UNIVERSITY OF NAIROBI

ASSESSMENT OF THE NEONATAL REFERRAL AND TRANSPORT SYSTEM FOR PATIENTS WITH GASTROSCHISIS REFFERED TO KENYATTA NATIONAL HOSPITAL

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STUDENT DECLARATION

I, Dr. Hetal Rajnikant Gohil, declare that this thesis for a dissertation is my original work and has not been presented for a degree in any other institution to the best of my knowledge.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

BP – Blood Pressure

CRT – Capillary Refill Time

HR – Heart Rate

KNH- Kenyatta National Hospital

NGT – Naso-gastric Tube

PSU – Paediatric Surgical Unit

RBS – Random Blood Sugar

RR - respiratory rate

DEFINITION OF TERMS

Bellwether procedure - A procedure which needs to be performed within two hours of injury or diagnosis. It is the first global surgical indicator that is used to measure surgical care delivery and monitor progress, by the Lancet Commission on Global Surgery. Examples of bellwether procedures include laparotomy, open fracture management and caeserian section in adults.

Gastroschisis – A birth defect in which the baby's intestines extend outside of the abdomen through a hole at the umbilical region. The size of the hole is variable, and other organs including the stomach and liver may also appear to lie outside the baby's body.

Primary intervention – Management of eviscerated bowel by placement of a silo bag by the bedside or under anesthesia, or by doing a surgical primary closure of the anterior abdominal wall defect under anesthesia.

Primary closure – A method of treatment of gastroschisis where the abdominal defect is closed by apposing tissues. Surgical wound closure facilitates the biological event of healing by joining the wound edges. Surgical wound closure directly apposes the tissue layers, which serves to minimize new tissue formation within the wound. However, remodeling of the wound does occur, and tensile strength is achieved between the newly apposed edges.

ABSTRACT

Background: Gastroschisis is a surgical condition where the bowel eviscerates through an anterior abdominal wall defect. This is a source of major heat and fluid loss and infection in the neonate. Patients with gastroschisis born within a tertiary level hospital with specialty

services available have better outcomes as compared to those who are born outside such a hospital. Birth outside a tertiary level facility confers serious challenges in pretransit and intra-transit care with resultant morbidity and mortality.

Objective: The main objective of this study was to assess the neonatal referral and transport system for patients with gastroschisis referred to KNH.

Materials and Methods: A prospective cross-sectional study design was used. Using consecutive sampling approach, patients received at Kenyatta Nation Hospital (KNH) pediatrics surgery unit(PSU) after referral from peripheral facilities were recruited. Data were collected on referring hospital factors, pre- and intra- transit factors, time and distance covered. Assessment of the neonatal referral and transport system for patients with gastroschisis referred to KNH was done using pre and intra transit factors as per the standard transport protocols in literature.

Stata 16.0 was used for data analysis. Descriptive statistics such as percentages, means, mode and medians were used to describe the characteristics of study participants. Data were presented in pie charts, bar graphs, frequency tables and written reports.

Results: Twenty-nine patients presented with gastroschisis during the study period. Mean age was 7.07 hours range 3 – 18 hours. There were 16 (55.2%) males and 13 (44.8%) females. Mean birthweight was 2019.8 grams, and a mean gestational age of 36.5 weeks. Mean duration of transit was 5 hours, median 5 hours and a range of 1 – 9 hours. Mean distance from referring facility to tertiary facility was 153.1 km, range 19 – 348.

Out of 10 pre-transit factors assessed, 27.6% of patients scored 7, 48.3% scored 6, 17.2% scored 5 and 6.9% of patients scored 4. Most affected factors in the pre-transit protocol

were lack of monitoring chart (0%) and comment on blood investigations (0%), gastric decompression (3.4%), prenatal obstetric scan (44.8%). Only 2/13 cases with gastroschisis were picked by the prenatal ultrasound.

For intratransit scores, out of 14 parameters, 9 were only in 6.9%, 8 in 17.2%, 7 in 20.7%, 6 in 24.1% and 5 in 31%. Most affected were incubator use (0), pulse oximetry (31%), thermometer (55.2%), blood pressure monitor (44.8%), neonatal resuscitation training (58.6%), functioning nasogastric tube (13.8%), bowel monitoring (0%), adequate bowel cover (34.5%), parent content (48.3%).

Conclusion: This study demonstrates that pretransit and transit care of neonates with gastroschisis is grossly inadequate. Interventions to promote care of neonates with gastroschisis are advised to reduce mortality. Such interventions would target areas of need as identified by this study.

CHAPTER ONE

1.0 INTRODUCTION

Gastroschisis is a congenital abdominal wall defect through which intraabdominal organs herniate and it requires surgical intervention soon after birth(1).

It has been proposed that gastroschisis be used as a bellwether to measure the capacity of a health institution to deliver a package of neonatal surgical care, because there are usually no associated co-morbidities but the condition tests the key elements that are involved in the successful management of any newborn with a surgical condition(2). It poses serious pathophysiological challenges that negatively affect outcome if timely and appropriate intervention is not given.

There are a number of factors that affect outcomes for this condition, for example, gestational age, type of gastroschisis, birth weight among others. The neonatal transport factor is just one of them. Compared to neonates born within the tertiary hospital or those born after maternal transfer, neonates who require acute postnatal transport have higher risk of morbidities such as glucose abnormalities, hypoxemia, intra-ventricular hemorrhage and death. Several factors have been associated with adverse neonatal outcomes after transport, including the condition of a neonate around the time of transport and lack of intensive care during transport(5). Duration of transport may also affect outcomes(6).

Instructions on appropriate initial care and transport of these neonates who are at high-risk should be given to surgical neonatal care providers. Provision of highest quality of service by those involved in emergency transfer is important.

Excellent communication between the referring hospital, the operational team, and their receiving PSU is required for inter-hospital patient transfers. This communication starts with the initial telephone call and ends after the patient is admitted to the receiving PSU(5).

The aim of this study, therefore, is to assess the referral and transport practice for neonates with gastroschisis referred to KNH. The results of this study can help towards formulation of a neonatal transport protocol for gastroschisis patients at our facility.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Definition

The International Clearing house for Birth Defects Surveillance and Research defines gastroschisis as “a congenital malformation characterized by visceral herniation usually through a right side abdominal wall defect to an intact umbilical cord and not covered by a membrane” (7–11). About 10% of neonates with gastroschisis have intestinal stenosis or atresia(1) resulting from compromise of blood supply due to a volvulus or compression of vascular pedicle by a narrowing abdominal wall defect(11)

2.2 Pathogenesis

A list of hypotheses has been proposed to explain the embryologic pathogenesis of gastroschisis. Some of these include a failure of differentiation of the embryonal mesenchyme due to a teratogen (12), rupture of the amniotic membrane around the umbilical cord, involution of the right umbilical vein leading to impaired viability of surrounding mesenchyme, interruption of the omphalomesenteric artery leading to necrosis of the abdominal wall at the base of the cord, failure of the yolk sac and related vitelline structures to be incorporated into the umbilical stalk leading to a perforation in the abdominal wall separate from the umbilicus, and abnormal folding of the embryo leading to a ventral body wall defect(13).

More recently, a model whose evidence is lacking to be occurring in humans has been proposed. It is explained as the normal involution of the umbilical vein creating a potential

site for thrombosis adjacent to the umbilical ring. This thrombosis, associated with factors increasing maternal estrogen levels, is known to weaken the umbilical ring, thereby forming a site for potential herniation. This can explain the morphology (location at the umbilical ring and right-sidedness) as well the epidemiologic risk factors (rising incidence due to increasing environmental contamination with estrogen disruptors).

Recent human evidence supports the theory that gastroschisis is not a defect of the abdominal wall, but an abnormality of the rudimentary umbilical ring, resulting in a separation of the fetal ectoderm from the amnion's epithelium on the right side(11).

2.3 Epidemiology

Gastroschisis is increasing worldwide for unidentifiable reasons. In the past thirty years, there has been a steady rise in incidence to a recent estimate of 1 in 2,000–4,000 live births(2,7,11). With an estimated 32 million births per year in sub-Saharan Africa (SSA), an expected 16 000 neonates with gastroschisis are born in the region yearly(14). A report from South Africa put gastroschisis at 15% of neonatal surgery admissions and another single center report from Ethiopia calculates that abdominal wall defects made up 1.3% of all pediatric surgery conditions (10). At Kenyatta National Hospital we see, on average, 30 – 40 cases per year. Management has remained a challenge in the low and middle-income countries (LMICS), with reported mortality rates ranging between 33 and 100%, whereas survival rates in high-income countries are above 95%(15).

2.4 Neonatal Transport For Gastroschisis Patients

Standardised care protocols of neonates with gastroschisis between perinatal centres and paediatric surgical centres encompass, but not limited to, time, distance, pretransit and transit factors such as:

Pretransit Factors:

- Management of the eviscerated abdominal contents
- Fluid management during stabilization
- Bowel decompression
- Infection prevention measures
- Interfacility communication systems

Transit Factors:

- Approach to fluid management and monitoring of physiology in the on-going preoperative phase prior to arrival at surgical centre
- Appropriate transport medium
- Skills of accompanying medical personnel
- Appropriate documentation

2.4.1 Transfer Time And Distance

Time between key periods of neonatal transport are divided into clinically relevant intervals. These included: time from birth to when the referral call was made, time from the referral call to admission acceptance by the accepting PSU, time from admission acceptance to departure of the transport team, time from departure of the transport team to arrival at the referring facility, time from start of evaluation by the transport team to admission at the accepting PSU. Total time of transport is calculated from time of referral to admission at the accepting PSU(6).

The "three delays" model by Thaddeus and Maine (1994) describes a conceptual framework for the factors and phases of delay that govern the timely accessibility of care in obstetric emergencies and eventually contribute to maternal deaths. The model has been utilized for analysis of obstetric referral interventions, perinatal deaths, and neonatal deaths by many studies. For this study as well, this conceptual framework for the phases of delay that affect transport and the timely arrival to specialty neonatal care has been adapted. Critical delays, which are a major contributing factor to neonatal mortality, include:

I. delay in deciding to seek care for reasons such as cultural and socioeconomic factors,

II. delay in reaching an appropriate medical facility, and

III. delay in receiving adequate care on reaching an appropriate medical facility due to poorly equipped, staffed, and managed facilities.

For this study, the parameters that are examined will include Phase I and II delays. The issues confronted in Phase I include the process of seeking care and the processes involved in the preparation of transfer of the patient; and those issues confronted in Phase II include the ability to access an appropriate health facility, the time taken to reach that appropriate health facility, and the morbidity or mortality associated with reaching that health facility.

A better prognosis has been described for shorter birth-to-surgery interval. It has been shown that immediate gastroschisis repair in the delivery room increases the rate of primary closure and facilitates early extubation and feeding, and therefore, reduces duration of hospital stay. There is also literature suggesting that a silo should be placed or surgery performed within twelve hours of delivery, with mortality doubling every hour thereafter

(7). A retrospective study in Japan and another systemic review of neonatal transports documented that inter-facility transport longer than one hour is associated with a higher risk of neonatal death compared to transports of shorter duration(6,16). A prospective study done on twenty four cases over a fifteen month period in Egypt showed that the median transfer time of a gastroschisis patient was 8 (1.5–35) hours, and 64% survived if transferred before 8 hours. Only 25% had antenatal scans in that study(9). Their recommendation was that of the need of more efficient referral networks to reduce the transfer time to less than 8 hours and better antenatal detection.

In Uganda, Wesonga et al recorded that a significant proportion of babies (58%) arrived at Mulago Hospital within 12 hours of birth, however 52% were breastfeeding instead of being nil per oral, 53% did not have intravenous access and only 19% had adequate bowel

protection in place. Four patients (9%) arrived with gangrenous bowel. Nonetheless, despite delays in accessing health care, abnormal serum chemistries was seen in only 25% of babies (7).

In a tertiary hospital in Thailand, an 11-year review on infectious complications in gastroschisis patients who were referred from peripheral facilities showed the average time used for patient transfer to their institute was 6.92 hours (range, 1-36 hours). Metabolic derangement was detected on arrival in 15 (26.8%) of 56 referred patients; mainly severe metabolic acidosis (4 cases), hyperglycemia (4 cases), and hypoglycemia (4 cases). (17,18)

In a study done in South Africa, 91% of babies required transportation over distances from 7 to 300 kilometres because of being born outside the tertiary center.

In a study by Mori et al(16) the neonates who were transported for more than ninety minutes had a risk more than twice normal of death, and a recommendation of transporting the patient by air if estimated transport duration was more than 2 hours, was made.

2.4.2 Pretransit Protocol

Newborns with gastroschisis require emergent surgical intervention, which necessitates treatment in a tertiary care hospital with pediatric surgical services. Gastroschisis is usually diagnosed by ultrasound during the second trimester anomaly scan, at about twenty weeks gestational age(19). In order to eliminate the dangers of transporting these fragile newborns, the need for in-hospital delivery or emergent neonatal transfer is highlighted by the importance of prenatal diagnosis in helping locate and plan perinatal care (7,14,20–22).

In Uganda, Wesonga et al followed up all babies with gastroschisis over a one year period in Mulago Hospital, Kampala and found that thirty-nine mothers (93%) had prenatal care,

but only ten (24%) received a prenatal ultrasound. Of these, only two had an anterior abdominal wall defect diagnosed, and one was wrongly diagnosed with omphalocele.

Therefore, only 2% of mothers received a correct prenatal diagnosis of gastroschisis, which is almost negligible. A majority of the cases in high-income countries are prenatally diagnosed using maternal serum alpha-fetoprotein measurement and mid-trimester ultrasound, which facilitates planned delivery in a center equipped with pediatric surgical care. The low rates of antenatal diagnosis in their study, as well as a lack of adequate referral centres for pediatric surgery, are a major barrier to planning timely, specialized postnatal care required for these children(7).

The protocols available include a national pretransit/postnatal management guidelines for transport of gastroschisis patients in Ireland, which were published recently, another one from Seattle Children's Hospital and also from Children's Hospital of Orange County in the USA. For the relevance of this study the Irish guidelines are summarized as shown below(5):

Birth Suite

- Cut the umbilical cord at least 10 - 30cm from the baby to preserve the option of sutureless umbilical closure after tying with a suture instead of a clamp.
- Prepare as any anticipated high risk birth
- Manage airway, breathing and circulation and administer vitamin K
- Once the cardio-respiratory status has been stabilized, inspect the bowel and correct any twists on its pedicle or discoloration due to ischaemia
- Position the bowel over the abdomen and wrap in cling film.

Bowel decompression:

- Insert a large bore 10Fr for full term infant or 8Fr for preterm infant or LBW infant less than 2500g nasogastric/orogastric tube and aspirate the stomach
- Allow gastric tube on free drainage and aspirate frequently to prevent gastric distension, which could cause compression of the small bowel mesentery and subsequent bowel ischaemia
- Ensure adequate thermal control

Management of Exposed Bowel

- Following assessment, the exposed bowel should be wrapped with cling film to minimize fluid and heat loss and for protection
- Place cling film under the baby's buttocks and back
- Place exposed organs on baby's abdomen
- Wrap cling film around the abdomen and exposed organs gently
- **DO NOT** cover bowel with saline soaked gauze, the bowel must be visible through cling film
- Ensure bowel edges are not exposed to air
- Do not compress bowel, it should remain mobile but protected
- Monitor the bowel every fifteen minutes for dusky or blanching colour changes during pretransit and transit period
- Remove and rewrap as above if compression, kinking or twisting is suspected

- Any concerns regarding bowel position, colour or viability, seek senior medical advice or paediatric surgical review early
- Prevent occlusion of the blood supply where the bowel exits the defect in the abdominal wall by supporting the intestines.
- Where possible nurse a neonate on their right side as defect usually to right of umbilicus, with the wrapped bowel supported perpendicular to the umbilicus.

Fluids and Intravenous access

- Insensible losses will expectedly be high
- Initiate maintenance fluid 10% dextrose at 80mls-100mls/kg/day to maintain blood glucose >3mmol/l.
- Establish vascular access – ideally 2 peripheral IV cannulas (one to give maintenance fluids and one to give fluid boluses/antibiotics etc). Take blood cultures, FBC and glucose when IV inserted
- Administer a 20ml/kg fluid bolus of normal saline within an hour of birth.
- Monitor infant regularly for evidence of fluid depletion (as above) and replace with additional boluses of 10mls/kg of 0.9% saline
- Maintain a fluid balance record for all infants, which includes gastric losses
- Monitor central and peripheral capillary refill time every 15 minutes along with heart rate and blood pressure to help guide fluid management (see below). This monitoring should be continued during transit every 15minutes and charted by the transport team.
- Signs of fluid depletion include:

I. Prolonged capillary refill time

II. Tachycardia

III. Hypotension

Antibiotics administration

- Intravenous benzylpenicillin, gentamicin and metronidazole. Dose is not specified in the protocols.

Communication

Communication to the receiving facility by the referral facility prior to transport is essential. Information on availability of bed space, clinical status of the child, and estimated time of departure should be exchanged during this communication.

A direct line (not through the hospital switchboard) or "hotline" connecting to the Paediatric Surgical Unit that is assigned to incoming calls and also open to outgoing calls will make conversations between consultants considerably easier and more effective. The number should be advertised widely in the catchment area.

The family of a sick neonate needs relevant information and reassurance, without misconstrued optimism.

Their child is being taken from them in an ambulance to a possibly remote place, which they might never have visited before. A statement of reassurance to the effect that the child is very sick but stable and that the transport team has been undertaking transfers

successfully will provide great comfort. Families have admitted that they felt that once the child left it was sure to die. They need to be told that risk is present but it is small.

The Paediatric Surgical unit must provide feedback about stabilization so as to enlighten the referring institute personnel.

The transport team from referring hospital, will:

- treat the referral as time sensitive,
- leave the gastroschisis undisturbed and wrapped after ensuring it is well supported and the bowel has remained well perfused,
- continue fluid management regime

2.4.3 Transit Protocols (Principles Of Safe Transport)

Surgical neonates have special requirements and they need to be transferred in specially equipped vehicles and by adequately trained personnel. Gastroschisis patients are at higher risk for perioperative hypothermia due to exposed viscera, poor thermoregulation in neonates, and excessive heat loss.

Safe inter-hospital transfer principles are outlined here under the following headings as per the recommendations by the Pan-American Health Organization(23,24):

• Team composition

The operational team is the nurse, paramedic, medic and pilot or driver carrying out an interhospital patient transfer. If a child requires only basic care it is possible that a nurse,

without a medic, may accompany him or her. Critically ill patients require a transport team of a minimum of two personnel, both adequately experienced and accompanied by the ambulance, helicopter or airplane staff. The team leader will usually be a doctor, although advanced neonatal nurse practitioners (ANNPs) are increasingly leading neonatal transports. Personnel are the most valuable component of a transport team both in the performance of the service and it's organization.

• **Mode of transport and equipment**

Three options are available for interhospital patient transfers. The patient may be:

• sent via the local emergency services;

•sent via the local (referring) emergency medical services i.e. via ambulance with the referring physician and/or nurse;

•fetched by a specialised critical care transport team.

Paediatric patients are often "held" waiting for the transport team to arrive in facilities designed for adults. These may have limited paediatric supplies. The American Critical Care Society lists the equipment required in transport. Reference to this list can form the basis of a transport service's checklist.

The equipment needed during transport of a critically ill child:

I. Patient movement

- Trolley
- Metal pole or shelf system to secure ventilator, pumps, monitors
- Incubator for child < 5 kilograms
- Adjustable belts (safety belts) to secure patient in transfer
- Equipment bags: multiple compartments to allow access to individual items
- Box for drugs

II. Airway management

a. Equipment to establish and maintain a secure airway like bag-valve device with selected mask sizes, endotracheal tubes, stylet and Magill forceps, laryngoscope with assorted size blade

b. Portable mechanical ventilator small, lightweight with economical gas usage capable of ventilating infants and children of all ages. Portable oxygen supply provide high pressure supply with low pressure metred flow sufficient to last duration of transfer with reserve, usually 1–2 hours

c. Suction—portable, battery powered

III. Intravenous infusions - Equipment to establish and maintain venous and arterial access

a. Drugs - resuscitation drugs, infusions of sedating and paralysing agents (for ventilated patients) inotropic infusions

b. Infusion pumps – small, light weight, long battery life

Monitoring – Portable, battery powered machine for monitoring cardiac activity, pulse oximetry, non-invasive blood pressure, temperature, capnography.

IV. Document folder

a. Recording chart, audit form, consent form

b. Infusion charts and crash drug charts—filled in prior to transfer

c. Information for parents, i.e. maps and telephone number

• Documentation

A concise written clinical record is important with any patient treatment, but possibly more important during interhospital patient transfers as these are patients who are usually critically ill and who in addition, for the duration of the transfer, are not managed in an optimal environment. Important features of this transport documentation are:

I. Demographic data

a. Patient: name

b. Date of birth

c. Sex

d. Weight (*very important for drug calculations*)

II. Referring institute: Referring physician, Contact telephone number, referring hospital and ward or unit where patient was located

III. Operational data:

a. Staff member receiving call

b. Times:

of receiving call of arrival at

referring hospital of departure

from referring hospital

of arrival at Paediatric surgical unit at receiving hospital

IV. Clinical data

a. Predeparture: provisional diagnosis, reason for transfer, request initial vital signs and pertinent physical findings, relevant laboratory results, for example random blood sugar, treatment given, for example, infusions, antibiotics recommendations given.

b. Assessment on arrival at referring hospital: clinical findings by transport team, including treatment, for example, intravenous fluids.

c. In transit: vital signs (monitoring) during transfer, medication administered by transport team problems encountered and treatment given.

V. Checklists

a. For referring hospital

b. Predeparture (*focuses on equipment needed*)

c. Prereturn (*focuses on patient care*)

• Monitoring a patient.

Before transport all patients must have a stable airway, adequate ventilation, and vascular access.

If any of these is recognised to be deficient at the initial call, the referring hospital has to have the capability of intervention: the basics of airway maintenance, ventilation, and vascular access should be available at all facilities that provide care to children. Other

interventions such as drug therapy (for example, antibiotics, anticonvulsants, sedation) and tube placement (for example, urinary catheter, nasogastric tubes under free drainage) could be advised.

When the transport team arrive, their priorities are:

a. A rapid assessment of the patient, focusing on Airway, Breathing, and Circulation
b. To receive current information from the referring team
c. To review blood tests
d. To secure all lines and tubes before loading the patient.
e. To maintain temperature control.
f. There is no advice or guidance on whether the parent/guardian should accompany the baby or not, so practices of transport teams are based on personal biases and experience as well as practical considerations.
g. Continuous stabilization
h. Careful and continuous assessment
i. Monitoring and recording throughout
j. Consideration for staff and parents

Monitoring of body temperature, oxygen saturation, blood pressure and heart rate should be done every fifteen minutes. WHO definition for hypoxia is an Spo2<90%; poor perfusion is Capillary Refill Time>3 sec, and hypoglycemia is when random blood sugar is <47 mg/dl(2.6mmol/l). Heart rate of < 110 (bradycardia) or >160 (tachycardia) beats per min, and

respiratory rate of <30 (bradypnea) or >60 (tachypnea) breaths per min or moderate to severe hypothermia (temperature 34–35.5 _C) is considered abnormal(25).

Temperature regulation is more likely to be a major part of the transfer process if the patient is smaller. A small child has a higher ratio of surface area to body mass, which results in rapid heat loss. Heat loss increases oxygen consumption by increasing the metabolic rate. This can lead to hypoxia and lactic acidosis. Poor post-transfer temperature is a better predictor of death in premature infants than birthweight or gestation. Loss of temperature can occur:

- With movement from one environment to another
- during procedures
- with exposure for evaluation and management
- with the initial event, i.e. severe illness,

Standard warming devices should be available at the referring hospital:

- Infants:
  - Covering the head
  - Incubator for infants weighing less than 5 kilograms(26)
  - Warming mattress

As temperature control by incubator during transport is not available in resource limited settings kangaroo mother care used by attendant or mother is an alternative way to regulate temperature along with other local alternative methods like plastic wrap or thermacol boxes (26). According to WHO classification of hypothermia, the newborn with a body temperature of 36 – 36.4C has mild hypothermia; with a temperature of 32–35.9C has

moderate hypothermia while a temperature below 32C is severe hypothermia. Mild hypothermia has been considered as a cause for concern. Moderate hypothermia has been associated with danger to the neonate and warming the neonate is recommended. Severe hypothermia has been associated with adverse outcomes requiring urgent skilled care.

Most acute transfers occur during the first twenty-four hours after delivery, the mother is often still recovering or may still be affected by general anaesthesia. Sufficient time, however, should be spent with the parents or caregivers before leaving the referring hospital. The reasons for transfer should be explained and the team members must be introduced. The parents' coping mechanism can be of disbelief, aggressive outburst, or complete withdrawal, but the team must respond with calm reassurance to reduce parental anxiety(24).

Financial constraints and visiting problems can add to the emotional problems of guilt, grief, and shock that many parents go through after birth of a baby with gastroschisis. This can also seriously hinder their bonding with the baby(24).

Fourteen retrospective and prospective studies examined the physiologic state during transport and identified the modifiable risk factors associated with clinical deterioration and mortality or differential outcomes between inborn and outborn (transported) neonate. Eleven of the studies identified hypothermia as a factor strongly associated with deterioration or mortality (Buch 2012, Goldsmit 2012, Lucas da Silva 2012, Mathur 2005, Mathur 2007, Sehgal 2001, Silveira 2003, Singh 1996, Vieira 2011). Other risk factors associated with bad outcomes included hypoglycemia, hyperthermia, poor perfusion and length of transport time.

In India, a retrospective study by Poddutoor Preetham Kumar et. al (2008) compared the inter hospital long distance transports undertaken by a qualified transport team versus those done by other means. It was a retrospective descriptive study of the neonatal transports done during

a period of thirty three months from various maternity and pediatric centers to a pediatric tertiary referral centre. The results showed that temperature and biochemical abnormalities are more common in babies transported on their own and a specialized neonatal transport service could improve the survival of these babies. Babies who were transported in adequately equipped transport vehicles had lesser incidence of hypoxia, apnea, hyperglycemia, hypoglycemia, hyperthermia or hypothermia on admission. In a study in India, by Singh et al, in babies who were transported on their own by road had 26% mortality as compared to this study by Kumar PP et al where, under the care of specialized neonatal transport team, the overall mortality was 5.3%(27). In another cross sectional study in India, by Sehgal et al, a longer time of transport contributed to mortality in transported neonates and was considered an independent risk factor.

At a tertiary centre in Ahmadabad, India, Ekta Dalal et al's study recorded only one out of all transported newborns (n=300) was referred with kangaroo mother care on the way though majority of newborns were covered with more than one layer of clothes. Hypothermia was significantly seen in transported newborns. 47.3% were transported in ambulance, 33% in auto rickshaw, 18.3% in open vehicle; 55.7% were accompanied by untrained relatives, 15% by doctor or nurse, 28% by paramedic; pretransport stabilization done only in 37.6%, referral hospital informed prior to transport only in 28%. (26)

A Ugandan prospective study (Wesonga et al) recorded that of the babies (n=42) with gastroschisis who were transported to Mulago hospital, only 35% were transported by ambulance. Many mothers came on motorbikes, which can predispose the newborn to severe hypothermia and increase the risk of injury to the exposed bowel. Even the babies brought

by ambulance often did not have nasogastric decompression, intravenous access, bowel protection, or skilled health attendant(7).

2.5 Statement Of The Problem

Gastroschisis has poorer outcomes in developing countries as compared to the developed countries. The transport of newborns with gastroschisis is rarely considered a vital component of regionalized perinatal care in Kenya and maybe inefficient. Prenatal diagnosis of this condition has been a challenge and this has led to poor planning of delivery at a facility equipped with optimum equipment and skill-set.

It is crucial to identify which newborns are likely to deteriorate during transport so that the team transporting can prepare and respond appropriately. In addition, understanding the association of transport time intervals with deterioration during transport provides information on the quality of the neonatal transport process and may lead to opportunities for improvement.

This study will help to identify the transport time intervals and transport characteristics that are associated with increased risk of clinical deterioration during transport. It will also help in finding solutions like improving access to timely and better primary health care, or increasing the number of specialists in peripheral facilities so that there is no delay in management of this group of patients.

2.6 Study Justification

In gastroschisis, the eviscerated intestine is a source of major fluid and heat loss and infection. These newborns can be safely transferred between health facilities, over long

distances, provided some essential criteria are met. In spite of the availability of access to the neonatal surgical units, a poor survival outcome of these transferred newborn infants remains; firstly, because of possible complications that may develop during transportation, and secondly because of lack of knowledge of protocols for safe transfer. Although it has been shown that certain clinical features are associated with adverse events after transport, not much is known about factors that cause clinical deterioration during transport.

The goal of this study is to identify the level of implementation with various management protocols involved in transit of patient including transport characteristics and duration of transport as these factors are known to be associated with increased risk of deterioration during transport. It is important to understand the level of implementation of these protocols during transport of these patients to mitigate on risk of clinical deterioration. In addition, understanding the effect of transport time intervals on outcomes during transport provides information on the quality of the neonatal transport process and may lead to better opportunity for improvement.

2.7 Study Question

What is the level of implementation of neonatal transport protocol for patients with gastroschisis referred to KNH?

2.8 Study Objective

Broad Objectives

To assess the implementation of neonatal transport protocol for patients with gastroschisis referred to KNH.

Specific objectives

i. To determine the transfer time and distance covered for neonates with gastroschisis referred to KNH

ii. To assess the level of implementation of pre-transit protocol for neonates with gastroschisis referred to KNH iii. To assess the implementation of inter-transit protocol for neonates with gastroschisis referred to KNH

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study Design

This was a cross-sectional descriptive study where implementation of pretransit and intratransit protocols were assessed including the individual components at the time of encounter with the patient.

3.2 Study Site

This study was carried out at Kenyatta National Hospital's Paediatric Surgical Ward, Paediatric Emergency Unit and Neonatal Intesive Care Unit.

KNH is a national referral hospital where expertise on care of complicated Paediatric surgery cases is undertaken. The hospital receives all referrals across the country with such conditions due to availability of expertise as well as resources such as Neonatal ICU to manage such cases.

3.3 Study Population

This study included all neonates, born outside of KNH, with gastroschisis presenting for primary definitive management at KNH having being referred from the facility of birth.

3.4 Inclusion criteria and Exclusion criteria

3.4.1 Inclusion criteria

i. All neonates, born outside of KNH with gastroschisis who presented to Kenyatta National Hospital and whose parent/guardian and the accompanying officer incharge of transporting the neonate were willing to give consent for participation in the study.

3.4.2 Exclusion criteria

i. Any patient with primary intervention performed in other facilities prior to admission at KNH.

ii. Any patient who is not a referral from a health facility.

3.5 Sample Size Determination

The sample size was calculated using the Cochran's formula (1963) and further adjusted for finite population correction.

$$N = \frac{Z^2 P(1-P)}{d^2}$$

Z = value from standard normal distribution corresponding to the desired confidence level (Z=1.96 for 95% CI)

P is the expected true proportion of poor compliance to the neonatal transport protocol. 50% is used since it is no studies in the region have demonstrated the level of poor compliance.

d is the desired precision (half desired CI width) = 0.05

$$N = \frac{(1.96^2) \times 0.5 (1 - 0.5)}{(0.05)^2}$$

$$N = \frac{0.9604}{0.0025}$$

Therefore, N = 384 participants

Expected total number of patients seen over the study duration is 3 per month * 8 months of data collection.

Thus, adjusting for finite population correction using the formula nf = n0 / {1 + (n0 - 1) N} nf = 384 / {1 + (384 - 1) / 24} = 23 participants nf = finite population

N = Sampling frame ie Total number of patients eligible for the study

3.6 Sampling Procedure.

Convenience sampling method was used in this study, where consenting parents/guardians of the patients and the accompanying healthcare worker were recruited into the study as they were received in the KNH until the desired sample size was achieved.

3.7 Recruitment of Study Participants

The relevant units in the hospital were informed on sending a notification to the principal investigator of this study when they received the first call from the referring health facility and also when the neonate arrived at the hospital, so that the recruiter was present in good time. The recruiter of the study participants was the principal investigator or a research assistant.

Once a patient was received in the department i.e Paediatric Emergency Unit, Neonatal Intensive Care Unit and/or Paediatric Surgical Ward of KNH, both the parent/guardian of the neonate and the accompanying healthcare worker were recruited.

The parent/guardian were directed to a private room in the unit where the study protocol was explained to, after which they were requested for permission to participate in the study and if they accepted, an informed consent was administered.

Similarly, the officer in-charge of transporting the child to the hospital was as well approached and he/she was required to sign an informed consent prior to giving relevant information regarding the study protocol.

3.8 Study variables

The study collected data involving implementation of expected pre and intra – transit activities for patients with Gastroschisis.

Thus study variables included

3.8.1 Dependent variables:

Implementation of components required during pre – and intra – transit protocol.

3.8.2 Independent variables:

Distance of facility from KNH, time of transit

3.8.3 Assessment of implementation of transport protocol for neonates with Gastroschisis :

The standard transport protocol was used to assess individual component implementation and overall implementation with neonatal pre and intra – transit protocol (Appendix 1). A score of 0 was applied if no treatment measure was applied whereas a score of 1 was assigned where a treatment measure was applied. This helped to derive total implementation score for each neonate.

3.8 Data Collection

A structured data collection sheet was used to collect information of interest to the study. Study participants were captured immediately on admission where eligibility was assessed on being received to the relevant department. Once eligible and having accepted to participate into the study, informed consent was administered. Thereafter the data collection sheet was administered.

Once recruited, the guardians and the officers in-charge of pre and intra – transport of patient gave necessary information as required by the study protocol.

3.9 Data management and quality assurance

Once data was collected, the collected data was de-identified by assigning study specific unique identifiers to the study participants. The structured data collection tools was stored in a safe to avoid unauthorized access. The data was converted into software data via Epi info 3.5.4. All electronic data was stored in an external hard drive and password protected after encryption.

All data was verified on collection before uploading it to excel sheet for cleaning and coding. All data was secured by a password to make sure that its only accessible to principal investigator and data manager.

3.10 Data analysis

Stata 16 was used for data analysis.

Descriptive statistics were used to describe characteristics of study participants such as mean birth weight, mean time of transit, mean distance from referring facility.

Proportions and percentages shall be used to describe the various component indicators of adequacy of implementation.

Spearman rank correlation was used to assess correlation between two continuous variables e.g. distance from KNH and transit time.

Data was reported in frequency tables, pie charts, bar charts and written reports.

3.11. Ethical considerations

Permission and approval to conduct this study was sought from Kenyatta National HospitalUniversity of Nairobi Research and Ethics Committee. The researcher did not use incentives or coercion to recruit participants. Participation into this study was purely voluntary by the consenting participants.

The participants identification particulars such as the name and hospital inpatient number were not included in the data collection tool. Data collection tools were kept in a cabin under lock and key while data was stored in a password protected excel sheet. Confidentiality of patient information was observed at all stages of this study.

3.12 Data Dissemination

Findings from this study were to be published in medical journals and presented in pediatric surgical conferences. The results were also be shared with the Department of Pediatric Surgery and Department of Surgery for KNH.

CHAPTER 4

4.0 RESULTS

The results were analyzed for 29 participants for the study and presented in accordance to objectives after presentation of social demographic and clinical characteristics.

4.1 Socio-demographic and clinical characteristics

4.1.1 Age

Mean age of the study participants was 7.07 hours, SD 3.41, Median 6 hours. Range 3 – 18 hours.

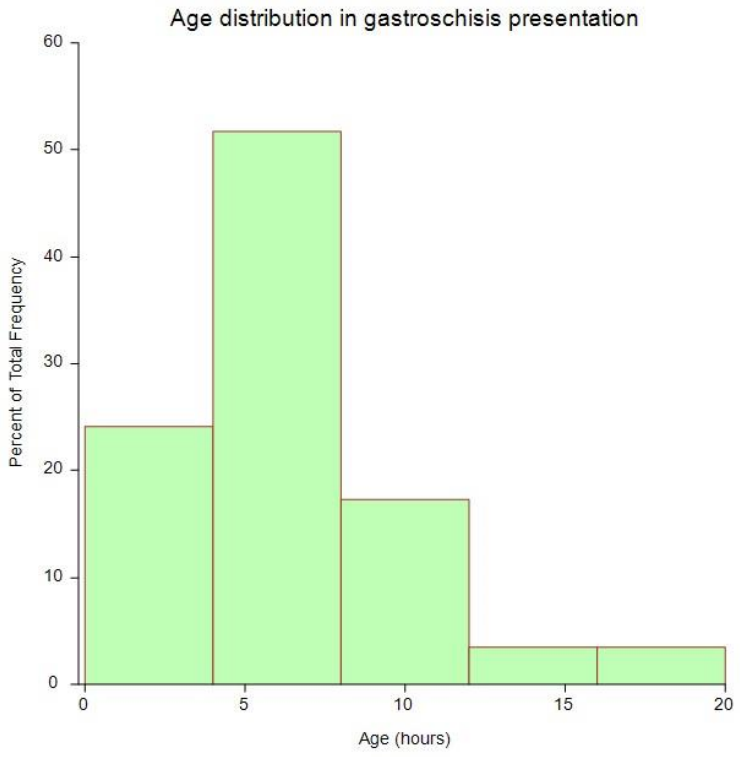

Figure 1: Bar chart of Age distribution

4.1.2 Sex

There were 13 (44.8%) females compared to 16 (55.2%) males.

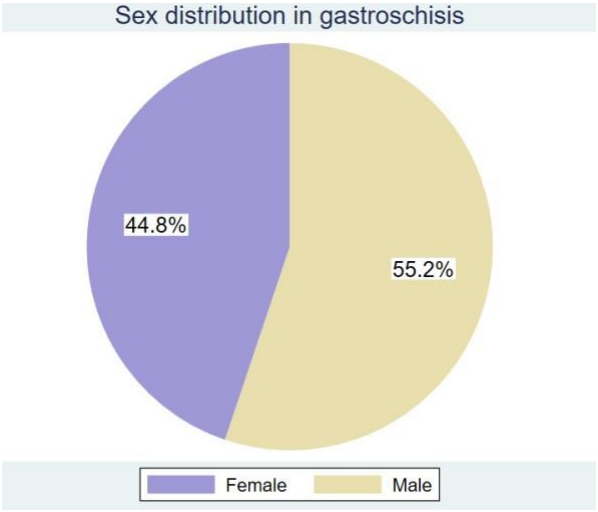

Figure 2: Pie chart of sex distribution

4.1.3 Birth weight

The mean birth weight was 2019.8 grams, SD 261.6, Median 2000 gms, Range 1500 – 2695.

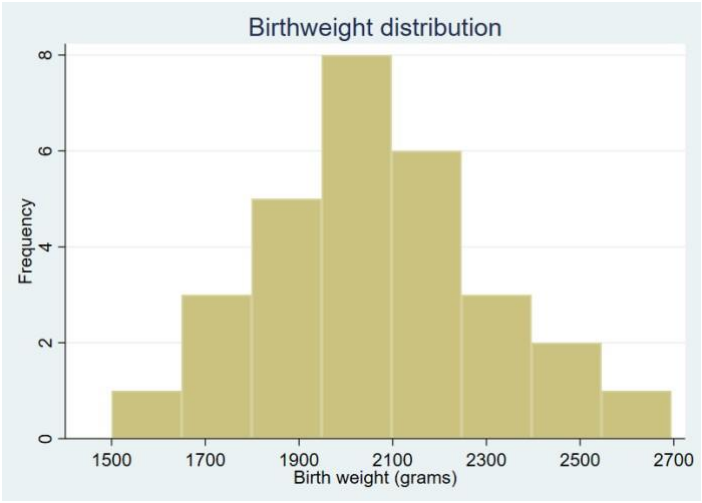

Figure 3: Histogram of weight distribution

4.14 Gestational age

The mean gestational age was 36.5 weeks, SD 1.35, Range 33 – 38, median 37 weeks.

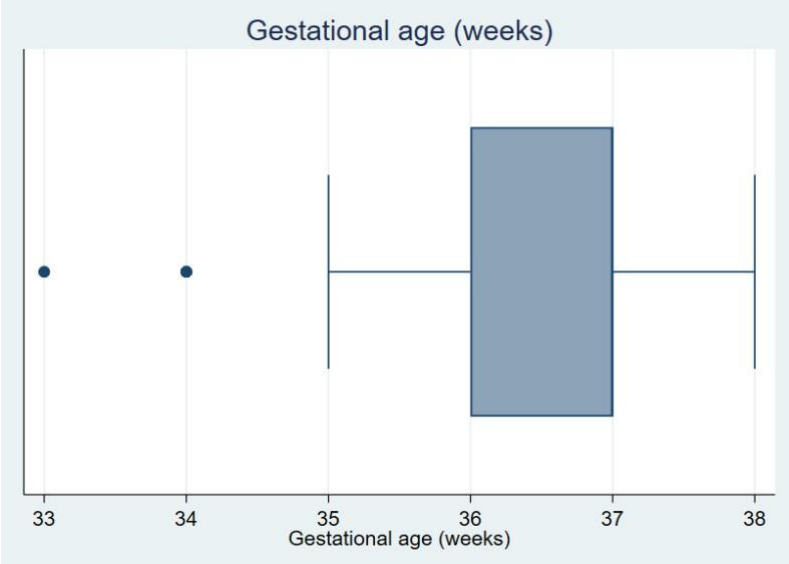

Figure 4: Box plot of gestational age

4.2 Objective 1: The transfer time and distance covered for neonates with gastroschisis referred to KNH

The mean duration in transit was 5 hours, SD 1.89, Median 5, Range 1 – 9. (Figure 5). The mean distance to the national referral facility, KNH was 153.1kms, SD 87.8, Median 140, Range 19 – 348 (Figure 6). There was a positive correlation between the distance to facility and time taken to arrive, p value <0.001 (Figure 7).

Figure 5: Histogram of distance covered to referral facility

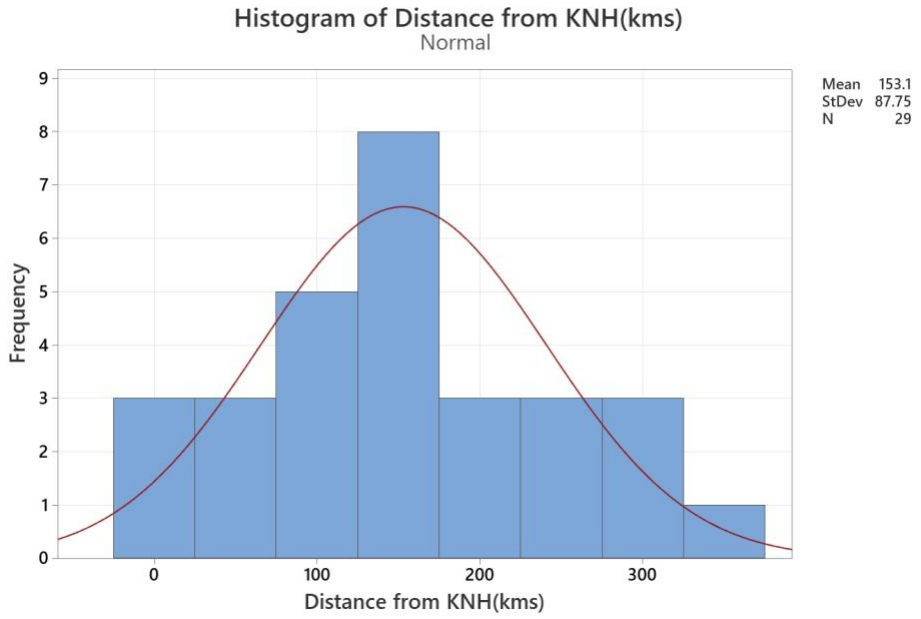

Figure 5: Histogram of distance covered to referral facility

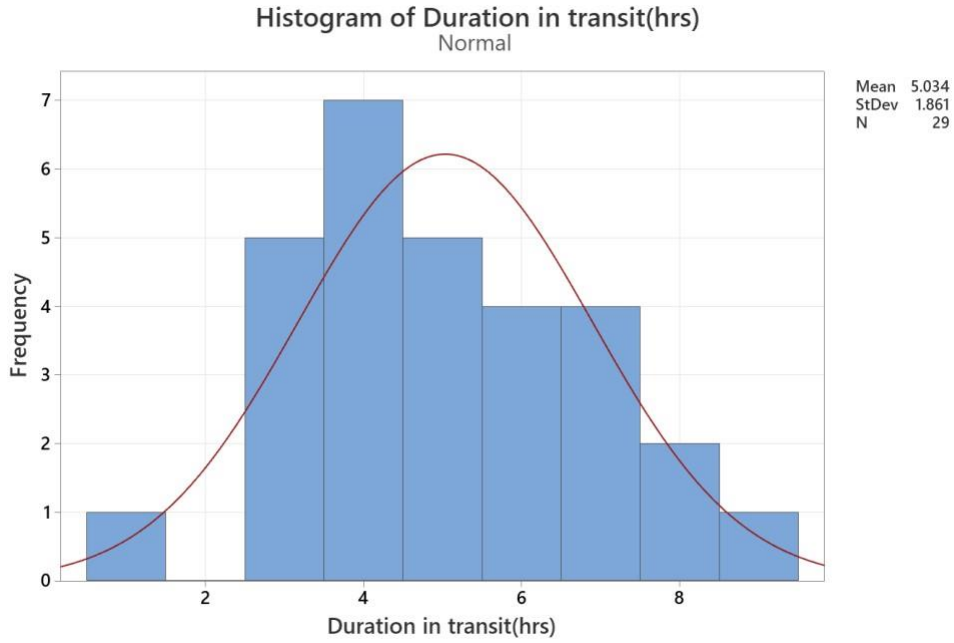

Figure 6: Histogram of duration of transit

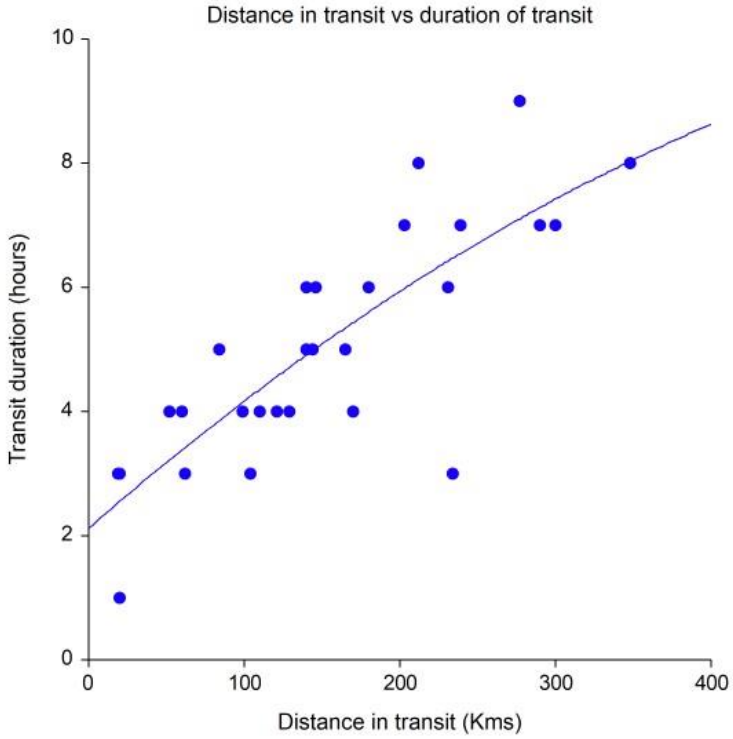

Figure 7: Association between distance during transit and transit time

Thus indicates a positive correlation between distance travelled by neonates and time duration in transit.

4.3 Objective 2: The level of implementation of pre-transit protocol for neonates with gastroschisis referred to KNH

From a total of 10 factors that should be implemented during pre-transit protocol (Table 1).

Table 1: Pretransit implementation scores

Pre-transit implementation score	Frequency	Percent
0	0	0
1	0	0
2	0	0
3	0	0
4	2	6.9
5	5	17.2
6	14	48.3
7	8	27.6
8	0	0
9	0	0
10	0	0
Total score = 10	29	100%

Table 2: Pre-transit factors affected

Factors assessed	Overall number of patients / 29	Percent
Prenatal Obstetric scan	13	44.8
Pre-referral communication	23	79.3
IV access	29	100
IV fluids given	29	100
Prophylactic antibiotics given	22	75.9
Gastric decompression	1	3.4
Bowel covered	27	93.1
Written referral note	29	100
Monitoring chart	0	0
Blood investigations comment	0	0

Thus, from the table, most affected areas were prenatal obstetric scan, gastric decompression, monitoring chart and comment on blood investigations.

NB: Only 2 / 13 (15.4%) neonates who underwent prenatal obstetric scan had an abnormality of gastroschisis picked prenatally.

4.4 Objective 3: Implementation of inter-transit protocol for neonates with gastroschisis referred to KNH

Table 3: Intra-transit implementation scores

Intra-transit score	Frequency	Percent
1	0	0
2	0	0
3	0	0
4	0	0
5	9	31.0
6	7	24.1
7	6	20.7
8	5	17.2
9	2	6.9
10	0	0
11	0	0
12	0	0
13	0	0
14	0	0
Total score = 14	29	100%

Table 4: Transit factors affected

Transit factors	Overall number of patients affected/ 29	Percent
Most commonly affected		
Accompanying medic personnel	29	100
Oxygen supply	28	96.6
Baby covered well	25	86.2
Patent peripheral access	22	75.9
Neonatal Resuscitation training received	17	58.6
Thermometer	16	55.2
Parent content	14	48.3
Blood pressure monitor	13	44.8
Bowel cover adequate	10	34.5
Pulse oximetry	9	31.0
Functioning NGT	4	13.8
Omitted Factors		
15 min of monitoring bowel	0	0
On electric incubator	0	0
Commercial incubator	0	0

Thus, the factors mostly affected were 1) use of electric incubator, 2) Commercial incubator 3) pulse oximetry 4) Thermometer 5) blood pressure monitoring, 6) neonatal resuscitation received, 7) functioning NGT, 8) 15 minute of bowel monitoring and 9) parental content.

CHAPTER FIVE

5.0 DISCUSSION

Gastroschisis results in significant morbidity and mortality among neonates. Low-andmiddle income countries including Sub-Saharan Africa experience significant mortality ranging from 33 – 100% (15). Neonatal pre-transit and transit factors are hypothesized to contribute significantly to the unfavorable statistics associated with this condition. Thus, adequate interventions in this area of care of neonates with gastroschisis has the potential to improve care with resultant reduction in mortality. This study sought to investigate the adequacy of care amongst neonates with gastroschisis during the pre-transit in the facility of delivery and transit to the national referral facility.

5.1 Demographic and clinical characteristics

Mean gestational age was 36.5 weeks. These findings coincide with existing reports in literature which document the mean gestational age at spontaneous birth to be 36 weeks (29). Similarly, another study by Zaki et al found a mean gestational age at delivery of 36.3 weeks (30). However, fetal medicine physicians may prefer to deliver fetuses with gastroschisis at term if the conditions of the pregnancy and the fetus remain stable (31).

Mean birth weight of our study participants was 2019.8 grams. Gastroschisis is well known to contribute to low birth weight. Existing literature documents a higher mean birth weight of 2448±460 g (30) These findings were from a series of 191 neonates with gastroschisis in California, USA.

Sex distribution is similar in males and females. This is not limited to our study which showed a male to female distribution of 55.2% vs 44.8% respectively but in other series which show a very similar sex patterns (32).

5.2 Transit duration and distance

Mean duration of transit for the neonates to the Kenyatta National Hospital was 5 hours with a median of 5 hours. Data from our study indicates that 28/29 (96.5%) had a transfer time of greater than 3 hours. Mean distance covered during transit was 153 kms, range 19 – 348 kms. Longer distance was positively associated with longer transit time.

Studies have associated the transfer time to complications and mortality. In a study conducted in Egypt by Shalaby et al, (2020), recommends a transfer time of lesser than 8 hours which was associated with a survival rate of 64% (9). Other studies have recommended a transfer time of less than 90 minutes. According to Mori et al, from Japan, a greater duration of transit exceeding 90 minutes doubles the risk of mortality. Thus, recommends that air transport is a feasible means if transit time is expected to exceed 120 minutes (16). Complications identified in literature to be associated with increased transfer time include metabolic derangements such as hyperglycemia, metabolic acidosis, hypoglycemia and sepsis (17).

5.3 Pre-transit protocol implementation

Care of neonates with gastroschisis begins immediately after birth. Delays in instituting the correct management plan invariably results in complications and mortality. Optimal pretransit care involves implementation of various aspects including prenatal obstetric scan, pre-referral communication, IV access, administration of IV fluids and prophylactic antibiotics, gastric

decompression, cover of bowel, a written referral note, monitoring chart, and comment on blood investigations.

Out of these 10 factors, this study found out that 7 factors were implemented in 27.6% of patients, 6 in 48.3%, 5 in 17.2% and 4 in 6.9% (Table 2). Most affected aspects of this were prenatal obstetric scan, gastric decompression, monitoring chart and comment on blood investigations (Table 3). This demonstrates that there exist significant gaps in implementation of pre-transit protocol which could result in increased morbidity and mortality.

Due to dangers associated with transport of the neonates with gastroschisis, pre-natal ultrasound can help in diagnosing the condition before birth and this would aid in planning location of birth and care post-delivery. In our study, prenatal ultrasound was only conducted in 13 / 29 (44.8%) of the participants. Of these only 2 /13 (15.4%) had an abnormality picked. A study in Uganda by Wesonga et al (2016) found that only 24% of patients received prenatal ultrasound, and only 2% of these had a correct prenatal diagnosis. However, current reports indicate that World Health Organization does not recommend routine utilization of antenatal ultrasound (33). Other recommended test that can improve diagnosis of gastroschisis include maternal serum alpha-fetoprotein (7).

5.4 Intra-transit protocol implementation

Safe transit of gastroschisis patients is mandatory to reduce mortality in these patients. The requirements for adequate intra-transit transport include incubator, pulse oximetry, oxygen supply, temperature monitoring, blood pressure monitoring, accompaniment by skilled medical professional, adequate knowledge on neonatal resuscitation, patent peripheral access,

functioning NGT, adequate baby cover, adequate bowel cover, 15 minute of bowel monitoring, and parental content (23, 24).

The findings in this study established that there was generally inadequate intra-transit protocol implementation. Out of an implementation score of 14 only 44.8% of patients more than half of the factors implemented (Table 4). The factors most negatively affected were 1) use of electric incubator, 2) Commercial incubator 3) pulse oximetry 4) Thermometer 5) blood pressure monitoring, 6) neonatal resuscitation received, 7) functioning NGT, 8) 15 minute of bowel monitoring and 9) parental content (Table 5). Of note is that there were no incubators used in transport of all patients, pulse oximetry was only used in 9 patients with gastric decompression only in 4 patients. Adequate bowel cover was only in 34.5%.

According to Wesonga et al (2016) in Kampala Uganda, 81% of patients did not have adequate bowel coverage, 54% had no intravenous access, 83% did not have a decompressing NG tube, 52% were being breastfed, 58% arrived within 12 hour since birth, and ambulance transport was available for only 35% (6).

Contemporary reports indicate that majority of neonates in the Sub-Saharan Africa are born in facilities without adequate paediatric surgical care and would therefore need transport to a referral facility (33). In terms of place of delivery, our study demonstrates that 3 patients were born at home, 16 patients were born in a district level hospital, 9 patients in a community clinic and 1 patient in a private facility. Two out of 29 patients (6.9%) travelled using a private car rather than an ambulance.

5.5 Limitations

Our study was limited by a small sample size which could have affected validity of the results. However, data was meticulously collected to ensure that the relevant information was captured as outlined in the study protocol.

5.6 Conclusion

Care of neonates with gastroschisis is critical to prevent morbidity and mortality. The findings of this study indicate gross inadequacies in care of such patients, both in the pretransit period and intra-transit period. Improvement in such care would reduce mortality from gastroschisis complications.

Thus the following recommendations are suggested

1. Establishment of guidelines targeting neonatal transport
2. Training of healthcare personnel on neonatal transport
3. Equipping district level facilities and ambulances with tools and equipment to support neonatal transport.
4. Prenatal screening of gastroschisis with ultrasound and maternal alpha fetal protein test to promote proper planning of birth in an ideal facility.
5. Parental information on the need to deliver in the facilities.

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LIST OF APPENDICES

APPENDIX 1: DATA COLLECTION SHEET

(Tick where appropriate)

PARTICIPANT DEMOGRAPHICS

Patient serial number ……..

Age in hours ……

Gender: Male …… Female ……

Place of delivery (home/community clinic/ district level hospital/provincial level hospital)

Birth weight(grams) ……..

Gestational age (weeks) …….....

PRE-TRANSIT FACTORS:

			YES	**NO**
1.	a)	Was an obstetric scan done prenatally?		
	b)	If yes, did it show any abnormality?		
2.		Any pre-refferal communication done with KNH staff?		
3.		**Fluid management:**		
	a)	Was there an intravenous access?		
	b)	Were intravenous fluids given?		

		If yes, specify type and amount:		
4.		Administration of prophylactic **antibiotics**?		
		If yes, specify type and dose		
5.		Gastric **decompression** done prior to transport?		
6.		**Bowel handling:**		
	a)	Was bowel covered?		
	b)	If covered, was it plastic, non-occlusive?		
7.		**Documentation :**		
	a)	Was there a referral note written?		
	b)	Was there a monitoring chart attached?		
	c)	Any investigations done attached or commented on the note?		
	c)	Details of pretransport vital signs, pertinent physical findings and laboratory investigations done (e.g random blood sugar, FHG, temperature, heart rate, general examination findings)		

TRANSIT FACTORS:

1. Type & Name of Referring facility:

Name:……

Type: Health dispensary/ Community clinic/ District hospital/ Provincial hospital

2. Distance of referring facility (in kilometers) from KNH ……..

3. Duration in transit (time in hours between departure from referring facility upto arrival at KNH) …….

4. Mode of transport : ___ Public (specify type) ……

___ Private (specify type) ……

___ Ambulance

			YES	NO
5.		Availability of **Equipment** in transport service :		
	a)	Non-electric incubator		
	b)	Commercial incubator		
	c)	Pulse oximeter		
	d)	Oxygen supply		
	e)	Thermometer		
	f)	Blood pressure monitor		
6.		Medical Personnel accompanying the neonate:	Nurse/ Medical doctor/ Paramedic/ None	

7.		Has the medical personnel received neonatal resuscitation training?		
8.	**a)**	Any clinical complications that occurred during transport?		
	b)	If yes, specify (Hypothermia/ Desaturation/ Respiratory distress/ Hypoglycemia/ Convulsions/ Mortality/ other/ unknown)		

Status of continuation of care during transit, as seen on arrival at KNH:

			YES	**NO**
9.		**Fluid administration:**		
	a)	Patent peripheral access		
	b)	Hydration status on arrival: **CRT** ……seconds, **HR**…….bpm **BP**…….. **RBS**……. mmol/l		
10.		**Gastric decompression:**		
	a)	Functioning nasogastric tube?		
	b)	NGT on free drainage?		
11.		**Thermoregulation:**		
	a)	Was the baby covered well?		
	b)	Body temperature on arrival (C)		
12.		Care of exteriorised **bowel contents:**		
	a)	Was the covering of bowel plastic, non-occlusive?		
	b)	Was monitoring of bowel done every 15mins for dusky or blanching color changes?		
	c)	Appearnce of bowel on arrival : Pink/ dusky/ ischaemic/ necrotic/ edematous/ matted/ other e.g contents of covering material used that is adherent to the bowel)		

11. Was the parent/guardian content regarding the transport system and handling of the child during the transfer? Y/N (specify)

……

……

…….....

APPENDIX 2: INFORMED CONSENT FORM

This informed consent is for the parent/guardian of the patient and the health worker accompanying the patient in the Paediatric Emergency Unit department, Neonatal Intensive Care Unit and Paediatric Surgical ward who was recruited into the study entitled;

ASSESSMENT OF THE NEONATAL REFERRAL AND TRANSPORT SYSTEM FOR PATIENTS WITH GASTROSCHISIS REFFERED TO KENYATTA NATIONAL HOSPITAL

Principal investigator: Dr. Hetal Rajnikant Gohil

Institution: Department of Paediatric Surgery, School of Medicine, University of Nairobi.

This form consists of four parts :

1. Information sheet,

2. Informed consent form for the parent/guardian of the patient,

3. Informed consent form for the healthcare worker accompanying the patient, and

4. Statement by the researcher or research assistant. **Information sheet Introduction:**

My name is: Dr. Hetal Rajnikant Gohil, a post graduate student pursuing a masters degree in Paediatric surgery at the University of Nairobi. I am carrying out a study on the assessment of neonatal referral and transport system for patients with exposed intestines at birth referred to Kenyatta National Hospital.

The purpose of this research is partly as a curriculum requirement for completion of postgraduate studies as well as bettering patient care in clinical practice.

This was a study documenting the status of implementation of expected pretransit and transit activities for new born babies whose intestines are exposed at birth, and the duration and distance covered during the transport.

Your participation in this study will help bridge the knowledge gap in our referral and transportation system for patients with such conditions. It will also add value in making a protocol in the future for better outcomes for these surgical conditions.

Voluntary participation.

Participation in this study is voluntary. You have the right to turn down our request for the child's participation or even withdraw from the study at any point when you consent into it. Should you choose to decline or withdraw from the study, there are no repercussions and treatment was provided as usual.

Confidentiality.

The child's name or inpatient number will not appear on any of our data collection sheets. A serial number was used which will not have any of his/her identifying details. Information collected from you was held confidentially and will not be shared with any unauthorized person.

Sharing of results:

Once data is collected, cleaned and analyzed, it was shared with the department of surgery in KNH. Findings was published in medical journals and presented in medical conferences.

Risks and benefits.

This study confers no risks to the child as a participant and therefore no harmful effects was experienced. Equally, the child will not get any direct benefits.

Cost and compensation

The child will not be compensated for participating in this study. No monetary or other enticing benefits was offered to you. You will not incur any cost beyond the cost of treatment when the child participates in this study.

Who to contact:

If you wish to ask any questions later, you may contact:

Principal Researcher:

Dr. Hetal Rajnikant Gohil,

Department of Paediatric Surgery, School of Medicine, University

of Nairobi.

P.O. Box 19676 KNH, Nairobi 00202.

Mobile no. 0722528929

Dr. Francis Osawa,

M.B.ch.B (UON), MMed (Paediatric Surgery) (UON)

Consultant Paediatric Surgeon and Lecturer,

Department of Paediatric Surgery, University

of Nairobi.

Dr. David Kihiko Kuria,

M.B.ch.B (MOI), MMed (Paediatric Surgery) (UON) Consultant

Surgeon and Lecturer, Department of Surgery, University of

Nairobi.

Dr. Timothy Jumbi,

MBchB (MOI), MMed Paediatric surgery(Nairobi), FCS PaedSurg(COSECSA)

Consultant surgeon and Lecturer, Department of Paediatric Surgery,

University of Nairobi/ KNH

If you have any ethical concerns, you may contact:

Secretary, UON/KNH-ERC,

P.O. Box 20723- 00202, KNH, Nairobi.

Tel: 020-726300-9 EXT 44355

Email: uonknh_erc@uonbi.ac.ke

Certificate of Consent:

I have read the above information, or it has been read/ and translated to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction.

I consent voluntarily to participate as a participant in this research.

Name of Participant _____

Name of Parent/ Guardian _____

Signature of Parent/Guardian _____

Date _____

Name of officer in charge of transport team

_____

Signature of officer in charge of transport team

_____

Date

_____

Statement by the researcher

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands that: Refusal to participate or withdrawal from the study will not in any way compromise the care of treatment, all information given was treated with confidentiality and that the results of this study might be published. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my knowledge and ability.

I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Name of researcher/research assistant

_____

Signature of researcher/research assistant_____

Date_____

APPENDIX 3: CONSENT FORM (SWAHILI VERSION)

FOMU YA MAKUBALIANO KUSHIRIKI KATIKA UTAFITI

Fomu hii ya ridhaa iliyo na habari ya wagonjwa watoto waliozaliwa na shida ya matumbo yanayojitokeza mtoto anapozaliwa wanaotumwa katika Hospitali ya Kitaifa ya Kenyatta kwa matibabu zaidi

Idhini iliyo na habari ina sehemu 3:

1. Karatasi ya habari

2. Cheti cha idhini

3. Taarifa ya mtafiti

SEHEMU 1: SHEMA YA HABARI

KICHWA: MAKADIRIO YA KANUNI ZA KUSAFIRISHA WATOTO WALIOZALIWA NA SHIDA YA MATUMBO YANAYOONEKANA WANAPOZALIWA WANAOTUMWA HOSPITALI KUU YA KITAIFA YA KENYATTA.

HATUA YA WAANDISHI:

Mimi ni Dkt. Hetal Gohil, mwanafunzi wa Shahada ya Uzamili ya Upili wa Chuo Kikuu cha Nairobi. Ninafanya utafiti ili kujua kiwango ambacho kanuni za kusafirisha watoto wanaozaliwa na shida ya matumbo kujitokeza wanotumwa hospitali kuu ya Kenyatta kwa matibabu zaidi katika ya kitaifa ya Kenyatta zinatimizwa. Ninakuomba ushiriki katika utafiti huu na madhumuni ya fomu hii ni kwako kuamua ikiwa unashiriki au la.

Soma fomu hiyo kwa uangalifu na ujisikie huru kuuliza maswali yoyote au wasiwasi wowote unao kuhusu utafiti huu kwangu.

Utafiti huu umeidhinishwa na Kamati ya Maadili na Utafiti ya KNH / UON. Nambari

ya itifaki ……

Mimi, mchunguzi, nitapatikana kwa ufafanuzi wowote wakati wa kujaza fomu na hata baada ya kujaza.

MAELEZO MAFUPI YA UTAFITI

Ugonjwa wa kuzaliwa matumbo yakionekana ni ugonjwa ulio na maafa ya juu Zaidi humu nchini. Maafa haya yanaletwa na kutotii kanuni zinazoweza kusaidia mtoto huyu kuishi wakati amezaliwa au anaposafirishwa kupata matibabu halisi. Utafiti huu unaangalia kiwango ambacho kanuni hizi zinatiliwa maanani. Kulingana na majibu ya utafiti huu, itajulikana sababu haswa ya maafa haya ili kuweza kuyazuia.

USHIRIKI

Ukichagua kushiriki katika utafiti, utakabidhiwa dodoso la kujaza ambalo halipaswi kuchukua zaidi ya dakika 10 za wakati wako.

Dodoso linahusu habari ya mshiriki, mawasiliano na madaktari, mawasiliano na wauguzi, mawasiliano juu ya dawa, kutoa habari wakati wa kuruhusiwa kuenda na kiwango cha jumla cha hospitali. Takwimu zilizokusanywa zitabaki bila kujulikana na zitahifadhiwa salama.

HATARI ZITAKAZOTOKEA UKISHIRIKI KATIKA UTAFITI HUU

Hakuna hatari au matukio mabaya yaliyotambuliwa kutokea kwa kushiriki kwenye utafiti huu, hakuna habari ya kitambulisho cha kibinafsi itakayokusanywa na takwimu itabaki siri na haiwezi kufuatiliwa kwako.

FAIDA ZA KUSHIRIKI KATIKA UTAFITI HUU

Takwimu itakayokusanywa itatoa habari inayofaa juu ya maeneo ya uboreshaji wa huduma za afya ili kufanya kukaa kwa wa mgonjwa katika taasisi yetu kuwa bora.

MASWALI NA KESI

Uko huru kuuliza maswali yoyote kwa mchunguzi mkuu kupitia njia ya mawasiliano itakayotolewa mwishoni mwa waraka huu. Ushiriki wako ni wa hiari kabisa na unaweza kuchagua kukataa kushiriki katika utafiti au kuondoa ushiriki wako katikati mwa utafiti bila athari yoyote.

SEHEMU YA 2: UJUMBE WA MTAFITI

CHETI CHA KUKUBALI KUSHIRIKI

Nimesoma kikamilifu fomu hii ya idhini au nimesomewa yaliyomo. Maswali yangu, ikiwa yapo yoyote, yamejibiwa kwa lugha ambayo naelewa. Hatari na faida zimeelezwa kwangu. Ninaelewa kuwa ushiriki wangu katika utafiti huu ni wa hiari kabisa na naweza kuchagua kujiondoa wakati wowote bila athari. Ninachagua kushiriki katika utafiti huu.

Sahihi ……. Tarehe…….

SEHEMU YA 3: TAARIFA YA MTAFITI

Mimi, niliyesaini hapa chini nimeelezea kwa undani maelezo muhimu ya utafiti huu kwa mshiriki na ninaamini mshiriki ameelewa na ametoa idhini kwa hiari yake.

Jina la mtafiti: ……

Sahihi:……Tarehe:……

……

Kwa mawasiliano zaidi ya habari:

DKT. Hetal Gohil

Simu: 0722528929

Barua pepe: P.O Box 19676 KNH, Nairobi 00202

Idara ya upasuaji ya watoto, Chuo Kikuu cha Nairobi.