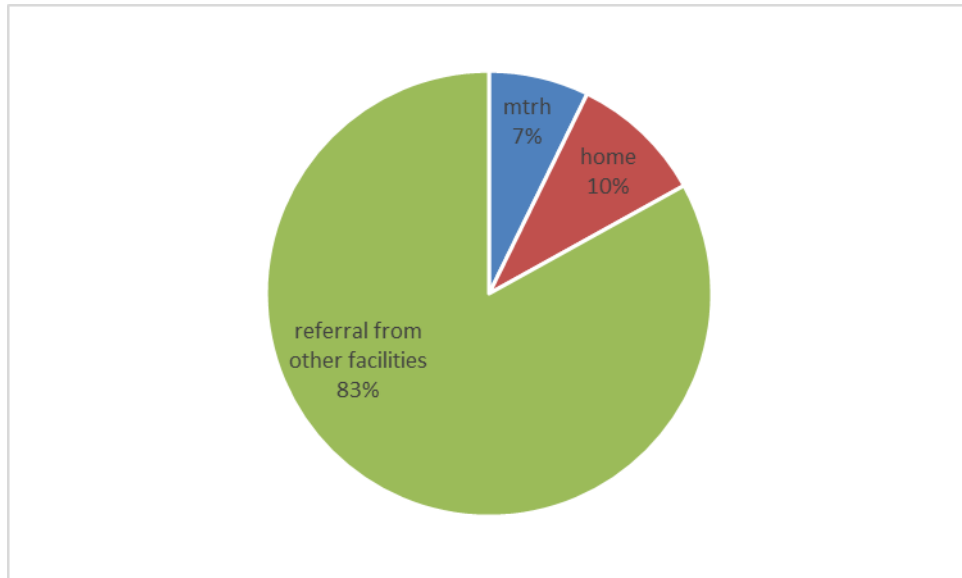
Figure 1: Neonates distribution according to Place of delivery

4.2 Neonatal Characteristics

The median age at admission was 2 days (IQR 1,5) with a range of 1 to 26 days.

Majority of the study participants 116(94%) were delivered via SVD. The other

modes of delivery are as shown in Figure 2.
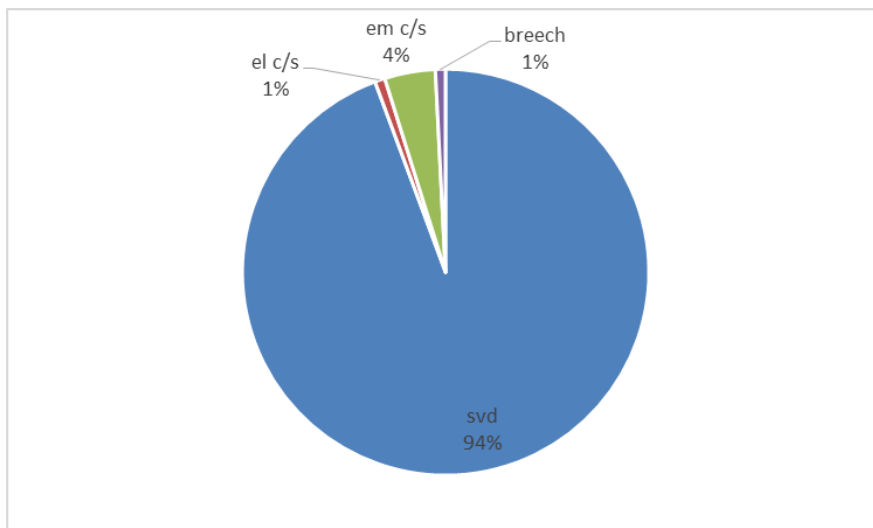
Figure 2: Distribution according to Mode of delivery

4.2.1 Neonatal Birth Weight

Most neonates 74(59.7%) had a birth weight of between 2.5-3.9kgs and the rest as
shown in Figure 3.
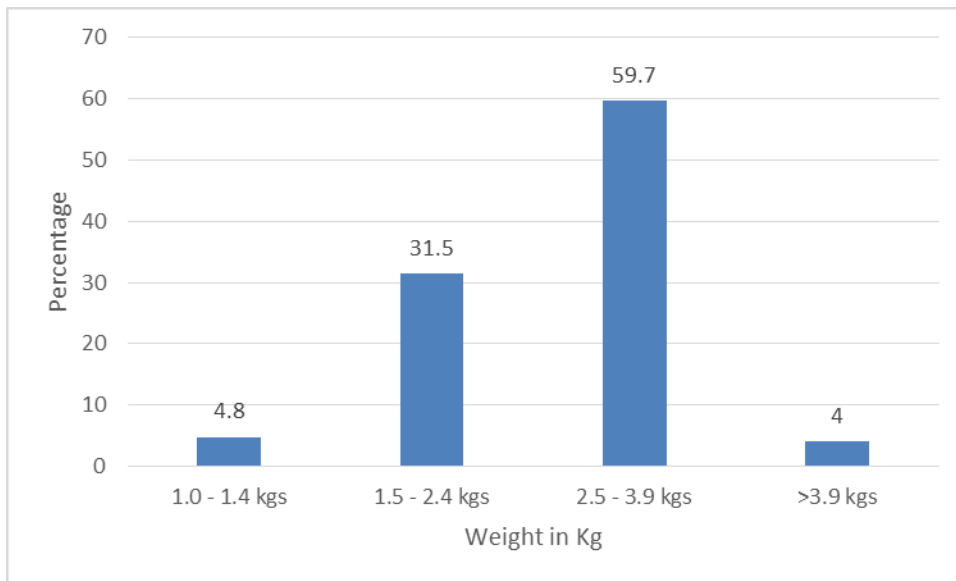
Figure 3: Distribution of neonates according to Birth weights

4.2.2 Data on Intervention Offered

Majority of the neonates 108(87.1%) had surgical interventions done. Of these

65(60.2%) were done as emergency surgery while 43(39.8%) were elective surgery.

4.2.3 Reasons for not doing Surgery

The reasons as to why surgery was not done on 16(12.9%) of the participants were as shown in Figure 4. All the neonates who were too sick to withstand surgery died thus no more associations were drawn.
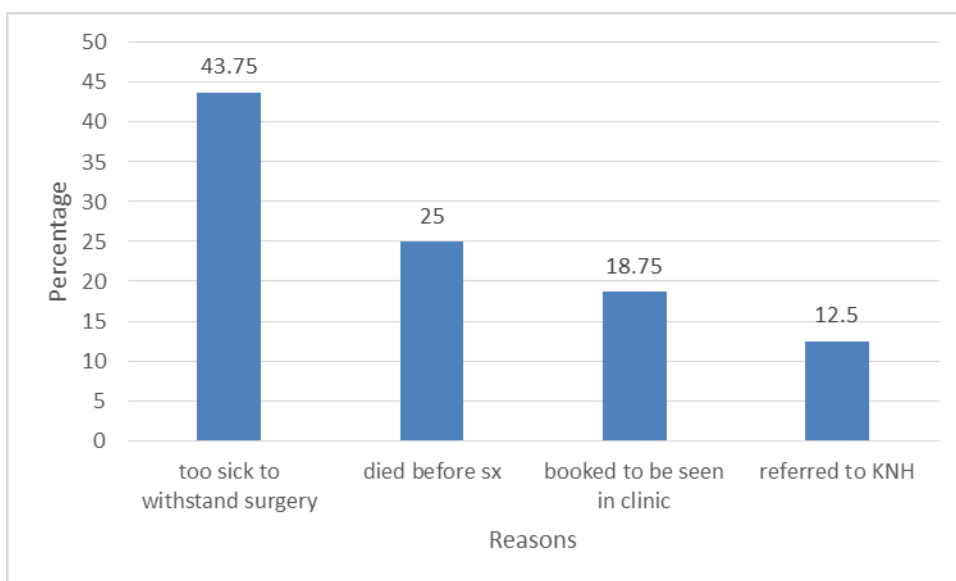
Figure 4: Reasons why surgery was not done

4.3 Outcomes

The overall mortality was 39(31.5%), with 83(66.9%) neonates being discharged,

2(1.6%) were referred to KNH for specialized surgery.

4.4 Spectrum of Diseases

Majority of neonatal surgical conditions were congenital 114(92%) while 10(8%)

were acquired. Most neonatal surgical conditions affected the gastro-intestinal system

at 86(70%) with the highest case contributed mortality at 43%. The top 5 diagnoses in

this study were: gastroschisis 33(26.6%), neural tube defects 25(20.2%), anorectal

malformations 25(20.2%), small gut atresia at 18(14.5%) and tracheoesophageal

fistula 4(3.2%). Others 19(15.3%) included; sacrococcygeal teratoma, pyomyositis,

cystic hygroma, meconium peritonitis, brain abscess and submandibular abscess.

The diagnoses were further sub classified as shown in Tables 3 and 4 below.

Table 3: Diagnosis based on systems affected

	Outcomes		(n/%)
System involved	**Discharge (n/%)**	**Mortality (n/%)**	**Total**
GIT	49(57)	37(43)	86(70)
CNS	23(92)	2(8)	25(20)
Musculoskeletal	13(100)	0(0)	13(10)
Total	85	39	124

Table 4: Case Fatality Rate for Top 5 diagnoses

Diagnosis	Frequency (n/%)	Discharge (n/%)	Mortality (n/%)
Gastroschisis	33(26.6)	14(42.5)	**19(57.5)**
Neural tube defects	25(20.2)	23(92)	2(8)
Anorectal malformation	25(20.2)	17(68)	8(32)
Small gut atresia	18(14.5)	13(72)	5(28)
Tracheoesophageal fistula	4(3.2)	1(25)	3(75)
Others	19(15.3)	17(89.5)	2(10.5)

4.4.1 Co-morbidities

Anemia was the leading co-morbidity among the neonates with surgical conditions at 69(55.6%), others included birth asphyxia, apnea and hypothermia as shown in Figure 5.
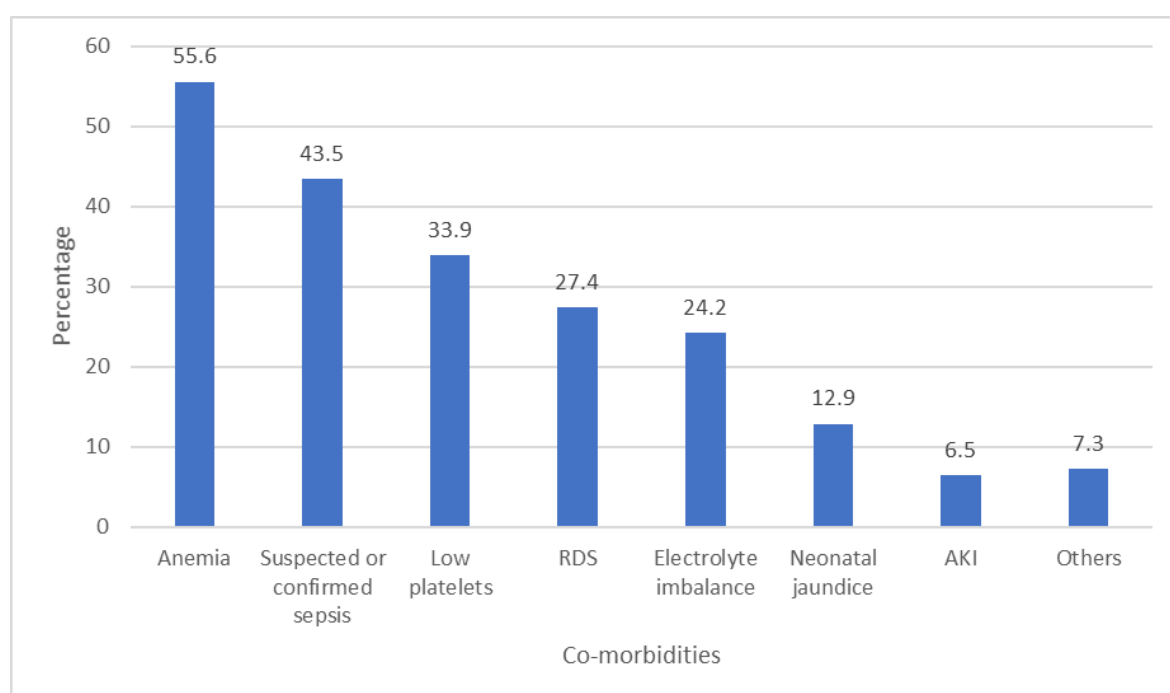
Figure 5: Distribution of co-morbid conditions.

Table 5 below shows the bivariate association between neonates who had surgical conditions and other co-morbid conditions like neonatal sepsis, acute kidney injury and neonatal jaundice in relation to mortality. The p value was statistically significant at 0.001 showing an association between presence of co-morbid conditions and mortality.

Table 5: Bivariate association between co-morbid conditions and mortality

	Mortality		p-value
Variable	**No (n/%)**	**Yes (n/%)**	
No co-morbidity	26(31.3)	2(5.1)	0.001
Co-morbidity	57(68.7)	37(94.9)	
Total	83	39	

4.5 Factors associated with outcomes

4.5.1 Time lag between admission and surgery

The time lag from when the participants were admitted to hospital to when the surgery was done ranged from 0 days to 93 days (IQR 1,9) with a median of 2 days

4.5.2 Time lag between time when decision was made to have surgery to the actual date of surgery

Time lag ranged from 0 days to 41 days (IQR 0,2) with a median of 1 day

4.5.3 Bivariate Association between variables and mortality

Table 6 below shows the bivariate association between independent variables and mortality. There was an association between birth weight, respiratory distress, and electrolyte imbalance with mortality (p-Value<0.05)

Table 6: Bivariate association between independent variables and Mortality (n-122)

	No (n/%)	Yes (n/%)	p-value
ANC attendance			
• None	12(54.5%)	10(45.5%)	0.325
• 1-3 visits	59(71%)	24(29%)	
• ≥4 visits	12(70.6%)	5(29.4%)	
Delivery place			
• Home	9(75%)	3(25%)	*0.750
• Health facilities	74(67.3%)	36(32.7%)	
Birth weights			
• <2.5kgs	20(45.5%)	24(54.5%)	**0.001**
• ≥2.5kgs	63(80.8%)	15(19.2%)	
Sepsis			
• Yes	33(62.3%)	20(37.7%)	0.230
• No	50(72.5%)	19(27.5%)	
Respiratory Distress			
• Yes	12(35.3%)	22(64.7%)	**0.001**
• No	71(80.7%)	17(19.3%)	
Electrolyte imbalance			
• Yes	10(33.3%)	20(66.7%)	**0.001**
• No	73(79.3%)	19(20.7%)	
AKI			
• Yes	2(25%)	6(75%)	***0.013**
• No	81(71%)	33(29%)	
*NB: *Fishers exact test*			

4.5.4 Complications from surgery

Majority of neonates who underwent surgery did not have any complications documented at 79(73.1%). Wound sepsis was the leading complication from surgery at 19(17.6%) and the rest as shown in Figure 6.
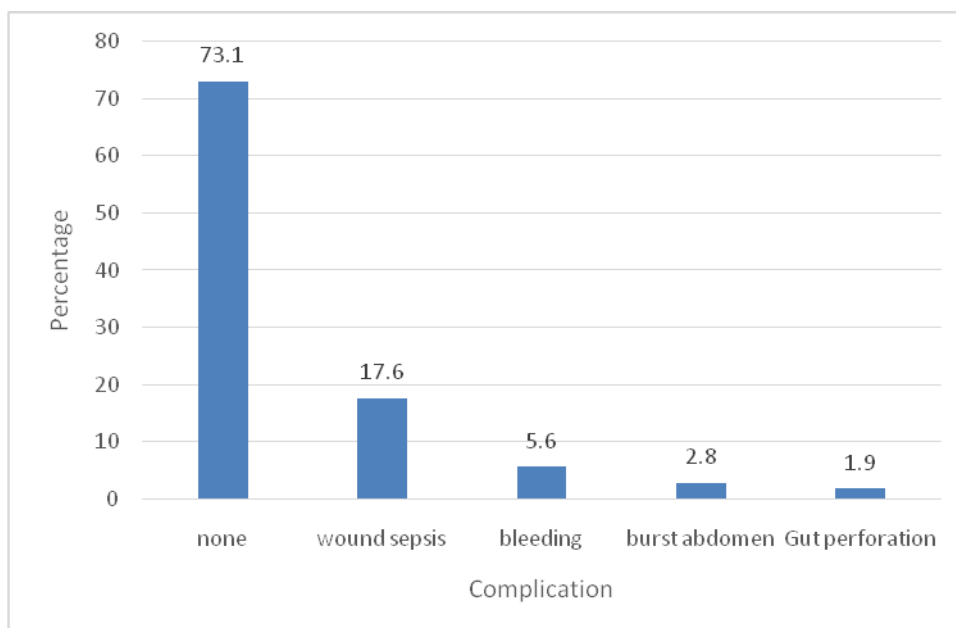
Figure 6: Complications after surgery (n=108)

4.5.5 Mode of feeding post operatively

Table 7 shows the mode of feeding in the immediate post-operative period. Most neonates 76(61.3%) were not fed in the immediate post-operative period. Partial Parenteral nutrition included use of 10% dextrose and use of intravenous amino acids whose supply was erratic.

Table 7: Mode of feeding post operatively

Mode of feeding	Frequency (n)	Percentage (%)
EBM/breastfeeding	46	37.1
Partial Parenteral Nutrition	18	14.5
NPO	76	61.3

The median number of days taken on nil per oral feeds was 4 (IQR 2,7) days, with a minimum of 1day and a maximum of 24 days.

Of those not fed in the immediate post-operative period, 37(48.7%) stayed without any enteral feeds for less than 72 hours while 39(51.3%) stayed for more than 72 hours.

4.5.6 Bivariate Association between laboratory parameters and Mortality

The table below shows the laboratory parameters and associated outcomes. The laboratory results were identified from the initial samples obtained at admission. For the blood culture results majority isolated Klebsiella pneumoniae species.

Table 8: Association between laboratory results and Mortality

	No (n/%)	Yes (n/%)	p-value
Hb (g/dl)			
<12.0	9(64.3)	5(35.7)	*0.759
≥12	72(69.9)	31(30.1)	
Platelets × 10^9/L			
<150	10(41.6)	14(58.3)	**0.013**
≥150	72(76.6)	23(23.4)	
Potassium (mmol/L)			
<3.5	11(57.9)	8(42.1)	0.355
3.5-5.1	34(75.6)	11(24.4)	
>5.1	37(67.3)	18(32.7)	
Creatinine (umol/L)			
<40	18(75.0)	6(25.0)	0.347
40-80	26(74.3)	9(25.7)	
>80	36(62.1)	22(37.9)	
Culture results			
Negative	2(50.0)	2(50.0)	*0.212
Positive	22(81.5)	5(18.5)	
*NB: *Fishers exact test*			

4.5.7 Logistic regression for independent associations and mortality.

Table 9 below shows independent associations with mortality. Neonates with respiratory distress and electrolyte imbalance were 4 and 6 times more likely to die respectively as opposed to those without. Those who attended ANC were less likely to die compared to those who did not attend ANC.

Table 9: Logistic Regression Showing Independent Associations with mortality

Variables	Odds ratio	p-value	Confidence Interval
Platelets 50-150 vs <50	0.2636	0.286	0.0227, 3.0598
Platelets >150 vs <50	0.1199	**0.042**	0.0156, 0.9252
ANC attendance vs none	0.1262	**0.013**	0.0248, 0.6429
Birthweight ≥2.5kgs vs <2.5kg	0.8463	0.792	0.2448, 2.9262
Sepsis Yes vs No	3.3573	0.069	0.9138, 11.6104
Respiratory Distress Yes vs No	**4.9024**	**0.038**	1.0896, 22.0572
Electrolyte imbalance Yes vs No	**6.1778**	**0.029**	1.2077, 31.6020
AKI Yes vs No	3.0720	0.381	0.2495, 37.8303

4.6 Length of Hospital Stay

The length of hospital stay ranged from 0 days to 102 days with a median of 14.5 days (IQR 6,32)

Table 10 below shows the association between independent variables and Length of hospital stay using Mann Whitney U test and Kruskall Wallis H test which are non-parametric test for two medians. The only significant finding was time to initiation of oral feeds post operatively and length of hospital stay.

Table 10: Associations between independent variables and length of hospital stay.

Variable	Category	Median	IQR	p-value
Initiation of oral feeds post op	≤ 72 hours >72 hours	10 23	3, 25 9, 39	**0.0071***
Surgical complications	No Yes	13 23	5, 31 9, 33	0.0712*
Platelets	<50 50-150 >150	13 12 15.5	9,43 6,33 6.5, 31	0.9634†
Place of delivery	MTRH Home Other facilities	15 20 13	14, 18 10, 34 5, 32	0.5164†

Key: * Mann Whitney U test.   † Kruskall Wallis H test

CHAPTER FIVE

DISCUSSION

The total number of males recruited in this study was almost equal to females which is contrary to a study done at MTRH by (R. Tenge-Kuremu et al 2006) who found a ratio of 1.7:1 although this was a retrospective study and it also comprised of participants with surgical cases handled by only the general pediatric surgical team as opposed to all surgical disciplines in this study. These findings are similar to those in a study by (Abdur-Rahman LO et al 2011) in Nigeria where there was an almost equal number of females compared to males at a ratio of 1.1:1.

Slightly more than half of the participants in this study had a birth weight of between 2.5-3.9kgs. There was statistical significance noted in neonates who had a birth weight of less than 2.5kgs with association to mortality compared to neonates who had birth weights greater than 2.5kgs. This could be explained by the fact that most premature neonates would be in this group with lower birth weights and thus are prone to increased mortality due to the other complications that they may have including respiratory distress syndrome, neonatal sepsis and hypoglycemia. They are also more likely to require more supportive care like respiratory support due to their immature lungs in conditions like respiratory distress syndrome and TPN use especially if they have surgical conditions affecting the gastro intestinal tract like necrotizing enterocolitis. It is important to note that there was no TPN offered to these neonates especially those with birth weights less than 1,250 grams as recommended thus this could explain the association to mortality. This is comparable to a study in Cameroon where 50% of the neonates had a birth weight of 2.5kgs, it is also similar to a study in Nigeria where more than 75% of neonates had a weight of more than 2.5 kilograms (Mouafo Tambo FF et al 2011; Abdur-Rahman LO et al 2011). The Nigerian study was however a retrospective study and looked at neonates with

anterior abdominal wall defects most of whom have low birth weights due to some maternal factors like young age.

The median age of presentation to hospital in this study was 2 days which is late for most neonatal surgical conditions especially anterior abdominal wall defects and small gut atresias. This could be explained by the high number of neonates who came in as referrals from peripheral health facilities and also some who were delivered at home. Thus there could have been delays in terms of transport and cost implications since MTRH has a large catchment population with some neonates in this study that came from as far as Turkana and West Pokot counties which have poor terrain. It could also be due to the fact that the care required by neonates with surgical conditions is limited to MTRH as the tertiary facility in the region due to scarcity of pediatric Surgeons available in lower level hospitals to offer such specialized care. This is in contrast to a study done in Nigeria with a median age of 23.5 hours (Abdur-Rahman LO et al 2011). This could be explained by the fact that this study looked at neonates with anterior abdominal wall defects thus mothers could have rushed the neonates to hospital due to the dramatic presentation of conditions like gastroschisis. Most neonates in the study done at Nigeria were delivered at peripheral health facilities then referred to the tertiary hospital which could explain the differences at presentation. It is however different to a study in Cameroon with a mean age of 3.7 days and Nigeria with a mean age of 5 days both being retrospective studies and looking at neonates with all surgical complications including conditions like cleft lip and palate and cardiac defects and also being tertiary level facilities where such care is offered (Ugwu RO et al 2013; Mouafo Tambo FF et al 2011). This is similar to this study since majority of the neonates were admitted as referrals from peripheral health facilities thus delays in reaching the tertiary hospital where this study was conducted.

The mortality rate observed in this study was 31.5% which is almost similar to the KNH study whose overall mortality rate was 33% (Ajanja Samson et al 2015). This could be explained by the fact that both centers of study are tertiary level hospitals managing neonates with surgical disorders referred from most of the peripheral facilities within their catchment population since they are the 2 National referral hospitals in the country. There could have been delays to reach the hospital for care thus leading to complications especially from fluid and electrolyte imbalances causing a higher mortality rate in both hospitals. The almost similar findings could also be due to the smaller number of neonates studied in both hospitals and a shorter duration of the study at 9 and 6 months. This was in contrast to a study done at MTRH by (R. Tenge-Kuremu et al 2006) where the overall mortality was 24%. It shows a shift in the outcomes 10years after this study was done considering that it was a retrospective study done over a 3-year period with fewer neonates with surgical conditions at 56 compared to this study with 124 neonates over a 9 month period. The MTRH study also focused on neonatal surgical emergencies managed by the general pediatric surgeon only as opposed to this study where other disciplines like neuro-surgery, orthopedics and plastic surgery were represented. The MTRH study was also done at the old New Born Unit which had a smaller capacity of neonates at 20 compared to this study done at the new unit which has a capacity of 60 neonates with an increase in the number of admission of neonates with surgical conditions over the years. Congestion at the unit could also explain the change in the mortality since if simple measures like hand washing and infection prevention are not adhered to then other co-morbidities like neonatal sepsis are likely to affect outcomes. This study however reported a lower mortality as compared to a study by (Ugwu RO et al 2013) in Nigeria

with a mortality of 48.2% after surgical intervention though in the Nigeria study neonates with any anomaly requiring surgical intervention were recruited as opposed to this study where neonates with an indication for surgical interventions in the neonatal period only were recruited. This was also a contrast to a study by (Kouame BD et al 2015) in Abidjan who found a higher mortality of 52% though those recruited in this study included neonates with all congenital anomalies which could have resulted in the very high mortality rate. It is different from this study which recruited only neonates with an indication for surgery in the neonatal period. Lower mortality rates were however reported in a survey done to compare outcomes in LICs versus those in HICs where as low as <25% mortality rates were reported in HICs compared to 50-75% in MICs and more than 75% in some LICs (Wright NJ et al 2015). This discrepancy could be explained by the fact that this was a survey done during an Annual scientific conference with self-reported questionnaires from the respondents thus a possibility of recall bias. The lower mortality rates reported in HICs could also be due to availability of NICU and TPN which are very important when it comes to supportive care of these neonates during their hospital stay.

The commonest diagnosis in this study was Gastroschisis representing a quarter of the study participants which is in contrast to a study done in the same center 10 years earlier where ARM was the commonest condition at 34%, followed by intestinal atresia at 14% then anterior abdominal wall defects at 13% of the total (R. Tenge-Kuremu et al 2006). It is also in contrast to the KNH study by (Ajanja Samson et al 2015) which reported ARM at the top with 19.2% followed by anterior abdominal wall defects at 17.2%. This could be explained by a shift in neonatal surgical conditions where gastroschisis cases for instance are reported to have increased from 6% in 2003 to 15% in 2007 in a retrospective study in Durban (Sekabira J et al 2009).

There has also been a global increase in anterior abdominal wall defects especially in gastroschisis cases with an increase in incidence from 2.5/10,000 in 1994 to 4.4/10,000 in 2004 according to the (British Isles Network of congenital Anomaly Registers). This could have contributed to the change in neonatal surgical conditions/disease presentations with gastroschisis leading in morbidity compared to the two studies previously done at MTRH and KNH which had ARM as the leading diagnosis. There was also a large catchment population for neonates with gastroschisis in this study some coming from as far as Kiambu, Turkana and Nakuru counties thus reflecting a rise in the number of cases of gastroschisis managed at MTRH. Lack of proper supplement use like folic acid during pregnancy has also been associated with the occurrence of anterior abdominal wall defects and neural tube defects which were the top two conditions in this study. Most neonates in this study were delivered to mothers who did not use folic acid during the first trimester and in the pre conceptual period as recommended which has been proven to lead to a reduction in the incidence of neural tube defects which was the second commonest diagnosis in this study. Over 50% of participants' mothers used supplements like folic acid and iron during the second trimester when organogenesis is already complete in the fetus thus use of these supplements could not have been of benefit to prevent neural tube defects.

Majority of participants in this study were delivered in peripheral health facilities though they were later referred for care to MTRH which is comparable to most studies and it could be explained by the fact that most of these studies were done in Tertiary hospitals where such care of neonates with surgical conditions is offered (Ugwu RO et al 2013; Shakya VC et al 2010; Abdur-Rahman LO et al 2011; R.

Tenge-Kuremu et al 2006; Ouedraogo I et al 2015). There is however a contrast in referral patterns between LICs and HICs with more referrals in the former group at 75% compared to only 27% in the latter (Wright NJ et al 2015). In one study referrals were as high as 92.9% though this was a retrospective study which looked at anterior abdominal wall defects only (Abdur-Rahman LO et al 2011). Most referred neonates in this study had poor outcomes with a mortality rate of 35.5% which is similar to other studies since there were delays in presentation to a health facility with a median age of 2 days (Ugwu RO et al 2013; Abdur-Rahman LO et al 2011; R. Tenge-Kuremu et al 2006). This is similar to other studies who had a median age of presentation to a health facility at around 3 days which is late for most neonatal surgical cases that require prompt interventions (Shakya VC et al 2010; Ameh EA et al 2000; Mouafo Tambo FF et al 2011; R. Tenge-Kuremu et al 2006). The high number of referred neonates could be explained by the limited number of specialists to perform such procedures since even MTRH which serves the whole of Western Kenya has only two pediatric surgeons who managed the bulk of the surgical cases in these neonates.

Although ANC attendance was associated with low rate of mortality, there was improper ANC attendance with only 13.7% of mothers completing the recommended 4 ANC visits during pregnancy. Low ANC attendance at 13.3% in some studies could also have contributed to a rise in some conditions like gastroschisis and neural tube defects due to improper supplement use in the periconceptual period as recommended (Ugwu RO et al 2013; Tarca E et al 2014). This is because appropriate use of nutritional supplements like folic acid in periconceptual period especially during the first trimester has been associated with reduction in these defects especially neural tube defects. Periconceptual use of nutritional supplements like folic acid has been

associated with reduction of up to 60% in some cases of anterior abdominal wall defects (Lorenzo D Botto et al 2002). In this study majority of the mothers to the neonates used supplements during pregnancy though it was after the first trimester for most of them. They thus missed out on important nutritional supplements like folic acid before conception and especially during the 1st trimester as is recommended with the aim of reducing the occurrence of some congenital anomalies. Poor as well as late ANC attendance and low rate of antenatal ultrasonography may have led to late or lack of diagnosis of most of these surgical conditions in utero in this study. In a study in Romania, use of 2D and 3D ultrasonography was associated with early diagnosis of some anterior abdominal wall defects with 80% sensitivity of identifying omphalocele during the first trimester thus having early diagnosis with good outcomes (Grigore M et al 2012). There was no neonatal surgical condition diagnosed in utero in this study since almost half of the participants' mothers went for their first ANC visit in the second trimester and only 4% of mothers had an ultrasound done during pregnancy with no congenital anomaly being identified. This could be explained by the fact that most ultrasounds done at peripheral health facilities are done by sonographers who may not have the expertise and required qualifications to diagnose or identify some of these anomalies. It could also be due to the lack of scheduled routine anomaly scans done in most developed countries at 18-20 weeks gestation thus more focus is on identifying various anomalies other than checking the lie and presentation of the fetus as done in most developing countries. Another explanation could be that most ANC visits are focused on the profile done during pregnancy like urinalysis and hemoglobin level checks and that only pregnant mothers with specific complaints or complications during pregnancy like vaginal bleeding are sent for ultrasounds. This is similar to other studies where poor ANC attendance and late diagnosis were

associated with poor outcomes (Ugwu RO et al 2013; Shakya VC et al 2010; Tarca E et al 2014; Kouame BD et al 2015). In one study only 1.5% of the surgical conditions were identified prenatally during ultrasounds done on pregnant mothers (Kouame BD et al 2015). This is a sharp contrast when compared to some HICs like Germany where prenatal diagnosis of omphalocele was as high as 69% and 88% for gastroschisis attributed to real time 3D ultrasonography use during the anomaly scans as opposed to most LICs and some MICs (Grigore M et al 2012).

Only 25% of participants had blood cultures done with proven sepsis in 21% of the participants and almost half the participants having presumptive diagnosis of probable sepsis. The number of neonates with confirmed sepsis could have been higher if more blood cultures were done to confirm the diagnosis since only 43.5% of neonates in this study had confirmed or suspected sepsis. This is because majority of neonates who had complications following surgery had wound sepsis as the leading complication. This finding could be explained by the prolonged hospital stay leading to hospital acquired infection. It could also be due to a breech in the skin for some conditions like anterior abdominal defects and frequent handling due to daily cleaning and dressing at incision site as well as presence of intravenous lines and naso-gastric tubes which could all predispose to neonatal sepsis. This compares to most studies where sepsis was a leading cause of morbidity and mortality with poor outcomes associated with sepsis. In one study, sepsis was a common cause of mortality at 87.5% and it was also associated with prolonged hospital stay (Shakya VC et al 2010). This is similar to another study in Nigeria with sepsis contributing to 70% of mortality (Ameh EA et al 2000). Klebsiella species was the leading organism among those with confirmed sepsis similar to a study in Nigeria which had the same

organism as the leading cause of sepsis (Ugwu RO et al 2013). This could be explained by the fact that in both studies participants were mostly neonates referred from peripheral health facilities with prolonged hospital stay thus having hospital acquired organisms as the leading cause of sepsis in these centers. The breech in skin barrier in other conditions like neural tube defects could lead to infections like meningitis during the hospital stay which may prolong the stay due to need of antibiotic use for treatment. Neonates with surgical conditions are also managed in the same unit as neonates with other medical conditions like neonatal sepsis and pneumonia thus a risk of cross infection.

In this study majority of neonates (51.3%) stayed NPO for more than 3 days with a range of 1-24 days showing the number of neonates who could have benefitted from TPN. Neonates who had respiratory distress in this study were 4 times more likely to die as opposed to those without respiratory distress; this could point towards the need to provide better respiratory support for these neonates. Poor outcomes in most developing countries have been associated to lack of supportive care like standard use of TPN and NICU services. Of the neonates who did not have surgical intervention during the study, about a half of them died before surgery or were too sick to withstand surgery. These poor outcomes could be attributed to the lack of NICU and proper ventilatory support for these neonates. This is reflected by 25% of participants who died before surgery and those who were too sick to withstand surgery that all died. There were no NICU services offered during this study. This is similar to a study in Nepal where poor outcomes were attributed to lack of NICU services (Shakya VC et al 2010). In another study in Durban despite NICU and TPN being both available poor outcomes were still attributed to late presentation to hospital thus an increase in complications (Sekabira J et al 2009). This was in contrast to the survey

done to compare outcomes in different centers where there was a huge difference in NICU availability with 100% availability in HICs, compared to 93% in MICs and only 36% in most LICs (Wright NJ et al 2015). This might explain the good outcomes with mortalities as low as <25% reported in HICs. TPN use has also been reported to be low in most developing countries at only 19% compared to 93% in MICS and HICs (Wright NJ et al 2015). This sharp contrast could however be explained by the fact that this was a questionnaire survey and thus it was not possible to ascertain the level of function of the reported facilities and if optimal care was offered in the centers reported to have NICUs.

There was an association to mortality in participants with a low platelet count, respiratory distress requiring CPAP or oxygen use and electrolyte imbalance in relation to poor outcomes, which is comparable to studies done in other centers which have shown that sepsis and multiple organ failure leading to respiratory distress and thrombocytopenia contribute more to mortality (Tarca E et al 2014; Arnold M et al 2010; P. Kuradusenge et al 2014).

The total length of hospital stay was 0-102 days with a median of 14.5 days which is in contrast to a study done in Nigeria who had a median of 10 days although this study was retrospective and involved participants with anterior abdominal wall defects mainly omphalocele major thus primary closure was done in most of them with a shorter hospital stay (Abdur-Rahman LO et al 2011). It is however in contrast to a study done at KNH with a median length of hospital stay at 10.2 days although both were cross sectional studies (Ajanja Samson et al 2015). The longer length of hospital stay in this study could be explained by the high number of neonates with gastroschisis who presented late thus had to undergo the staged closure causing prolonged hospital stay. There was an association between time to initiation of oral

feeds and length of stay. This could be explained by close to 50% of participants who stayed for more than 72 hours without enteral feeds who died thus showing a need to initiate appropriate feeding post operatively or the need for TPN to help in optimization of feeds following surgery. Presence of co-morbid conditions like neonatal sepsis and neonatal jaundice could also have contributed to the longer hospital stay. This is because presence of co-morbidities like neonatal sepsis may prolong the hospital stay since the recommendation for the treatment of confirmed sepsis requires antibiotic use for a minimum of 10-14 days. Presence of post surgical complication like wound sepsis and burst abdomen may also necessitate re-operation which may further interfere with duration of hospital stay. Majority of neonates also had anemia as the leading co-morbidity with delays in availability of blood products due to challenges at most blood transfusion centers. Anemia has been associated with poor wound healing and this could as well have prolonged the hospital stay.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

Gastroschisis, neural tube defects and anorectal malformations were the leading neonatal surgical conditions. The length of hospital stay in this study was long. The overall mortality was 31.5% with ANC attendance being associated with a low rate of mortality whereas sepsis and electrolyte imbalance were associated with increased mortality.

6.2 Recommendations

Effective management of sepsis and electrolyte imbalance will improve on outcomes and early initiation of appropriate feeding in the immediate post-operative period to shorten the length of hospital stay.

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APPENDICES

Appendix I: Consent Form

UNIQUE NUMBER: ……………..

TITLE OF STUDY: OUTCOMES OF NEONATES REQUIRING SURGICAL INTERVENTION AT NBU IN MTRH

Principal investigator: Dr Ikol Kasede

SM/PG/CHP/12/14

Registrar department of child health and pediatrics

BACKGROUND INFORMATION

You are being requested to participate in this study which aims to look at outcomes of neonates requiring surgical intervention at MTRH. By participating in this study you will help highlight issues that will help in the management of these neonates. 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. The length of stay to discharge and mortality will be assessed and outcomes on comorbid conditions. The conclusions and recommendations from this study will be used to improve care.

PURPOSE OF STUDY

The study will be looking at neonates who present to NBU who require surgical intervention and it aims to look at the outcomes in the neonates from the time the decision for surgery is made to the time of discharge, including any complications and death.

Procedure

After you understand what will be done and consent to the study, consecutive sampling will be used to recruit the participants according to exclusion and inclusion

criterion. 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 pertains the care of your child.

A structured questionnaire will be availed which will be interviewer administered for you to respond to once you consent to the study and all components in the questionnaire will be explained and interpreted word for word to the language best understood by the respondent without distortion.

No coercion or incentives will be used and no preferential treatment among the recruited participants.

Confidentiality

This will be upheld by use of unique code numbers on questionnaire and only the principal investigator and her research assistants will have access to the information. All data will be collected in full confidentiality and in private by the principal investigator and her research assistant and stored under lock and key. Data on the questionnaires will be de-identified and no information collected or recorded will be shared other than for research purposes for recommendations to stakeholders.

Benefits

This study will be done to mainly ascertain factors that determine the outcomes in neonates requiring surgical procedures in order to come up with recommendations that will improve the quality of care in the study population. There will be no direct benefit to the participants or incentives given.

Risks

There will be no direct risks involved to the participants for participating in this study. The participants will not be subjected to extra procedures in this study.

WILL TO WITHDRAW

You will be at will to withdraw from the study at will and at any given time with no consequences in relation to the standards of care and management given to the participants. There will be no consequences for choosing to withdraw from the study

and your child will still receive care at the unit as required without favor or being denied any treatment because of willful withdrawal.

Person to Contact

In case of any questions, complaints or concerns about this study, you can contact the principal investigator at Moi University, School of Medicine, department of Child Health and Paediatrics, Postgraduate programme; Dr. Ikol Kasede. Mobile number +254722451059   email ikolmourine@gmail.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

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.

Fomu Idhinisho

Idhini ya kushiriki katika utafiti

Nambari ya siri…………………

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

Mtafiti mkuu: daktari ikol kasede

SM/PGCHP/12/14

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 watoto ambao wamelazwa katika hospitali ya rufaa ya Eldoret,na shida aina tofauti zinazo hitaji upasuaji au operesheni huuendelea na 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 Ya Kufanya Utafiti

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 na 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. Rabari 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.

Madhara

Hakuna madhara 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:

Daktari Ikol Kasede

Nambari ya simu 0722451059

Barua pepe ikolmourine@gmail.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 II: Data Collection Tool

STRUCTURED QUESTIONNAIRE

STUDY SITE: MTRH ☐	**PATIENT INITIALS** ☐
APPROVAL NUMBER	**DATE OF DATA COLLECTION**
000147	**Dd / mm** ☐
UNIQUE NUMBER ☐☐☐☐☐☐	**I.P NUMBER** ☐

Maternal age

    1.<15years ☐

    2.15-24yeras ☐

    3. 25-34years ☐

    4. 35-44years ☐

    5. >44years ☐

Guardian incase mother deceased or in ICU

    6. Age ☐

    7. Relationship ………………..

Marital status

    8. Single ☐

    9. Married ☐

    10. Widowed ☐

    11. Separated ☐

    12. Divorced ☐

Place of delivery

    13. MTRH ☐

    14. Home ☐

    15. Referral from other facility ☐

State referring facility ……………….

Mode of delivery

    16. SVD ☐

    17. EMC/S ☐

    18. ELC/S ☐

    19. Breech ☐

    20. Assisted vaginal delivery ☐

ANC attendance

    21. >4 visits ☐

    22. 3-4 visits ☐

    23. 1-2 visits ☐

    24. None ☐

If yes above gestation at first visit

    25. <16 wks   ☐

    26. 16-24weeks   ☐

    27. 24-32weeks   ☐

    28. >32weeks   ☐

29. a) Were supplements issued

    Yes   ☐

    No   ☐

29. b) If yes above state which ones

    Folate   ☐

    Hematinics   ☐

    Calcium   ☐

    Others specify…………………………………………………………………..

30. Maternal HIV status

    a) Positive   ☐

    b) Negative   ☐

    c) Not known   ☐

31. a) Any ultrasound done during pregnancy

    Yes   ☐

    No   ☐

    Don't know   ☐

If yes above

32. Polyhydramnios

    Yes   ☐

    No   ☐

    Don't know   ☐

33.a) Congenital defects

    Yes   ☐

    No   ☐

    b) If yes above state which ones

      Neural tube defects   ☐

      Anterior abdominal wall defects   ☐

      Don't know   ☐

      Others. Specify …………………………..

                                              ☐☐   ☐☐☐ ☐☐☐☐

34. Day and date of birth

dd   mm/

year

35. Time, day and date of admission ☐☐ ☐☐☐ ☐☐☐☐ ☐☐☐

Dd   mm   year

hrs mins

Birth weight

36. >3.9kgs   ☐

37. 2.5-3.9kgs   ☐

38. 1.5-2.4kgs   ☐

39. 1.0-1.4kgs   ☐

40. Less than 1 kg   ☐

41. Gender

Male   ☐

Female   ☐

42. Date and time surgery indicated ☐☐ ☐☐☐ ☐☐☐☐ ☐☐☐☐

Dd   mm   year   Hrs

Mins

43. Date and time surgery done ☐☐ ☐☐☐ ☐☐☐☐ ☐☐☐

Dd   mm   year

hrs mins

Type of surgery done

44. Elective   ☐

45. Emergency   ☐

Diagnosis at presentation

46. Anterior abdominal wall defect ☐

47. ARM   ☐

48. Inguinal hernia   ☐

49. Small gut atresia   ☐

50. Spinal defects   ☐

51. Hydrocephalus   ☐

52. Intussusception ☐

53. Cystic hygroma ☐

54. Intestinal obstruction ☐

55. Others- specify……………………..

Investigations

	Dd	mm	yrs

56. Hemoglobin (g/dl) ☐☐☐   ☐☐   ☐☐☐   ☐☐

57. Platelets $\times 10^9$/L ☐☐☐   ☐☐   ☐☐☐   ☐☐

58. Random blood glucose mmol/L ☐☐   ☐☐   ☐☐☐   ☐☐

59. Potasium mmol/L ☐☐   ☐☐   ☐☐☐   ☐☐

60. Creatinine ųmol/L ☐☐☐   ☐☐   ☐☐   ☐☐

61. Blood culture ☐

If culture positive state organism isolated ………….

62. Intra operative diagnosis

63. a) Intervention

    Surgery ☐

    No surgery ☐

    b) If no surgery, Reasons why………………………………

Other problems noted

64. Respiratory distress (RDS) ☐

65. Suspected or confirmed sepsis ☐

66. Anemia ☐

67. Neonatal jaundice ☐

68. NEC ☐

69. Low platelets ☐

70. Electrolyte imbalance ☐

71. Birth asphyxia ☐

72. Others- specify …………….

Mode of feeding post op

73. EBM/Breastfeeding ☐

74. Formula ☐

75. TPN ☐

76. NPO ☐

77. If NPO state number of days   ……………

 Complications from surgery

78. Burst abdomen   ☐

79. Perforation   ☐

80. Intubation problems   ☐

81. Bleeding   ☐

82. Wound Sepsis   ☐

 Other procedures

83. Transfusions   ☐

84. Phototherapy   ☐

85. Oxygen   ☐

86. CPAP   ☐

87. Others-specify   ………….

Outcome

88. Discharge   ☐

89. Mortality   ☐

90. Transfer/referral   ☐

Form completed by   Signature………………………………

Date: …………………………….

Principal investigator   Signature………………………………

Date: …………………………….

Appendix III: Diagnostic Follow up Form

1. **NEONATAL SEPSIS**

   a) Proven sepsis

   Positive growth of microorganisms known to cause sepsis in neonates through blood, urine, CSF or pus swab cultures with features of systemic inflammatory response following suspicion of sepsis.

   b) Suspected sepsis

   Presence of at least two of the following in a neonate suspected to have sepsis;
   - ✓ Temperature instability: hypothermia or hyperthermia
   - ✓ Respiratory dysfunction
       Tachypnea - respiratory rate more than 70breaths/minute
       Hypoxemia - $PaO_2 < 70$ mmHg on room air
   - ✓ Cardiac dysfunction
       Tachycardia- heart rate>160beats/minute
       Delayed capillary refill>3 sec
       Hypotension
   - ✓ Altered consciousness

2. **RESPIRATORY DISTRESS SYNDROME**

   Tachypnea- respiratory rate >70 breaths per minute with onset within 24 hours of delivery.

    Features of respiratory distress- with flaring of ala nasae, intercostal recession, subcostal recession and grunting. The distress worsens over 72hours post-delivery and gets better afterwards.

3. **ANAEMIA**

   Hemoglobin level less than12g/dl from a complete blood count or heel prick sample.

4. THROMBOCYTOPENIA

Platelet count of less than $50*10^9$/L

5. JAUNDICE

Yellow discoloration of skin and mucus membranes on clinical examination.

Elevated serum bilirubin levels more than 2mg/dl.

6. APNEIC ATTACKS

Presence of either of these:

a) Cessation of spontaneous breathing for more than 20 seconds.

b) Cessation of breathing for 10seconds accompanied by cyanosis and

bradycardia.

7. NECROTIZING ENTEROCOLITIS

Presence of the following features;

Feeding intolerance determined by vomiting or gastric aspirates more than 20% of

previous feed.

Abdominal distension.

Grossly bloody stools or changes in stool character.

8. BIRTH ASPHYXIA

Apgar score less than 3 at 5 minutes accompanied by neurological changes which

may include; convulsions, abnormal posturing, hypertonia, hypotonia or coma.

9. HYPOGLYCEMIA

Random blood sugar of less than 2.5mmol/l

Appendix IV: Human Resource

The team comprised of the principal investigator and the following personnel:

PERSONNEL	STATION
2 Supervisors	Department of Child Health and Pediatrics and Department of Surgery Moi University, School of Medicine
1 Biostatistician	Moi University, School of Public Health, Department of Epidemiology and Preventive Medicine.
1 research assistant	Nursing officer New born unit at RMBH

The Supervisors worked closely with the principal investigator to ensure success of the study.

The Biostatistician was consulted during the whole process from proposal writing to data analysis and presentation.

The research assistant was recruited and trained to aid in data collection, entry and proper record keeping.

Appendix V: IREC Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

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

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

Reference IREC/2015/135
Approval Number: 0001475

23rd February, 2016

Dr. Ikol Mourine Kasede,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Kasede,

RE: APPROVAL OF AMENDMENT

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

"Outcomes of Neonates Requiring Surgical Intervention at Moi Teaching and Referral Hospital".

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

1. To restructure the questionnaire to be more specific on the section of ultrasound findings and use of supplement during pregnancy.
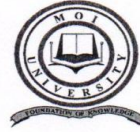
The amendment has been approved on 23rd February, 2016 according to SOP's of IREC. You are therefore permitted to continue with your research.

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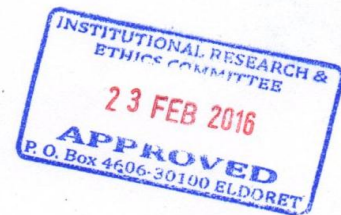
Sincerely,

PROF. E. WERE
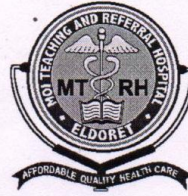**CHAIRMAN**
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

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

Appendix VI: MTRH Approval

MOI TEACHING AND REFERRAL HOSPITAL

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

P. O. Box 3
ELDORET

27th August, 2015

Dr. Ikol Mourine Kasede,
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:-

"Outcomes of Neonates Requiring Surgical Intervention at Moi Teaching and Referral Hospital".

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

DR. JOHN KIBOSIA
DIRECTOR
MOI TEACHING AND REFERRAL HOSPITAL

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