

**ADVERSE MATERNAL AND PERINATAL OUTCOMES IN  
SECOND-STAGE VERSUS FIRST-STAGE OF LABOUR  
PRIMARY CAESAREAN DELIVERIES AT MOI TEACHING  
AND REFERRAL HOSPITAL, KENYA.**

**BY**

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**A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE  
REQUIREMENTS FOR THE AWARD OF A MASTERS DEGREE  
IN REPRODUCTIVE HEALTH, MOI UNIVERSITY, KENYA**

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**DECLARATION**

**Student's Declaration**

I declare that this thesis is my original work and has not been presented to any other university/institution for consideration.

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## **DEDICATION**

This work is dedicated to all women undergoing caesarean delivery.

I recognize that undergoing caesarean delivery can be a challenging experience, both physically and emotionally. I acknowledge the impact that this procedure can have on your life and your family.

This research aims to increase understanding of the potential complications and outcomes associated with caesarean delivery, in order to identify ways to minimize the risks and optimize outcomes for both mothers and babies.

I hope that this research will provide the knowledge and support needed to make informed decisions about your care and the care of your baby.

## ACKNOWLEDGEMENT

This accomplishment has been made possible through the input of various persons and institutions. Firstly, I would like to thank the clients involved in this study. I am also appreciative to the consultants who have provided me with advice and guidance, particularly my supervisors *Prof. Edwin Were* and *Dr. Winfred Mwangi*.

I express my sincere gratitude to each participant for their cooperation and patience throughout the entire research process. Their willingness to share their experiences has enabled me to gain deeper understanding of the topic and make significant contributions to the field.

I am indebted to my family for their support and encouragement and to the Almighty God for His mercy and direction.

**LIST OF ABBREVIATION**

<b>ACOG</b>	American College of Obstetricians and Gynecologists
<b>ANC</b>	Antenatal Clinic
<b>BMI</b>	Body Mass Index
<b>CD</b>	Caesarean Delivery
<b>CS</b>	Caesarean Section
<b>EDD</b>	Expected Date of Delivery
<b>FHR</b>	Foetal heart rate
<b>ICU</b>	Intensive Care Unit
<b>IREC</b>	Institutional Research Ethics Committee
<b>LMP</b>	Last Menstrual Period
<b>MTRH</b>	Moi Teaching and Referral hospital
<b>NBU</b>	New born unit
<b>NICE</b>	National Institute of Clinical Excellence
<b>NICU</b>	Neonatal Intensive Care Unit
<b>NRFS</b>	Non reassuring foetal status
<b>PACU</b>	Post-anesthesia care unit
<b>PPH</b>	Postpartum hemorrhage

<b>RCOG</b>	Royal College of Obstetricians and Gynecologists
<b>RDS</b>	Respiratory Distress syndrome
<b>RMBH</b>	Riley Mother and Baby Hospital
<b>WHO</b>	World Health Organization
<b>FHED</b>	Foetal head elevator devices

## OPERATIONAL DEFINITION OF TERMS

**Adverse maternal outcome:** maternal morbidity or maternal in-hospital death.

**Adverse perinatal outcome:** perinatal morbidity or neonatal death within 24 hours of caesarean delivery.

**Maternal morbidity:** Intraoperative complications (ie atony, adjacent tissue injury, hysterectomy, bladder injury, uterine incision extension), primary postpartum haemorrhage (blood loss of 1000mls or more), length of post-operative hospital stay >3 days.

**Perinatal morbidity:** NBU admission, Apgar score  $\leq 3$  at 5min or neonatal trauma (scalp, facial bruising and fractures).

**Perioperative mortality:** Any death, regardless of cause, occurring during surgery or within 24 hours after surgery in the hospital.

**Primary caesarean delivery:** Birth of the foetus(es) from the uterus through an abdominal incision in a woman without a prior caesarean birth. Does not apply in abdominal pregnancy or ectopic pregnancy.

**Nulliparous:** A woman with a parity of zero.

**Parity:** The number of pregnancies reaching 28 weeks and 0 days of gestation or beyond, regardless of the number of foetuses or outcomes.

**Preterm:** Less than 37 weeks and 0 days gestation.

**Second-stage of labour:** Period of time between full cervical dilatation and expulsion of foetus from the birth canal. Divided into the propulsive phase - from full dilatation up to descent of the presenting part to the pelvic floor and expulsive phase - maternal bearing down efforts ending with delivery of the foetus.

**Primary postpartum haemorrhage:** Cumulative blood loss of 1000ml or more of blood loss accompanied by signs or symptoms of hypovolemia within 24 hours following the birth process (includes intrapartum loss).

**Failed Vacuum extraction:** An extraction duration exceeding 20 minutes or more than 3 cup detachments.

**First-stage of labour:** Period between onset of true labour and ending with full dilatation of the cervix. Divided into active phase and latent phase of labour

**Gravida:** A woman who currently is pregnant or has been in the past, irrespective of the pregnancy outcome.



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## ABSTRACT

**Background:** Caesarean deliveries are on the rise globally. Second-stage caesarean delivery may carry an additional risk owing to foetal head impaction into the pelvis and manipulations required to deliver the baby. At the national and institutional level, data on the outcomes and complications of this procedure are minimal.

**Broad Objective:** To compare adverse maternal and perinatal outcomes between second-stage and first-stage of labour primary caesarean deliveries at Moi Teaching and Referral Hospital (MTRH), Eldoret.

**Methods:** This was a hospital-based, ambi-directional cohort study.

A total of 222 women with term, live singleton pregnancies in vertex presentation; who had undergone emergency primary caesarean delivery during active phase of labour were recruited within 24 hours postpartum. The exposure of interest was second-stage caesarean delivery. Medical records were reviewed, and retrospective data was collected with respect to intra-operative details. These participants were followed up until hospital discharge for in-hospital mortality and length of hospital stay outcome. All eligible second-stage caesarean deliveries (73) were compared to 149 first-stage caesarean deliveries. A 1:2 'exposed' to 'non-exposed' ratio was used. The proportion of caesarean deliveries in the second-stage of labour was estimated. The composite adverse maternal outcome was evaluated. This was defined as any of the following; atony, adjacent tissue injury, hysterectomy, bladder injury, uterine incision extension, primary postpartum haemorrhage, blood transfusion, length of postoperative hospital stay >3 days or in-hospital maternal death. The composite adverse perinatal outcome was also assessed. It was defined as any of the following; neonatal trauma, newborn unit admission, Apgar score  $\leq 3$  at 5min or, death within 24 hours of caesarean delivery.

The composite outcomes as well the frequency, relative risks and 95% confidence intervals for each of the components of composite outcomes were calculated. Univariate analysis examined the difference in distribution of each potential confounder between the two groups. Multivariate log-binomial regression models were used to estimate the association between stage of labour and composite adverse maternal and perinatal outcomes adjusting for potential confounding variables. The study was from 1st August 2021 to 31st July 2022.

**Results:** Among women who underwent primary caesarean deliveries, the proportion of second-stage caesarean deliveries was 4.3% [95% CI: 2.9% - 4.7%].

Second-stage caesarean delivery was associated with an increased risk of adverse maternal outcomes compared to caesarean delivery in the first-stage labour (ARR 3.556, 95% CI 2.35-5.37,  $P < 0.001$ ). There was no in-hospital maternal mortality within the study.

Second-stage caesarean delivery was also associated with a significantly increased risk of adverse perinatal outcomes compared with caesarean delivery in the first-stage of labour (ARR 3.998, 95% CI 2.35– 6.79,  $P < 0.001$ ).

**Conclusions:** Caesarean deliveries performed in the second-stage of labour accounted for 4.3% of all primary caesarean deliveries at MTRH. Women who underwent caesarean delivery in the second-stage of labour had a significantly higher risk of adverse maternal and perinatal outcomes compared to the first-stage of labour caesareans.

**Recommendations:** Prevention by early identification of scenarios that can result in caesarean delivery in the second-stage of labour are key in reducing the associated adverse outcomes.

## CHAPTER ONE

### 1.0 INTRODUCTION

#### 1.1 Background Information

Caesarean delivery (CD) is considered a life-saving intervention for women and infants when complications occur during pregnancy and labour (Gregory et al., 2012). Caesarean delivery is the most common major surgical intervention in a majority of African countries (Biccard et al., 2018). As a major surgery, it is associated with direct maternal and perinatal risks and may have consequences for future pregnancies as well as long-term sequelae (Marshall et al., 2011; Timor-Tritsch & Monteagudo, 2012).

The World Health Organization (WHO), established that caesarean delivery is an essential treatment in pregnancy and is recommended at a rate of 10 % of all births (WHO, 2015). When the caesarean delivery rate goes above 10% there is no evidence that mortality rates improve (Betrán et al., 2016). Conversely, the statement notes that the relationship between caesarean delivery rates and other significant outcomes such as maternal and perinatal morbidity, stillbirths, neonatal outcomes as well as mental well-being could not be ascertained due to the lack of data at the population level. This lack of data signifies a drawback in these analyses that should be put into consideration.

In most countries, caesarean delivery use is at an incidence well above what is expected on the basis of obstetric indications. In the year 2015, more than one in five live births were by caesarean delivery (Boerma et al., 2018). The highest rates of caesarean delivery are found in Latin American and the Caribbean at 40.5% and South America is the sub region with an average caesarean delivery rate of 42.9%



(Betran et al., 2015). The same study highlighted Egypt as third among world countries with an estimated rate of caesarean delivery at 51.8%.

In Kenya, there exists disparities in caesarean delivery prevalence, the average rate being 11.6% in public healthcare settings (Yaya et al., 2018). Data from a four year study in a private facility in Kenya reported an overall caesarean delivery rate of 38.1% (Wanyonyi et al., 2006) .

With the general caesarean delivery rate increase, there is a corresponding increase in the rate of second-stage caesarean deliveries (J. Unterscheider et al., 2011). This has been demonstrated by data from maternity units in London, where caesarean delivery at full dilatation increased from 0.9% to 2.2% (Loudon et al., 2010). In the United Kingdom it is estimated that as many as 8000 CS are now performed in the second-stage of labour per year (Vousden et al., 2014a).

Evidence suggests that the cause of second-stage caesarean delivery trend is multifactorial; including a combination of lack of training and supervision for junior staff in second-stage decision-making, a loss of technique associated with difficult-assisted delivery and concerns relating to maternal and neonatal morbidity with associated litigious issues (Davis, Fleming, Ford, Mouawad, & Ludlow, 2015).

Second-stage of the labour is broadly defined as the duration from full dilatation of the cervix to expulsion of the products of conception. Both neonatal and maternal morbidity are influenced by the mechanisms of delivery. Second-stage caesarean deliveries may carry additional risk due to foetal head impaction into the pelvis and manipulations required to deliver the baby. When the foetal head is deeply impacted between the maternal bony pelvis and soft tissues, the surgeon may encounter difficulty in gaining access below the head. This scenario, although regularly

encountered by clinicians is associated with neonatal and maternal complications (Ascioglu et al., 2014). A study by Allen et al reported a significant increase in risk of maternal intraoperative trauma and perinatal asphyxia in women undergoing caesarean delivery at full cervical dilatation compared to caesarean delivery before full dilatation (Allen, O'Connell, & Baskett, 2005). Morbidity may be compounded by complications encountered during delivery.

Vacuum extraction, also known as ventouse, is a method to assist delivery of a neonate using a vacuum device. It is prescribed in the second-stage of labour (with specified prerequisites) for indications such as prolonged second-stage of labour and suspicion of immediate or potential foetal compromise. Towner et al. studied caesarean deliveries done after vacuum extraction and concluded; compared with vacuum extraction alone, caesarean delivery after a failed attempt at operative vaginal delivery was associated with significantly increased incidence of subdural or cerebral haemorrhage, mechanical ventilation and convulsions in the neonates (Towner, Castro, Eby-Wilkens, & Gilbert, 1999).

Most studies on second-stage caesarean delivery are from developed countries. This has resulted in the Royal College of Obstetricians and Gynaecologists (RCOG) recommending the presence of a consultant obstetrician during caesarean delivery in second-stage of labour (Thomas, 2001). As well as recommendations for technology such as the foetal pillow to reduce complications in these populations (Safa & Beckmann, 2016).

## **1.2 Problem Statement**

Caesarean deliveries are on the rise globally. Studies in developed nations recognise greater maternal and neonatal morbidity arising from caesarean deliveries during the second compared to the first-stage of labour (V. M. Allen et al., 2005; Asicioglu et al., 2014).

There is limited data comparing second-stage caesarean delivery outcome experience in low income or middle income populations. This has resulted in difficulty in assessing trend in this population and comparison of evidence. It is important to fill the knowledge gap in order to make decisions based on local figures. In clinical practice, the results of this study could serve as a baseline for interventions that may yield lower rates of potential adverse outcomes.

The primary aim of this study was to compare the incidence of maternal and perinatal adverse outcomes between the second-stage and first-stage of labour caesarean delivery.

## **1.3 Study significance**

The study will contribute to current evidence of outcome experience and management of second-stage caesarean delivery. It will as well compare these findings to similar studies done elsewhere.

We hope to inform guideline establishment at the institution level with objective and evidence-based data in relation to second-stage caesarean deliveries. The data will also advise on the need for additional teaching or adoption of medical devices to assist in safe caesarean delivery in the second-stage of labour.

#### **1.4 Research question**

What are the adverse maternal and perinatal outcomes in first-stage labour compared to second-stage labour among women who underwent primary caesarean delivery at MTRH?

#### **1.5 Objectives**

##### **1.5.1 Broad objective**

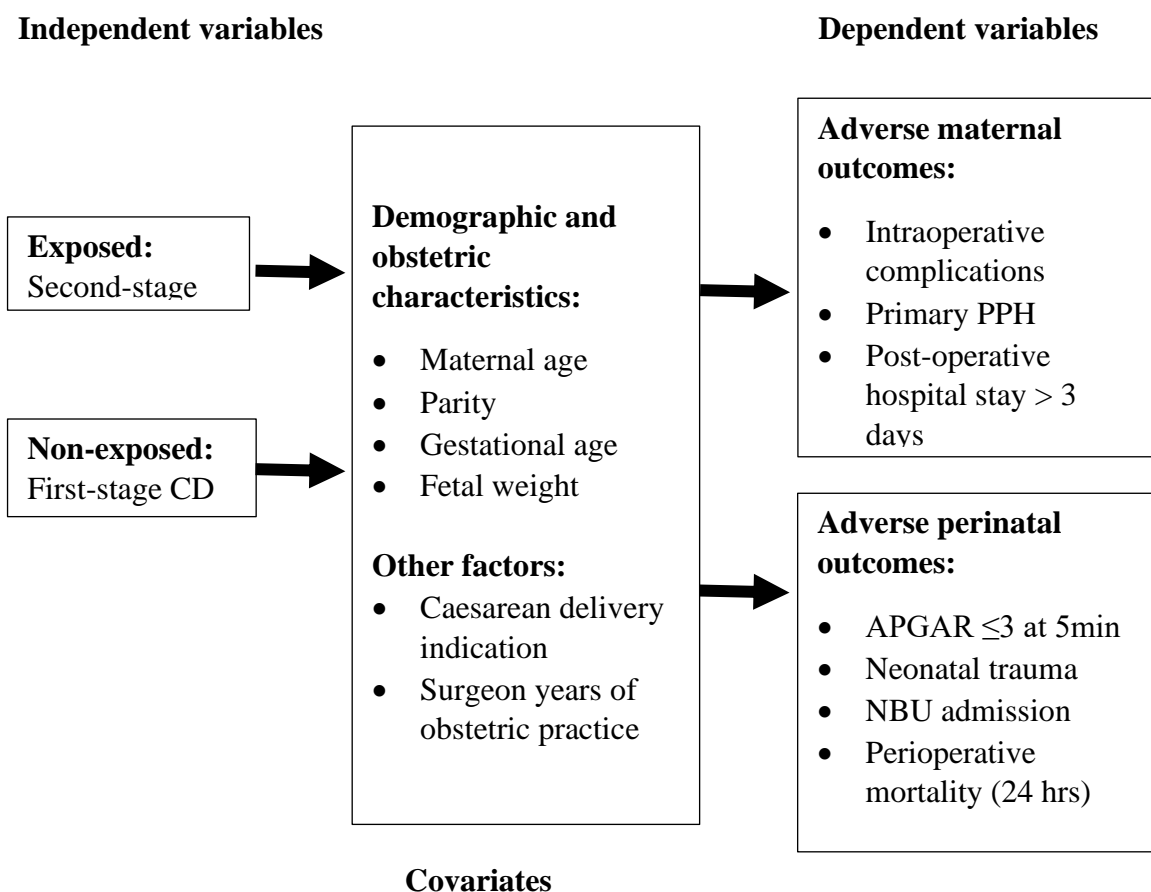
Compare maternal and perinatal adverse outcomes between second-stage and first-stage of labour primary caesarean delivery at Moi Teaching and Referral hospital (MTRH), Eldoret.

##### **1.5.2 Specific objectives**

1. To estimate the proportion of second-stage caesarean delivery among women undergoing primary caesarean delivery at MTRH.
2. To compare adverse maternal outcomes between second-stage and first-stage of labour primary caesarean deliveries at MTRH.
3. To compare adverse perinatal outcomes between second-stage and first-stage primary caesarean deliveries at MTRH.

## 1.6 Conceptual framework

The conceptual framework of the study was based on how independent variables highlighted together with patient demographic and obstetric characteristics interact to affect maternal and foetal outcomes.



**Figure 1: Conceptual Framework of the Study**

## CHAPTER TWO

### 2.0 LITERATURE REVIEW

#### 2.1 Definition of caesarean delivery

A caesarean delivery is defined as a surgical procedure in which an incision is made through abdomen and uterus to deliver a foetus. Caesarean delivery may also be termed caesarean birth, caesarean section, C-section, CS.

#### 2.2 Caesarean delivery in history

The early history of caesarean section remains masked in myth and is of uncertain accuracy.

It is commonly thought the term “caesarean” originates from the Roman emperor Julius Caesar (100-44 BC). The origin of the word is more complicated as Julius Caesar himself was almost certainly not born by caesarean delivery. His mother is known to have survived well into his adulthood. As such this origin of the word caesarean serves as an example of false etymology – a common misbelief about the origin of a word.

There is a high likelihood that the term originates from the Ancient Roman law the “Lex Cesare” which permitted surgical birth, after maternal death during or prior to childbirth. The term has been described in many historical societies as a means of maintaining population numbers (Low, 2009). The Latin word for cut is “caesus” giving another potential source for caesarean delivery and caesarean section. The Latin verb “caedere” translates as to chop or cut into pieces. The term “section” has its origins in the Latin verb “secare” meaning “to cut”. For comprehensiveness, “delivery” has its origins in the old French word “delivrer”, itself having its origins in the Latin word “deliberare”, meaning to set free.

As noted, caesarean section was historically performed if the parturient was dying or had died prior to childbirth; as a way to save the foetus. There were also religious laws prohibiting burying of a foetus in utero (Lurie, 2005; Todman, 2007).

The first documented successful caesarean delivery, was performed in Switzerland in the year 1500, by a sow gelder, Jacob Nufer. He performed the operation on his wife. The caesarean baby lived to be seventy-seven years old. Since this narrative was not recorded until eighty-two years later historians question its accuracy (Boley, 1991).

The success of caesarean delivery is defined from the outcome that the mother and foetus will survive for at least a month postoperatively. Successful caesarean delivery was performed internationally for the first time between 1826-1879, with one exception in 1792 when a caesarean delivery was performed in the Netherlands on a woman with a deformed pelvis (Van Dongen, 2009).

Francis Rousset is credited as the first writer, to advocate the performance of Caesarean section in living women, in 1581 (Rousset). The phrase Caesarean section was first used by Guillimeau in 1598 (O'sullivan, 1990); however, the term Caesarean operation was more common until the latter part of the 19th century.

### **2.3 Caesarean delivery rates worldwide**

A substantial proportion of women giving birth undergo emergency or elective caesarean delivery. Worldwide, there are about 18.5 million caesarean deliveries performed each year (Gibbons et al., 2010). Caesarean delivery rates vary among countries, ranging from 0.4 to 40 percent.

During the past decades caesarean delivery rates have increased worldwide, in Kenya, this rate slightly more than 25% in urban areas (Van Der Spek et al., 2020). In 1985 the World Health Organization (WHO) stated: "There is no justification for any

region to have caesarean delivery rates higher than 10-15%” (Gibbons et al., 2010). A WHO report from 2015 states that countries with caesarean delivery rates below 10% are considered underusing, while countries with rates above 15% are considered to overuse (Organization, 2015).

Countrywide variations in caesarean delivery rates are attributed to a number of factors, including differences in the availability and training of midwives and nurses, financial incentives, malpractice liability concerns, and the proportion of women who access private maternity care. For example, in Kenya there is evidence that private hospitals tend to perform more caesarean sections than public hospitals (Van Der Spek et al., 2020). Women in the age group 35-40 are also three times more likely to deliver by caesarean delivery than those in the 20-25 year age group (Herstad et al., 2016)

#### **2.4 Indication for primary caesarean delivery**

The overall aim for performing caesarean delivery is providing rescue from immediate threat to the life of mother and/or foetus. A caesarean delivery may be performed within different time frames depending on degree of urgency (and institutional protocols), from decision to action, that is; urgent, emergency or elective (Torloni et al., 2011; Women's & Health, 2011). Caesarean delivery indications vary from absolute medical indications such as uterine rupture, antepartum hemorrhage , placental abnormalities, multiple pregnancy or foetal malpresentation, obstructed pelvis, acute foetal distress, protracted labour, maternal/foetal diseases, to relative indications including maternal request (Tita, 2012).

A recent systematic review and meta-analysis aimed to estimate the prevalence, indication, and outcomes of caesarean section in Ethiopia showed cephalopelvic



disproportion [18.13% (95%CI: 12.72–23.53)] was the most common indication of caesarean delivery followed by non-reassuring foetal heart rate pattern [19.57% (95%CI: 16.06–23.08)] (Gedefaw et al., 2020).

A review of 1920 caesarean deliveries performed at Moi Teaching and Referral Hospital (MTRH), Eldoret, Kenya, in 2014 demonstrated the following: The most common indication for primary caesarean delivery was foetal distress 168 (43.8%). Among the maternal indications of caesarean section previous caesarean delivery accounted for 168 (43.8%) followed by poor progress at 58 (15.1%) (Kagoni et al., 2017).

## **25 Commonly accepted caesarean delivery indications in second-stage of labour include:**

### **2.5.1 Non-reassuring foetal status or foetal distress**

Non-reassuring foetal status (NRFS) is a term used to describe suspected foetal hypoxia. It is meant to substitute the more general term “foetal distress.” Foetal distress, is a term that is used to indicate changes in foetal heart patterns, foetal growth restriction, reduced foetal movement and presence of meconium stained liquor. It may be described as progressive foetal hypoxia and/or acidemia secondary to insufficient foetal oxygenation. Optimum delivery is within 30 minutes of making a diagnosis (James, 2001).

Current available methods of evaluating foetal distress are not accurately predictive for the definite foetal compromise. It has been suggested that continuous electronic foetal monitoring has led to a rise in the caesarean delivery rate for foetal distress without significantly improving perinatal mortality. A meta-analysis of electronic foetal heart rate monitoring versus intermittent auscultation reported a higher

caesarean section rate for continuous monitoring with no reduction in perinatal mortality (Vintzileos et al., 1995). The article however noted that there was a reduction in deaths attributed to hypoxia and also less neonatal seizures in the continuous foetal monitoring group.

### **2.5.2 Prolonged second-stage**

According to the American College of Obstetricians and Gynecologists (ACOG) ("ACOG Practice Bulletin Number 49, December 2003: Dystocia and augmentation of labour," 2003):

When the following times are exceeded without continuing progress, the risks and benefits of allowing labour to continue should be assessed and operative delivery considered: Nulliparous: 3 hours with a regional anesthetic or 2 hours without a regional anesthetic. Parous: 2 hours with a regional anesthetic or 1 hour without a regional anesthetic.

This definition diagnoses 10% to 14% of nulliparous and 3% to 3.5% of multiparous women as having a prolonged second-stage. Although current labour norms remained largely based on data established by Friedman in the 1950s, modern obstetric population and practice have evolved with time (Cheng & Caughey, 2017).

### **2.5.3 Labour dystocia**

Labour dystocia is defined as difficult labour or abnormally slow labour progression. Other terms that are often used interchangeably with dystocia are dysfunctional labour, poor progress labour (lack of progressive cervical dilatation or lack of descent), and cephalopelvic disproportion (CPD).

Labour dystocia encompasses a variety of concepts, ranging from “abnormally” slow dilation of the cervix or descent of the foetus during active labour to entrapment of the foetal shoulders after delivery of the head (shoulder dystocia).

Friedman's original research in 1955 defined the following three stages of labour (Friedman, 1955):

1. The first-stage starts with uterine contractions leading to complete cervical dilation and is divided into latent and active phases. In the latent phase, irregular uterine contractions occur with slow and gradual cervical effacement and dilation. The active phase is demonstrated by an increased rate of cervical dilation and foetal descent. The active phase usually starts at 3-4 cm cervical dilation and is subdivided into the acceleration, maximum slope, and deceleration phases.
2. The second-stage of labour is defined as complete dilation of the cervix to the delivery of the infant.
3. The third stage of labour involves delivery of the placenta.

Contemporary data suggest that the duration of labour is longer today than in the past (El-Sayed, 2012). For both nulliparous and multiparous women, labour may take longer than 6 hours to progress from 4 cm to 5 cm and longer than 3 hours to progress from 5 cm to 6 cm of dilation. Cervical dilation of 6 cm appears to be a better landmark for the start of the active phase. The 95th percentile for duration of the second-stage in a nulliparous woman with conduction anaesthesia is closer to 4 hours (Zhang et al., 2010).

Obstetric society guidelines as well as institutional protocol contain varied proponents of diagnosis of labour dystocia. They describe a strict criteria to diagnose poor progress labour coupled with interventions such as early amniotomy, judicious use of

oxytocin with adequate monitoring to promote progression of labour and eventual delivery (Richards, 1977). However if the above fails caesarean section is usually indicated (Stanton & Holtz, 2006).

#### **2.4.4 Umbilical cord prolapse**

In overt umbilical cord prolapse, the cord slips ahead of the presenting part of the foetus and protrudes into the cervical canal or vagina, or beyond. It is an obstetrical emergency because the prolapsed cord is vulnerable to compression, umbilical vein occlusion, and umbilical artery vasospasm, which can compromise foetal oxygenation. In occult umbilical cord prolapse, the cord slips alongside, but not ahead of, the presenting part. The occult prolapsed cord is also vulnerable to compression and its sequelae. Membranes are usually ruptured in both settings.

#### **2.4.5 Failed instrumental delivery**

Instrumental delivery is used to achieve or expedite safe vaginal birth for maternal or foetal indications. Examples include maternal exhaustion and an inability to push effectively; medical indications such as maternal cardiac disease and a need to avoid pushing in the second-stage of labour; prolonged second-stage of labour, arrest of descent, or rotation of the foetal head; and nonreassuring foetal heart rate patterns in the second-stage of labour.

There are two main instruments used in operative deliveries – the ventouse and the forceps. The choice is operator dependent, but forceps tend to have a lower risk of foetal complications, and a higher risk of maternal complications.

Data suggests that between 5 and 20% of infants are delivered by instrumental (operative vaginal) delivery in developed countries (Majoko & Gardener, 2012).

Overall, approximately 5–10% of attempted instrumental deliveries will fail (Schiff et al., 2001).

An unsuccessful instrumental delivery is defined as a delivery where an instrument was applied to the foetal head but was unable to achieve a vaginal birth. The common rule is, if after three contractions or pulls with any instrument there is no reasonable progress, the attempt should be abandoned.

#### **2.4.6 Malposition**

Foetal malposition occurs when the occiput of foetuses who are in vertex presentation is rotated so that it is not oriented anteriorly in the maternal pelvis. Vaginal delivery is most common when cephalic foetuses are both vertex (not deflexed) and occiput anterior position. When a cephalic foetus is in the occiput transverse or occiput posterior position it is considered to have foetal malposition.

The foetal occiput can be either in anterior [occiput anterior (OA)], posterior [occiput posterior (OP)], or transverse position [occiput transverse (OT)]. The foetus in a transverse position can be further specified relative to either maternal left (L) or right (R) side, so LOT or ROT. Further, if the presentation is between LOT and OA on the left side of the maternal pelvis it is described as left occiput anterior (LOA). A foetal presentation between ROT and OP on the right side of the maternal pelvis is described as ROP.

The diagnosis of foetal malposition is usually made by digital vaginal examination. The smaller, triangular-shaped fontanelle is the posterior fontanelle and the larger diamond shaped fontanelle is the anterior fontanelle. If the anterior fontanelle is anterior in the pelvis, the position is termed the occiput posterior (OP) position.

Persistent occiput posterior position (OP) is the most common malposition at delivery, with an incidence ranging between 2% and 13% (Caughey et al., 2015).

The 10-group classification system, known as the Robson classification has been developed to compare caesarean deliveries across hospitals. To categorize women according to the Robson classification (Robson, 2001), see Table 1

**TABLE 1: Robson classification**

<b>1</b>	<b>Nulliparous women with a single cephalic pregnancy, at greater than or equal to 37 weeks gestation in spontaneous labour</b>
<b>2</b>	Nulliparous women with a single cephalic pregnancy, at greater than or equal to 37 weeks gestation who either had labour induced or were delivered by caesarean section before labour
<b>3</b>	Multiparous women, without a previous uterine scar, with a single cephalic pregnancy at greater than or equal 37 weeks in spontaneous labour
<b>4</b>	Multiparous women, without a previous uterine scar, with a single cephalic pregnancy at greater than or equal to 37 weeks gestation who either had labour induced or were delivered by caesarean section
<b>5</b>	All multiparous women, with at least one previous uterine scar and a single cephalic pregnancy at greater than or equal to 37 weeks gestation
<b>6</b>	All nulliparous women with a single breech pregnancy
<b>7</b>	All multiparous women with a single breech pregnancy including, women with previous uterine scars
<b>8</b>	All women with multiple pregnancies, including women with previous uterine scars
<b>9</b>	All women with a single pregnancy with a transverse or oblique lie, including women with previous uterine scars
<b>10</b>	All women with a single cephalic pregnancy at less than or equal to 36 weeks gestation, including women with previous scars

## **2.6 Physiology of second-stage of labour**

The second-stage of labour begins with full dilatation of cervix and ends with delivery of the foetus. The transition from the first stage to second stage of labour is characterized by complete dilatation of cervix as evident by vaginal examination, initiation of bearing down effort, crowning of the head, urge to defecate during contraction when head presses the rectum, anal dilation during uterine contraction or early deceleration in foetal heart rate suggesting foetal head compression.

Second-stage of labour comprises two phases. Firstly, the pelvic phase or phase of descent, which is considered as an extension of first-stage until pushing starts. It starts with full dilatation of the cervix before or in the absence of involuntary expulsive contractions and ends when the head reaches the pelvic floor that initiates the 'bearing down efforts. Rapid descent of the presenting part of the foetus takes place. This phase does not put an extra stress on the foetus and assessment of foetal heart rate may be done at the same frequency as is done in the first-stage of labour. As cervical assessment is done 2 hourly, the beginning of this phase is difficult to define accurately. This may lead to misinterpretation of the duration of second-stage of labour.

Second phase is perineal phase or phase of expulsion. The second phase starts with the beginning of 'bearing down' efforts and ends with the delivery of the foetus. Normally uteroplacental perfusion and foetal oxygenation start to deteriorate, only when active pushing commences. Thus, undue prolongation of this phase of labour may result in foetal hypoxia. During second stage, uterine contractions are more frequent, more intense and they last longer. During descent of the presenting part, the resistance offered by the soft tissue and elastic recoil offered by

pelvic floor, is overcome by strong uterine contractions and retraction and the bearing down effort of the mother.

## **2.7 First-stage caesarean delivery technique**

### **2.7.1 Caesarean delivery personnel**

The primary personnel involved in a caesarean delivery procedure comprise a coordinated team with distinct roles. At the core of this team is the primary surgeon, who may be an obstetrician/gynecologist in training (registrar year 1-year 4), an obstetrician/gynecologist consultant, or a medical officer intern rotating in reproductive health, under supervision of a registrar or consultant. Assisting the surgeon could be an obstetrician/gynecologist registrar, medical officer intern, medical student rotating in reproductive health, a trained perioperative nurse or perioperative nurse student. The anaesthesia team, includes an anaesthesiologist and/or a nurse anaesthetist, and they ensure the patient receives analgesia, manage the patient's airway, and monitors vital signs, surgical blood loss, and urine output. The surgical team is complemented by the scrub nurse or technician, traditionally responsible for supplying necessary instruments but available to assist the surgeon when necessary. The circulating nurse, a non-sterile team member, retrieves additional equipment, documents procedures, and enhances patient safety, often collaborating closely with the scrub nurse. Another critical role is the healthcare professional caring for the neonate, responsible for initial resuscitation, assessment, and ensuring the newborn's warmth and well-being. In cases involving preterm infants or caesarean indications with high likelihood of neonatal resuscitation (e.g. foetal distress, pregnancy induced hypertension with foetal compromise, cardiac disease in pregnancy), additional staff from the newborn unit, such as a registrar or medical



officer in the paediatrics department, are alerted and are involved in receiving the newborn.

In the event of a challenging caesarean delivery or complication, the surgeon contacts the third on-call consultant obstetrician-gynecologist. A comprehensive briefing is provided to the consultant, outlining the specific issues and concerns encountered during the procedure. Subsequently, the consultant promptly arrives to lend their expertise and assistance in managing the situation effectively.

### **2.7.2 Surgical technique**

Different techniques are used to perform caesarean deliveries, with some having been evaluated through randomized clinical trials. Abdominal surgical incisions used in caesarean delivery fall into 2 categories:

- (1) Vertical Incision (Midline, Paramedian);
- (2) Transverse Incision (Pfannenstiel, Pelosi Maylard, Cherney and Joel-Cohen).

Each of these techniques has specific advantages, while suffering from different disadvantages. However, the Joe-Cohen method is the recommended technique by the WHO (Abalos et al., 2016).

**Pfannenstiel Incision Technique:** The Pfannenstiel incision technique was introduced by Pfannenstiel in 1900. This technique is a curvilinear incision (10-15 cm) just above the pubic symphysis in which the rectus and fascia sheaths are incised separately (Stark et al., 1995).

**Joel-Cohen-based Technique:** The Joel-Cohen-based technique was introduced for performing abdominal surgery by Professor Joel Cohen in 1974. This technique has been widely used for caesarean delivery ever since. It has gone through many modifications over time.

The modified form of this technique, known as Misgav Ladach, was introduced by Professor Michael Stark in 1998 (Ferrari et al., 2001). This technique involves a straight transverse incision located 3 centimetres above the symphysis pubic and below the anterior superior iliac spines (above the Pfannenstiel incision). The tissues and fascia are spread apart about 2 to 3 centimeters in the midline, where it is free of large blood vessels and the incision is more broadened with 2 fingers (a blunt dissection). Then, the vertical rectus muscles are separated, the peritoneum is opened transversely with fingers. After the baby and placenta are extracted, the womb is sewn by single-layer suturing. However, the parietal and visceral layers of the peritoneum are not sutured (Ferrari et al., 2001).

A commentary from the WHO Reproductive Health Library (Abalos et al., 2016) covering two Cochrane reviews (Hofmeyr et al., 2008) report that there are advantages for Joel-Cohen compared to the previously used Pfannenstiel incision with less postoperative morbidity, less need for analgesia, less blood loss, shorter surgery/delivery time and shorter hospital stay.

### **2.7.3 Intrathecal anesthesia**

Spinal anesthesia is the method of choice for caesarean delivery. If an elective caesarean delivery, a majority of women undergo the surgery with intrathecal anesthetic techniques, mostly spinal anesthesia with local anesthetics and today often with addition of an opioid (Lavoie & Toledo, 2013). General anesthesia is mainly used when under time pressure (e.g. foetal distress) or due to medical contraindications to intrathecal anesthesia. The epidural and spinal techniques are known as regional techniques because pain relief is limited to a certain anatomical region. One substantial benefit of intrathecal anesthesia is a conscious mother who has the possibility to have skin-to-skin contact with the baby immediately after the

baby is born and the relatively small doses of anesthetics needed. Intrathecal anesthesia is also a good start of effective pain relief, in combination with other drugs in the immediate postoperative period (Seal et al., 2010).

#### **2.7.4 Local surgery routines: pre-, peri- and postoperatively**

Preparations for caesarean delivery in our setting follow strict procedures and premedication is normally given.

Preoperative preparation practice done involves the placement of indwelling urinary catheter prior to caesarean section. Reasons for placement include better bladder exposure during surgery, decreased risk of intraoperative injury to the urinary system, urinary output assessment and prevention of postoperative urinary retention (Ghoreishi, 2003).

According to local routines, all patients receive a standardized intrathecal injection with bupivacaine (Marcain®) followed by fentanyl (Fentanyl®). The initial step in skin preparation involves the implementation of a "pre-surgical procedural cleansing" of the abdominal area, which consists of employing ordinary soap and water followed by the application of an antiseptic agent. Subsequently, an aseptic cleansing process is carried out using Iodophores like polyvinyl pyrrolidone (povidone-iodine) and chlorhexidine gluconate (at a concentration of 0.5% in a 70% propyl alcohol solution).

Caesarean delivery is then performed (as elaborated in **2.6.2** surgical technique).

Skin-to-skin contact between mother and child is initiated as early as possible, often in PACU (post anaesthesia care unit). The mother stays in PACU until full recovery from the intrathecal injection and pain is manageable, usually about two hours for uncomplicated caesarean deliveries.

Pain management is a key aspect of post-operative care. A regimen of routine analgesics is administered on a fixed schedule, including opioids, aceclofenac, and paracetamol for specific durations. Pain self-assessment is regularly conducted, adhering to established obstetric guidelines.

Thromboprophylaxis with low molecular-weight heparin is not routine for uncomplicated caesarean deliveries but is prescribed in specific circumstances, including caesarean deliveries with hysterectomy, a history of deep vein thrombosis, or the presence of multiple thromboembolic risk factors.

Intravenous fluid infusion includes the administration of glucose and Ringer lactate on Day 0 post-operation.

Mobilization starts from approximately 5-6 hours after surgery by, standing next to bed and walking around in the room.

Post-operative feeding recommendations vary based on the type of anaesthesia and the complexity of the caesarean delivery. Patients under spinal anaesthesia may resume fluids after 2 hours, while those under general anaesthesia may do so after 4 hours. For uncomplicated caesarean delivery, a light meal may be given 6 hours post-operatively, with no need to wait for the passage of gas.

The urinary catheter is typically removed 6 hours post operatively, unless specific conditions warrant its retention, such as blood-stained urine upon removal, low urine output, or peri/post-operative complications.

Dressing and suture management involve uncovering the wound on Day 2 post-operation. Skin sutures are usually absorbable.

Hygiene practices entail a simple shower, with no intravaginal cleansing required.

Initiation of breastfeeding is encouraged as soon as possible, with vigilant monitoring of the neonate for signs of drowsiness if the mother has received tramadol or morphine.

Finally, thorough documentation is maintained, including an operative report and, upon discharge, providing the patient with a document specifying the reasons for the caesarean delivery and the type of hysterotomy performed, which aids in determining the mode of delivery for potential subsequent pregnancies.

Normally the patient is discharged from hospital 2 days after a caesarean delivery. Pre-,peri- and postoperative routines are based on evidence and follow such recommendations as stated by MTRH management protocol.

## **2.8 Second-stage caesarean delivery techniques**

The techniques used to perform caesarean deliveries in the second-stage of labour are similar to those adopted in the first-stage of labour. In scenarios where the foetal head is deeply impacted (which may occur in first-stage but commonly occurs in the second-stage of labour), the following manoeuvres are known as alternatives to the standard vertex extraction of the deeply impacted foetal head (Fong & Arulkumaran, 1997; Saha, Gulati, Goel, Tandon, & Huria, 2014).

- 1) In the "push method," the surgeon extracts the foetal head from the pelvis through the uterine incision while simultaneously assisted by pushing the foetal head cephalic through the vagina. Pressure on the foetal head should be widely distributed using cupped fingers or the palm to minimise the risk of injury to the skull.
- 2) In the "pull technique" or "reverse breech extraction method," the surgeon inserts a hand locating both feet and gently pulls them to extract the foetus by its breech.

When the reverse breech extraction method is planned, a low vertical uterine incision or high transverse incision can facilitate this manoeuvre. If a low transverse incision was initially made, it may be necessary to extend it to a 'T' or 'J' uterine incision. This procedure is performed with ease when the foetus is in the occiput posterior position, as the lower limbs are most accessible. The foetal head will also naturally flex in this position during caesarean delivery. Performing the reverse breech extraction method is more difficult when the foetus is in the occiput anterior position; this is due to the foetal back dominating the area of exposure. As a result, the superior foetal arm must first be released; then, the foetus has to be rotated laterally - to create room to access the lower limbs; the lower limbs are then both delivered in a controlled delivery. Finally, the inferior arm is released.

- 3) The Patwardhan technique (shoulder first technique), in case of occipital-transverse or occipital-anterior positions with the head deeply impacted in the pelvis, an incision is made in the lower uterine segment, at the level of the anterior shoulder, which is delivered out. The posterior shoulder is also delivered with gentle traction on this shoulder. Next, the surgeon hooks the fingers through both the axillae and with gentle traction, aided by fundal pressure applied by an assistant, the foetus's body is brought out of the uterus. The baby's head, the only part of the foetus still inside the uterus, is gently lifted from the pelvis. This technique was originally described in 1957 in India by Patwardhan BD (Patwardhan & Motashaw, 1957).

A meta-analysis conducted in 2015 (of majorly observational studies) compared caesarean delivery techniques in the second-stage of labour. In the six studies (n = 455) examining the primary outcome, the evidence gathered suggested that the

'reverse breech extraction' method, when compared to the 'push' method, is associated with significantly lower risks of uterine incision extension, mean blood loss, operative time and infection. However, the evidence to support the 'Patwardhan' method was inadequate (Jeve et al., 2016).

A systematic review and meta-analysis in 2022 compared the maternal and neonatal outcomes of caesarean delivery techniques in an impacted foetal head. Nineteen studies (n = 2,345) were analysed, the meta-analyses demonstrated that the 'reverse breech extraction' method is associated with lesser risks when compared to the 'push' method, and the 'Patwardhan' technique is safer than the 'push' or the 'reverse breech extraction' method (Rada et al., 2022).

### **2.8.1 Foetal head elevator devices (FHED).**

Obstetric and gynaecological devices classified as foetal head elevators are a group of instruments developed over the last ten years to assist in the dis-impaction of the foetal head. The premise is that most second-stage caesarean delivery complications result from foetal head impaction into the maternal pelvis.

The published evidence of foetal head elevator efficacy is still scarce. Some of these devices include:

- **The Foetal Pillow**

Also termed the "foetal dis-impacting system", the foetal pillow is a single-use disposable silicone device consisting of a foldable base plate, with a balloon. Just before the caesarean delivery, the base plate is inserted into the vaginal orifice and applied to the foetal head. It is then insufflated with normal saline solution, which allows an elevation of the foetal head to about 3–4 cm from the original position. This aids in dis-impaction, making foetal delivery easier. The balloon is deflated upon

the foetus's delivery and pulled out by hooking one's finger into the base plate. Some studies suggest that the use of the foetal di-simpacting system reduces maternal trauma, vaginal and uterine tears in second-stage caesarean deliveries (Seal et al., 2016).

A large RCT (n=471) was designed to investigate if the use of the foetal pillow in second-stage caesarean delivery in reducing blood loss, need for blood transfusion as well as the duration of hospital stay did not demonstrate any significant benefit of its use compared to when it was not used (Sacre et al., 2021).

- **Coyne spoon assisted delivery, Selheim spoon and the Murless head extractor.**

These devices function as an obstetric 'shoe horn'. They take up less space than the obstetrician's hand and are slipped through the uterine incision and below the foetal head. They are easier to cup onto an impacted head.

The spoon is utilised to aid in dis-impacting and elevating the foetal head from the maternal pelvis during delivery, and the subsequent delivery of the foetus proceeds through the conventional method using the spoon. Care must be taken in lifting the handle cephalad or vertically relative to the mother, rather than forcing it caudad to avoid bladder injury (maternal) and to minimise uterine incision extension.

Whereas there are theoretical benefits to using these instruments, there isn't enough data demonstrating their effectiveness or safety in controlled studies with meaningful endpoints.



- **The Tydeman Tube**

The Tydeman Tube, developed by Guys and St. Thomas' National Health Service (NHS) Hospital Trust and Victoria Hospital (NHS Fife) is a sterile, single-use silicone tube with a rounded cup at one end. The cup contains four pads to minimize point pressure and foetal trauma. The selected silicones provide stability and some flexibility for manipulation, while being biologically inert. The tube has a slight curvature, and the rounded cup is positioned at a 45-degree angle, facilitating easy insertion and encouraging deep placement below the foetal head. If the foetal head is believed to be impacted, the tube can be placed in the vagina prior to surgery or inserted if difficulties arise. The design allows the surgeon's fingers to easily pass between the cup and the foetal head for delivery. The hollow tube also permits air entry into the vagina, potentially releasing any vacuum. In an ex-vivo experimental evaluation, the device showed effectiveness in delivering impacted foetal head (on simulator) (Vousden et al., 2017).

## **2.9 Short-term Complications of Caesarean Delivery**

When compared to vaginal delivery, caesarean delivery is associated with higher rates of surgical complications and maternal re-hospitalization, as well as with complications that require neonatal intensive care unit admission. Hospital charges for a caesarean delivery were reported as almost double those for a vaginal delivery (Menacker, 2010).

The recorded incidence of complications of caesarean deliveries varies by method of data collection: population studied, time to follow-up and definitions of complications adopted (Table 2).

Evidence of maternal complications related to caesarean delivery is largely based on observational studies.

### **2.9.1 Intraoperative Surgical Complications**

Acknowledged intraoperative surgical complications include damage to adjacent organs, including the urinary tract, bladder, and bowel, and unintentional damage to the uterus or cervix. According to Bergholt et al., in their study in Denmark (n=7,782), one or more of these complications occurred in approximately 12.1% of caesarean deliveries (Bergholt et al., 2003).

In a review of the US Maternal-Foetal Medicine Units (MFMU) Network publications, a surgical injury (i.e broad ligament hematoma, bowel injury, cystotomy, ureteral injury) occurred in 0.2 - 0.5% of women undergoing a primary caesarean delivery (Hammad et al., 2014). In another US study of about 30,000 primary and repeat caesarean deliveries, the lower urinary tract injury rate was 0.27% ; 3% were ureteral, and the rest were full or partial thickness bladder injuries (Oliphant et al., 2014). In that study, the risk of cystotomy was higher for second-stage caesareans compared to first-stage caesarean deliveries.

In a prospective observational study of 2,751 caesarean deliveries, intra-operative complications, including lacerations of the cervix, vagina and bladder, increased with advanced cervical dilatation (Häger et al., 2004; Lurie et al., 2014)

A retrospective study of intraoperative and post-operative maternal complications of caesarean delivery during a 10-year period in Europe indicates an overall maternal intraoperative complication rate of 14.8%. The most common complication was laceration of the uterus corpus 10.1%. For those undergoing an emergency caesarean birth, factors associated with an increased risk of complications include the relationship of the presenting part to spines, previous surgery, labour before caesarean

delivery, prematurity, ruptured membranes before caesarean delivery as well as the skill level of the surgeon (Nielsen & Hökegård, 1984).

### **2.9.2 Blood Loss & Transfusion**

The average estimated blood loss during caesarean delivery is around 1000 mL, and roughly 18% of initial caesarean births involve a calculated blood loss of over 1500 mL. However, the accuracy of estimated blood loss is limited (Larsson et al., 2006; Schorn, 2010).

In the MFMU network review of prospective studies of over 70,000 caesarean deliveries, 2-4% of women undergoing primary caesarean required blood transfusion. In this review, haemorrhage resulted from various causes, including uterine atony, placenta accreta spectrum, extensive myometrial injury, and extension of the incision into uterine vessel (Hammad et al., 2014).

In a population based register study in Norway, risk of severe obstetric haemorrhage (defined as blood loss of 1000 ml or more) was three-fold following emergency caesarean delivery compared with vaginal delivery (AlZirqi, Vangen, Forsen, & Stray Pedersen, 2008).

Complications detailed after caesarean delivery may result from underlying maternal conditions resulting in a caesarean delivery, and not from the procedure per se. Preeclampsia increases the risk of haemorrhage and thromboembolism (Hoxha et al., 2017; Lindqvist, Dahlbäck, & Marşál, 1999). Chronic hypertension, diabetes and multiple births are all risk factors for severe sepsis . Dystocia and high birth weight are related to uterine atony and blood loss (Häger et al., 2004).

According to Van Ham et al, caesarean delivery carried an overall maternal post-operative morbidity rate of 35.7%, fever (24.6%), blood loss between 1000ml and

1500ml 4%, hematoma 3.5% (Van Ham et al., 1997). Second-stage caesarean delivery has been associated with higher risk of intensive care unit (ICU) admission, blood transfusion and infectious morbidity.

### 2.9.3 Local data on complications

Review of the caesarean sections performed at Moi Teaching and Referral Hospital (MTRH), Eldoret, Kenya, in 2014 reported the most common complications of caesarean delivery as post-partum haemorrhage at 13.6% and neonatal iatrogenic prematurity at 70% (Kagoni et al., 2017) .

Another retrospective study performed on the trends of caesarean delivery over a 10–year period at Ilorin, Nigeria showed the common causes of caesarean delivery related maternal mortality were sepsis, 31.0%, hemorrhage, 27.6%, anesthesia, 13.8% and embolism at 13.6% . There were 29 and 12 maternal deaths following caesarean delivery and vaginal delivery respectively (Ijaiya & Aboyeji, 2001).

**Table 2: General complications of delivery by caesarean delivery\***

<b>Complications</b>	
<b>Intraoperative complications</b>	Organ injury (bladder, intestines, ureter, etc.) Risks associated with anesthesia Need for blood transfusions Hysterectomy as a treatment for severe bleeding, e.g. from placenta praevia
<b>Postoperative complications</b>	Thromboembolic complications (embolism, thrombosis) Adhesions Persistent pain
<b>Risks for subsequent pregnancies</b>	Intrauterine growth retardation and preterm delivery Spontaneous abortion Ectopic pregnancy Stillbirth Uterine rupture Infertility Placenta previa, increta, or accreta and associated risks e.g., need for blood transfusion or hysterectomy

\*It is not possible to give accurate estimated prevalences owing to differences between patient groups studied, study endpoints, and various medical and socioeconomic factors.

#### **2.9.4 Maternal mortality**

Maternal mortality has been defined by World Health Organization (WHO) as the death of a woman while pregnant or within 42 days of the termination of pregnancy irrespective of the duration and site of the pregnancy for any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes (Gabel & Weeber, 2012).

Maternal mortality following caesarean delivery is rare in developed countries. For example, in the US surgical maternal mortality is 13 per 100,000 caesarean deliveries (Clark et al., 2008) and 8 per 100 000 caesarean deliveries in the UK (Chan et al., 2009).

A significant proportion of these caesarean morbidities and mortalities are related to the underlying factors, both medical and obstetric that dictate the delivery.

Within LMICs, caesarean related maternal mortality is high. A systematic review in 2019 (largest study to date) that included approximately 3 million caesarean deliveries in LMICs reported surgical maternal mortality of 760 per 100,000 procedures; the highest burden being in sub-Saharan Africa (1090 maternal deaths per 100,000 procedures (Sobhy et al., 2019). Moreover, 23.8% of all maternal deaths in LMICs were in women who had undergone caesarean delivery (95% CI 21.0–26.7;  $\tau^2=0.62$ ). Failure to progress was the most frequent indication for caesarean delivery in cases of maternal death, constituting 25% of the procedures. Postpartum haemorrhage was most common cause of death, accounting for one-third of all maternal deaths.

The study authors noted a significant proportion of maternal deaths in countries with low rates of caesarean delivery, indicating that minimal access to the procedure may be an indicator of inadequate specialized medical personnel, blood products, and or other critical care resources necessary to prevent these mortalities. The authors also highlighted inadequate antenatal care, insufficient resources for indicated caesarean delivery, and delayed referral of patients having obstructed labour as contributing factors to high maternal mortality rates.

## **2.10 Neonatal Complications associated with Caesarean Delivery.**

### **2.10.1 Admission into NBU and NICU.**

Admission into neonatal intensive care unit (NICU) is a potential complication of caesarean delivery, especially in emergency situations. A retrospective chart review of 2,595 caesarean deliveries in Jordan conducted by Khasawneh et al. in 2020 demonstrated a rate of NBU admission of 43% among emergency caesarean deliveries (Khasawneh et al., 2020). Several factors were identified that increase the risk of NICU admission in infants delivered by caesarean section. These included grandmultiparity (having given birth five or more times), gestational diabetes, maternal employment, prolonged rupture of membranes , foetal distress, prematurity, low birth weight (weight less than 2,500 grams at birth), high order multiple gestation (when a mother is carrying three or more babies) and low 5-min APGAR score (Khasawneh et al., 2020). Admission to the NICU often results in increased healthcare costs, prolonged hospital stays, and stress for both the infant and their family.

### **2.10.2 Neonatal trauma**

Neonatal trauma, a rare but serious complication of caesarean delivery, is characterized by abrasions or lacerations experienced by the baby during the procedure.

Abrasions and lacerations to the foetus sometimes may occur as scalpel cuts during caesarean delivery. Infection remains a risk, but most of these lesions uneventfully heal

According to a study by Alexander et al, neonatal trauma complicates around 1.1% of all caesarean deliveries (Alexander et al., 2006). The frequency of foetal injury at caesarean delivery varies with the indication for surgery as well as with the duration of the skin incision-to-delivery interval and the type of uterine incision.

Neonatal trauma can range from mild abrasions or lacerations that may heal without medical intervention to more severe injuries that require suturing or other treatments. Although most lesions uneventfully heal, infection remains a risk and parents should monitor their newborns for signs of infection or complications.

### **2.10.3 Birth asphyxia**

Asphyxia is an impairment of gas exchange, leading to hypoxia, hypercarbia, and acidosis depending on severity and duration. Birth asphyxia, or impaired gas exchange during perinatal period, has no specific biochemical criteria (Rainaldi & Perlman, 2016). Birth asphyxia results from insult to the newborn or foetus from failure to breath or poor breathing resulting in decrease oxygen perfusion to organs.

Caesarean delivery has been associated with an increased risk of birth asphyxia compared to vaginal delivery likely due to the lack of physiological stimulation of the baby during a caesarean, which helps to initiate the respiratory and circulatory

systems and thus prevent asphyxia. A systematic review and meta-analysis of the risk factors associated with birth asphyxia among neonates delivered in Ethiopia found that birth asphyxia was more than four times more likely to occur among women delivering by caesarean than in vaginal birth (Ahmed et al., 2021).

Four million deaths occur annually due to birth asphyxia, accounting for 38% of all deaths of children under 5 years. In low-income countries, a quarter of all neonatal deaths occur due to birth asphyxia (WHO, 2012).

The APGAR is a scaled rating system that was developed by Dr Virginia Apgar during the 1950s to assess the new-born's need for life support.

The APGAR score parameters include: new born heart rate, respiratory effort, muscle tone, reflex irritability and, color. A score of 0, 1, or 2 is assigned for each of the five elements. **Table 3**

**Table 3: APGAR score chart**

Sign	Score		
	0 points	1 points	2 points
Activity (muscle tone)	Absent	Arm and legs flexed	Active movement
Pulse (Heart rate)	Absent	Below 100 bpm	Over 100 bpm
Grimace (reflex irritability)	Floppy	Minimal Response to stimulation	Prompt response to stimulation
Appearance (Skin color)	Pale	Blue	Pink
Respiration	Absent	Slow and Irregular	Vigorous cry



The APGAR score is applied at 1 minute after birth of the new-born and 5 minutes, however, in some instances the new-born evaluation may continue for as long as 20 minutes when resuscitative efforts are required.

A normal APGAR scores is a score of  $\geq 7$  at 1 minute and  $\geq 8$  at 5 minutes. An APGAR score of  $\geq 7$  indicates that the new-born does not require re-evaluation. APGAR scores of between 6 and 4 indicate that new-born support is needed; scores 3 or less signal the urgent need for resuscitation (ICD-10, 2010).

A 1 minute Apgar score of 0 to 1 is not predictive of an adverse clinical outcomes or long-term morbidity as most infants, may have normal scores by 5 minutes. Combining a low 5 minute Apgar of 0 to 3 with an umbilical artery blood pH  $\leq 7.0$  increases the risk of death among infants (Casey et al., 2001).

Perinatal birth asphyxia may be classified according to the WHO - The International Classification of Diseases (ICD)10, into:

Severe birth asphyxia is when the APGAR score at 1 min is 0–3. Mild and moderate birth asphyxia is when Apgar score at 1 min is 4-7(ICD-10, 2010; Pitsawong & Panichkul, 2011).

Birth asphyxia in new-borns can result in both short and long-term neurological complications. Severe birth asphyxia has been associated with cerebral palsy, mental retardation, epilepsy as well as learning disabilities (Morales et al., 2011).

The risk factors for birth asphyxia include extremes of maternal age i.e. under 16 or over 35 years, gestational age of less than 37 weeks or more than 41 weeks, hypertensive disorders in pregnancy, diabetes mellitus, illicit substance use, antepartum haemorrhage and labour lasting more than 24 hours before spontaneous vertex delivery, caesarean delivery, pre-labour rupture of membranes, maternal

infection and anaemia during pregnancy and delivery (Antonucci et al., 2014; de Souza et al., 2016).

#### **2.10.4 Perinatal death**

LMIC's have high risks of stillbirth and perinatal deaths. In the systematic review of caesarean deliveries in LMICs as discussed prior (Sobhy et al., 2019), the rate of stillbirth among infants delivered via caesarean delivery was 56.6 per 1000 caesareans, with the highest rates observed in sub-Saharan Africa at 82.5 per 1000. The perinatal death rate for caesarean deliveries was 84.7 per 1000, with the highest rates in the Middle East and North Africa at 354.6 per 1000, followed by sub-Saharan Africa at 100.4 per 1000.

## **CHAPTER THREE**

### **3.0 METHODOLOGY**

#### **3.1 Study design**

This was a hospital-based, ambidirectional cohort study.

The starting point of the study was post-delivery, within 24hrs participant admission into the PNW. Retrospective data from medical records was collected on maternal morbidity, perinatal morbidity and mortality outcomes. All participants were followed up until discharge from the PNW for the maternal post-operative length of hospital stay outcome as well as any sub-acute complications.

#### **3.2 Study area and period**

Riley Mother and Baby Hospital (RMBH) unit at the Moi Teaching and Referral Hospital (MTRH) was the primary site of the study.

RMBH provides obstetric services within the public tertiary health-care centre with averagely 12,000 deliveries annually (MoH, 2018). From annual records data, in 2020 there were a total of 11,780 deliveries. Of these, 2882 were via emergency caesarean delivery. Caesarean deliveries done in the second-stage of labour was recorded as 87.

MTRH is located along Nandi Road in Eldoret Town, Uasin Gishu County (310 Kilometers Northwest of Nairobi). The hospital serves a population of approximately 24 Million from Western Kenya, parts of Eastern Uganda and Southern Sudan (MTRH, 2016). It is the second largest public teaching and referral hospital in Kenya. In addition, MTRH is the teaching hospital for the College of Health Sciences, Moi University. The RMBH unit is staffed by about 16 consultant obstetrician/gynecologists from both Moi University and MTRH, 45 residents/registrar and 88 nurses/midwives. The unit consist of; an antenatal ward (ANW), postnatal ward (PNW) and labour ward (LW) and two operating rooms (OR) for obstetric and gynaecological related surgical procedures.

The study was conducted over twelve months, between 1st August 2021 and 31st July 2022.

### **3.3 Target population**

Women who had undergone emergency primary caesarean delivery at MTRH-RMBH.

### **3.4 Study population**

Women who had undergone emergency primary caesarean delivery at MTRH-RMBH between 1<sup>st</sup> August 2021 and 31<sup>st</sup> July 2022

### **3.5 Eligibility criteria**

#### **3.5.1 Inclusion criteria**

- i. Age  $\geq$  18year old who had undergone emergency primary caesarean delivery performed during active phase of labour.
- ii. Singleton pregnancy.
- iii. Vertex presentation.
- iv. Term gestation (between 37 + 0 and 40 + 6 weeks).

#### **3.5.2 Exclusion criteria**

- i. History of a previous caesarean delivery.
- ii. Multiple pregnancy.
- iii. Pregnancies with known major foetal abnormalities.
- iv. High risk pregnancy i.e significant maternal disease or pregnancy complications such as, hypertension, diabetes or intrauterine growth restriction.

### 3.6 Sample size considerations

The sample size estimate for this cohort study was calculated using the formula described by Kelsey et. al., (Kelsey et al., 1996). As shown in Fig 2. Calculations were done using Windows Excel.

Two-sided significance level (Type I error rate,  $\alpha$ ) was set at 0.05, and a Type II error rate,  $\beta$  was set at 0.10.

Calculations were based on a similar study by Asicioglu (Asicioglu et al., 2014), which found the incidence of intraoperative complications as 6.0% in first-stage caesarean delivery and 25.5% in second-stage caesarean delivery. To show a similar difference, the required sample size is 55 women per group with a 1:1 ratio. Total sample size of 110 participants.

The incidence of PPH in first-stage caesarean delivery was reported to be 5.4 % and 37.5% in second-stage caesarean delivery. The required sample size is 26 women in the exposed group and 26 in the unexposed group. Total sample size of 52 participants.

A study by Cebekulu et. al., comparing neonatal outcomes in the two stages of caesarean delivery was used to estimate sample size required for the neonatal outcome objective (L. Cebekulu & E. J. Buchmann, 2006). The APGAR score  $\leq 3$  at 5min in first-stage caesarean delivery was 0.1% and 18% in second stage caesarean delivery. Using a 1:1 ratio, the required sample size is 41 women in the exposed group and 41 in the unexposed group. Total sample size of 82 participants. Using a 1:1 ratio, the required sample size is 41 women in the exposed group and 41 in the unexposed group. Total sample size of 82 participants.

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

and

$$n_2 = r n_1$$

where

$n_1$  = number of exposed

$n_2$  = number of unexposed

$Z_{\alpha/2}$  = standard normal deviate for two-tailed test based on alpha level (relates to the confidence interval level)

$Z_{1-\beta}$  = standard normal deviate for one-tailed test based on beta level (relates to the power level)

r = ratio of unexposed to exposed

$p_1$  = proportion of exposed with disease and  $q_1 = 1-p_1$

$p_2$  = proportion of unexposed with disease and  $q_2 = 1-p_2$

$$\bar{p} = \frac{p_1 + rp_2}{r+1} \quad \text{and} \quad \bar{q} = 1 - \bar{p}$$

## Figure 2: Formula used for sample size calculation

In the same study, admission into NBU in first-stage caesarean delivery was reported as 8% in first-stage caesarean delivery and 44% in second-stage caesarean delivery. The required sample size is 24 women in the exposed group and 24 in the unexposed group. Total sample size of 48 participants.

There are uncertainties with respect to the incidence second-stage caesarean delivery. Reported literature of rate ranges from 4.8 – 8.6 % (Moodley et al., 2009; J. Unterscheider et al., 2011).

To better determine the average values of outcome data and minimise errors from testing a small number of possibly atypical samples; the study evaluated all eligible second-stage caesarean deliveries carried out at the study site for 12 months'. The study adopted a 2:1 'non-exposed' to 'exposed' ratio to improve power.

We approximate 180 'non-exposed' and 90 'exposed' participants (ratio 2:1). Total sample estimate of 270 participants.

**Exposed:** All women who had undergone emergency primary caesarean delivery in second-stage of labour at MTRH- RMBH during the study period.

**Non-exposed:** Women who had undergone emergency primary caesarean delivery in first-stage of labour at MTRH- RMBH.

### **3.7 Recruitment technique**

Recruitment was within the PNW in MTRH- RMBH. The hospital obstetric procedure register was examined daily for caesarean deliveries performed in the preceding 24 hours.

Women in labour, including referrals from other health care facilities are routinely admitted into RMBH labour ward for labour management and delivery. Decisions with regard to intrapartum caesarean delivery is therefore generally made from labour ward.

The obstetric procedure register contains information pertaining to patient name, in-patient number, previous ward of admission, indication for caesarean delivery and gestation at the time of caesarean delivery.

Caesarean deliveries done in women previously admitted in labour ward with singleton pregnancies and vertex presentation, at term were identified. The inpatient numbers of women who have undergone primary caesarean delivery were traced to the PNW department. These women were identified for recruitment. Investigators sought informed written consent from potential participants after explaining the rationale, benefits and risks of the study. After obtaining written informed consent, a structured questionnaire on socio-demographics and antenatal care was administered

by investigator to each selected participant. The medical records were retrospectively reviewed from respective files in the postnatal ward records department. Data was collected using a data abstraction form (Appendix 1). Intrapartum caesarean deliveries were confirmed through the diagnosis made as documented in the patients file. Either as detailed by the registrar review notes and/or nursing cardex.

All 'Exposed' cases were recruited. "Exposed" cases were compared with two 'non-exposed' participants per case considered as representative of the category of caesarean delivery indication (one of three groups as described in data collection procedure). The selection of the 'non-exposed' women is a central point of the study to reduce selection bias. Two 'non-exposed women' were selected immediately after the 'exposure' is identified in the same category of caesarean delivery indication (i.e group 1, 2 or 3 detailed in 3.8.4). Both 'exposed' and 'non-exposed' women were recruited within 24hrs post caesarean procedure. Women were followed up until hospital discharge.

### **3.8 Data collection and measurement**

#### **3.8.1 Study variables**

**Independent:** maternal age, parity, gestational age, caesarean delivery indication, surgeons' years of obstetric practice.

**Outcome measures:**

The study primary outcome was the composite adverse maternal outcome.

The secondary outcome was the composite adverse perinatal outcome.

To avoid an arbitrary choice between several important outcomes, composite measure was adopted. The use of composite measures was preferred especially for the rare outcome of mortality and the short study duration. The benefits of the composite



measure include increased statistical efficiency and reduced costs (McKenna & Heaney, 2020).

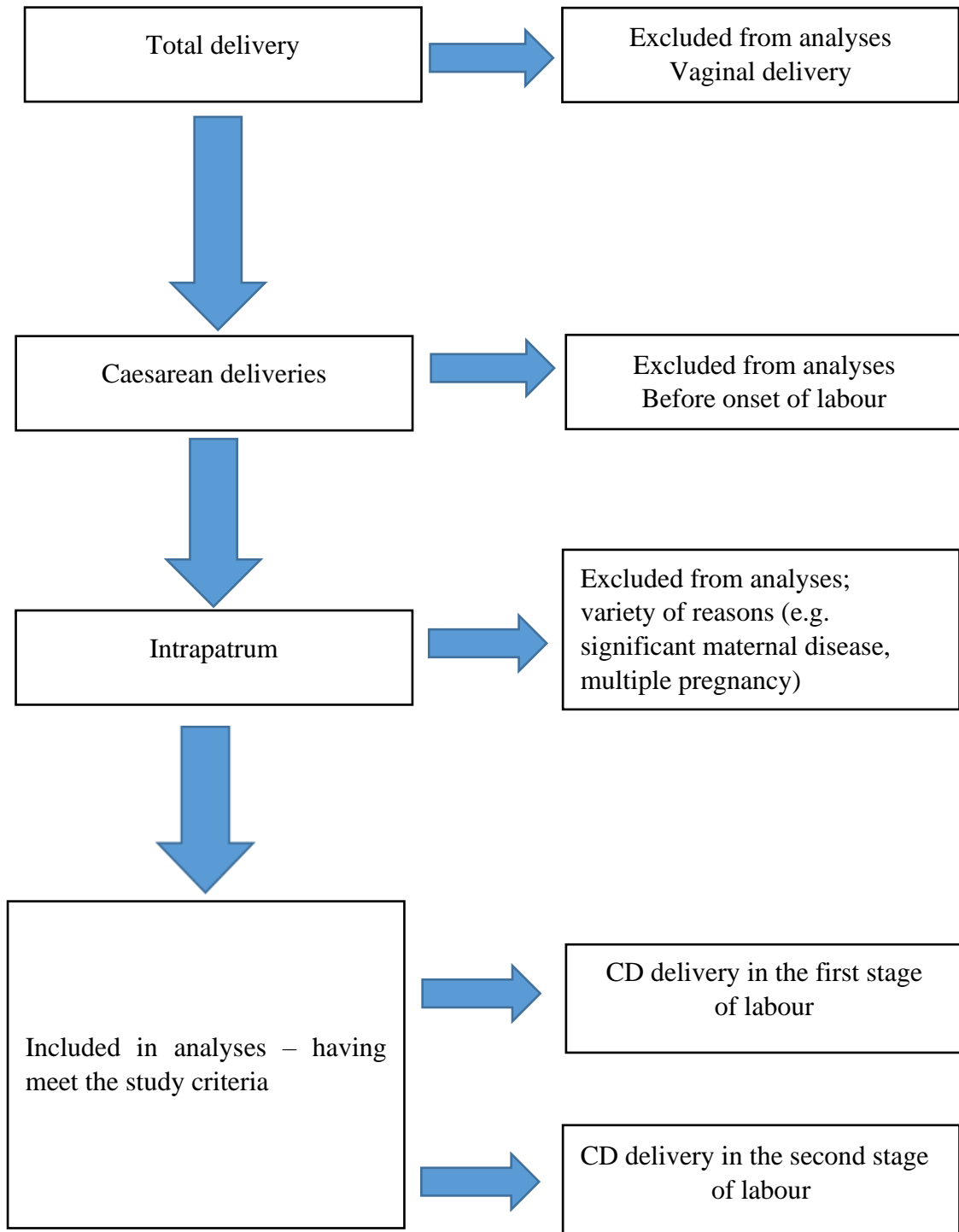
**Composite adverse maternal outcome.** A woman were considered to have this composite outcome associated with caesarean delivery if she experiences any one or more of the following: intraoperative complications (ie atony, adjacent tissue injury, hysterectomy, bladder injury, uterine incision extension), primary postpartum haemorrhage (blood loss of 1000mls or more), blood transfusion, intensive care unit (ICU) admission, length of post-operative hospital stay >3 days or in-hospital maternal death.

**Composite adverse perinatal outcome.** A neonate considered to have this composite outcome associated with caesarean delivery if the foetus/neonate experiences any one or more of the following: neonatal trauma (ie scalp, facial bruising and fractures), New Born Unit (NBU) admission and Apgar score  $\leq 7$  at 5min or, death within 24 hours of caesarean delivery.

Composite endpoints were chosen due to the relatively small sample size and short duration of follow up. All components of the endpoints were of clinical importance.

Exploratory endpoints included the proportion of second-stage caesarean deliveries among women undergoing primary caesarian deliveries, operating time (skin incision to closure), and duration of urethral catheterization.

### 3.8.2 Case selection flow chart



**Figure 3: Case selection flow chart**

### **3.8.3 Data collection instrument**

A data abstraction form was used to collect the data (Appendix 2).

Information regarding age, parity and gestational age at time of caesarean delivery were derived from history of LMP, or ultrasound available. Engagement of head during labour, duration of labour, indication for caesarean delivery, intraoperative complications were noted. Puerperium data including; weight of baby, features of trauma, APGAR score and NBU admission were recorded. Maternal outcome measures of interest were detailed.

### **3.8.4 Data collection procedure**

Training was provided to one clinical officer. The author was the lead investigator. The lead investigator and the trained clinical officer visited the RMBH operation theatre register, as well as postnatal wards each day to identify all emergency caesarean deliveries.

The inpatient numbers for eligible participants who had undergone emergency caesarean delivery were identified from the RMBH obstetric procedure register in order of time of procedure. The participants were then be traced to the PNW. After obtaining informed written consent (Appendix 1), a data abstraction form (Appendix 2) was used to collect the data necessary for achieving the study objectives, from files in the PNW records department. Participants were followed up to the point of discharge from PNW.

This was done for the twelve-month study period. All relevant data, viz. maternal, neonatal, decision for caesarean delivery, intra-operative, post-operative data and duration of hospital stay of mother and baby were captured onto the data abstraction form (Appendix 2).

Information about comorbidities, obstetric complications, interventions during pregnancy and delivery are routinely recorded in patient files, according to International Classification of Diseases ninth revision (ICD–10). This was to enable the exclusion of women with any preexisting medical risk factors, as well as infants with any congenital malformations, to prevent possible confounders.

Reliable information on the length of gestation was also be a criterion for enrolment. Information was considered to be reliable if the woman certain of the date of her last menstrual period (as recorded in the patient admission notes) or if the date of the last menstrual period was uncertain but results were available from ultrasonography performed before 14 weeks 0 days.

The onset of labour is defined by the initiation of regular, painful uterine like contractions along with cervical changes.

The first-stage of labour was defined as the period of time when there were regular contractions associated with cervical change (dilatation of 4 – 10 cm). The second-stage of labour was defined as the period of time from full cervical dilatation (10 cm) to delivery. Information on stage of labour at time of decision for emergency caesarean delivery was extracted from the hospital obstetric procedure register. It was confirmed by midwife/ registrar recorded partograph, nursing cardex, as well as the labour ward review notes.

The selection of indication for caesarean delivery was based on the primary indication for caesarean delivery as stated by the attending obstetrician/ registrar in training. Each delivery was assigned to the primary indication noted for that pregnancy, regardless of other indications reported. In order to further enhance analysis, indications for caesarean delivery was classified into groups based on their similarities and agreed management approaches. Comparable to a similar study (Lurie

et al., 2014), classification was also done in order to retain enough statistical power to demonstrate clinically important differences. All appropriate caesarean deliveries was allocated to one of three categories:

Group 1: Poor-progress labour/cephalopelvic disproportion/prolonged or obstructed labour/dystocia

Group 2: Foetal distress/Non-reassuring foetal heart rate pattern/cord prolapse/ failed vacuum delivery

Group 3: Other than group 1 & 2.

The group 1 category poor progress labour included all types of obstructed, protracted or non-progressive labours. The diagnosis of failure to progress is routinely made in accordance with the guidelines of the American College of Obstetricians and Gynecologists. Non-reassuring foetal heart rate pattern is routinely defined as severe variable decelerations, late decelerations, prolonged decelerations (3–10 min), or baseline bradycardia of less than 100 beats per minute. Foetal blood sampling in order to confirm foetal distress in cases of non-reassuring foetal heart tracing during first-stage of labour is rarely performed in the reproductive health department. Cases of failed attempts of instrumental deliveries was also included in this group. The category group 3 included indications such as malposition and haemorrhage. Haemorrhage included bleeding during labour with the leading reason for operation being the amount of bleeding without significant non-reassuring foetal heart rate pattern. The presumed cause for bleeding in these cases is abruption of placenta that will not lead to foetal compromise.

Time of surgery was defined as either day case (08.00 am to 05.59 pm), or night case (06.00 pm to 07.59am).

The majority of the caesarean deliveries at the study site are performed by registrars in training who were grouped as junior or senior registrars. A junior registrar was in the first 2 years of a 4-year training period.

A standard method of caesarean delivery as detailed by WHO is routinely performed at the study site and all women received intravenous prophylactic antibiotics following clamping of the umbilical cord at delivery of the foetus.

The duration of surgery is routinely measured with a chronometer by the scrub nurse present in the operating room and is defined as the time elapsed between skin incision and skin closure. Data on duration of surgery was extracted from the nursing cardex and anaesthesia chart- as documented in practice.

Adjacent tissue injury was defined as any extension of uterine wall defect, either laterally into the uterine vasculature and ligaments; vertically into the cervix and vagina, or contractile uterus that required additional surgical steps to repair. Uterine artery injury was defined as disruption of the vessels that required placing a suture to achieve adequate haemostasis. Information on intraoperative complications was extracted from surgeons procedure notes. Estimated blood loss (EBL) constituted the blood loss at caesarean delivery procedure and during the first 2 hours after delivery while the parturient is in post anaesthesia care. Excessive bleeding during the procedure was defined as an estimated blood loss of 1,000 ml or over. Blood loss is routinely measured by: 1) collecting and recording of blood in bedpan containers, and 2) weighing of materials including soaked sponges and pads on a scale and subtracting the known dry weights of these materials.

Information on blood loss was extracted from both the nursing cardex and anaesthesia operation notes.

Additionally, duration of urethral catheterization was used as a proxy variable for bladder trauma; measured in days as documented by surgeon in the post-operative instructions. Proxy variable was used in anticipation of shortfalls in the documentation of the surgeon-operation process and complications. Intraoperative findings that suggest bladder injury include: extravasation of urine, appearance of the Foley bulb, gross hematuria in the Foley bag, and visible detrusor muscle laceration (Rahman et al., 2009). The bladder is continuously drained with the use of a Foley catheter for at least 7–10 days postoperatively in instances such as bladder oedema and repaired bladder injury.

Information about outcome measures of interest was obtained from the surgical operation notes, nursing cardex and anaesthesia notes (intra-operative and post-anaesthesia care unit), as routinely recorded. Patient safety and good practice dictates standard documentation of caesarean delivery procedure including, steps in caesarean delivery, any/all complications experience, perinatal outcome, estimated blood loss as well as recommendation over duration of urethral catheterization.

Participants were followed up to the point of discharge, for the length of stay outcome. The duration of post-operative hospital stay was measured in days from day of caesarean delivery operation, to day of decision to discharge as documented in the in-patient file daily rounds notes.

### **3.9 Data Management**

Data captured using the data abstraction form was entered into an electronic database created using Microsoft Access. Data cleaning was conducted prior to analysis to rule out outliers, to check for any data entry errors, invalid and inconsistent entries as part of data quality assurance. The individual participant data was de-identified to ensure that participant confidentiality is maintained. The verified and cleaned database was

encrypted with a password to protect against unauthorized access. The database was backed-up to cushion against data loss. The paper forms were kept in a safe cabinet under a lock and the key retained by the lead investigator.

### **3.10 Data analysis**

Descriptive statistics: continuous variables was expressed as mean values with standard deviation and the nominal variables as numbers and percentages.

Differences in the maternal characteristics was stratified by stage of labour at delivery and examined using chi-square tests for categorical variables and T-test for continuous variables.

Indications for caesarean delivery was listed based on established groups (group 1, 2 & 3). Frequencies and percentages were used to summarize the indications for caesarean delivery.

The proportion of caesarean deliveries in the second-stage of labour was estimated by computing incidence proportion (Risk), defined as the fraction of all emergency primary caesarean deliveries, which were performed at second-stage of labour .

The frequency and relative risk were calculated for each of the components of composite adverse maternal outcomes. These were: intraoperative complications (i.e. atony, adjacent tissue injury, hysterectomy, bladder injury, uterine incision extension), primary postpartum haemorrhage (blood loss of 1000mls or more), blood transfusion, intensive care unit (ICU) admission, length of post-operative hospital stay >3 days or in-hospital maternal death.

The frequency and relative risk were also calculated for each of the components of composite adverse perinatal outcomes. This included: neonatal trauma (ie scalp, facial



bruising and fractures), New Born Unit (NBU) admission and Apgar score  $\leq 7$  at 5min or, death within 24 hours of caesarean delivery.

Potential confounders included sociodemographic characteristics (maternal age, parity, foetal weight and gestational age), caesarean delivery indication and surgeon years of obstetric practice (junior vs senior). Univariate analysis examined the difference in distribution of each potential confounder between the two groups to identify variables to be included in the multivariate analysis. The significance level for covariate inclusion to multivariate analysis was set at  $p \leq 0.005$ . Multivariate log-binomial regression models were used to estimate relative risk and 95% confidence interval for the association between stage of labour ( first versus second) and composite adverse maternal and perinatal outcomes adjusting for potential confounding variables.

Data analysis was done using STATA version 15 SE.

### **Statistical method for handling missing data**

The mean value substitution method was used, replacing the missing value with the average value calculated over all the values available from the other waves of data collection.

### **Loss to follow up**

No loss to follow-up was anticipated in this study, due to the short follow-up period limited to only the hospital stay.

### **3.12 Ethical consideration**

The study commenced after obtaining ethical approval from Moi University institutional research ethics Committee (IREC). Written permission to conduct the study at the institution was obtained from MRTH management. Investigators sought informed written consent from potential participants after explaining the rationale, benefits and risks of the study. Autonomy was respected by giving all the necessary information and freedom to withdraw from the study at any point throughout the study without need for justification. Confidentiality and privacy was assured. All data was maintained as confidential and no individual was identified in dissemination of findings. Alphanumeric codes were used in the structured proforma to protect privacy of participants. Computers for data entry and analysis had password accessible only to principal investigator. Printed research data was kept in a locked office with limited access. In addition, any clinical evidence of any adverse outcomes was expeditiously addressed through timely interventions to minimize these outcomes.

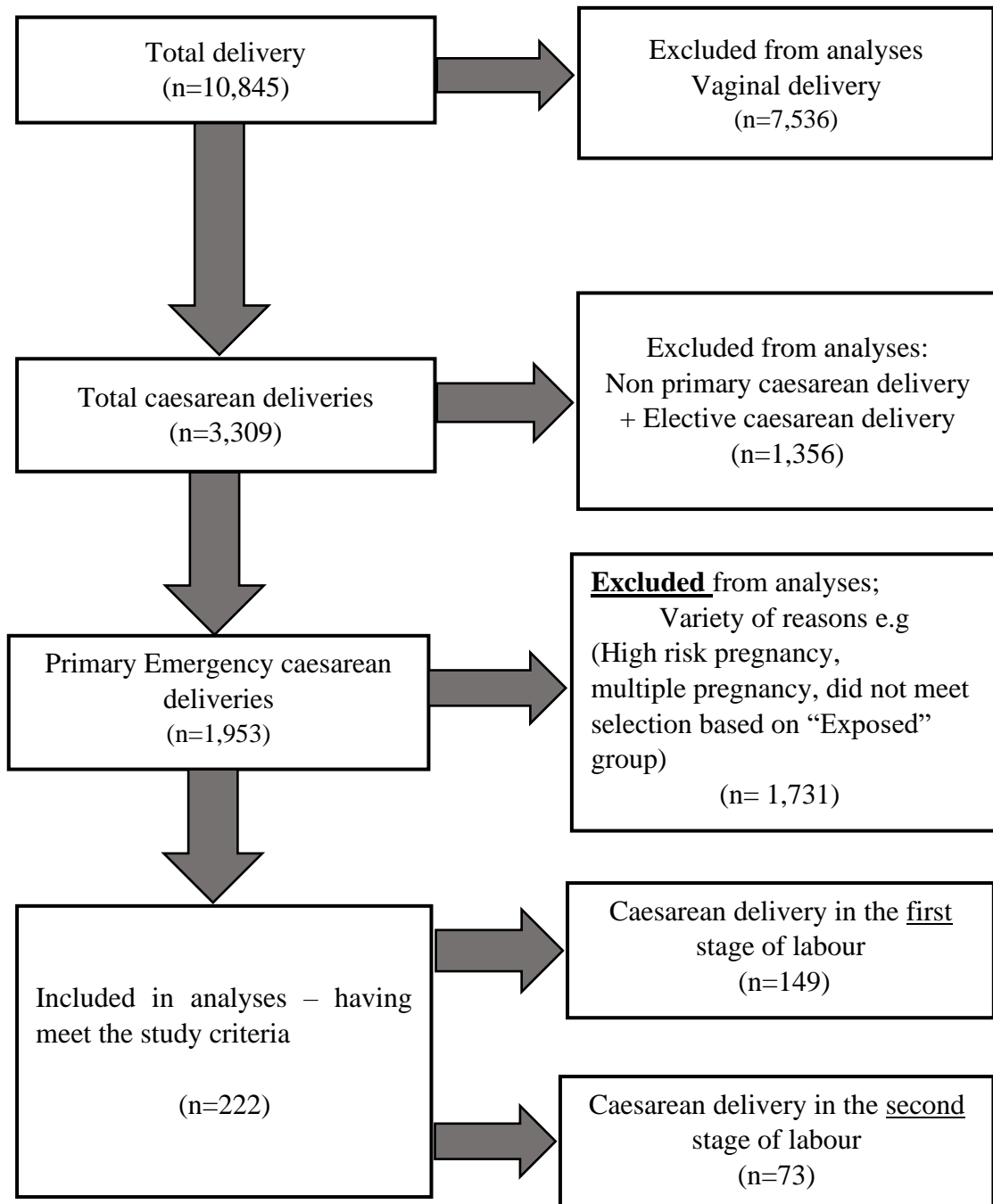
### **3.13 Dissemination of findings**

Study findings will be presented to Moi University in partial fulfilment for the award of degree in Master of Medicine (Reproductive Health). A copy of this thesis will be made available at the institutional library for public access and consumption.

The study findings will also be shared in peer reviewed journals for publication.

## CHAPTER FOUR

## 4.0 RESULTS



**Figure 4: Flow diagram of modes of delivery during study period with case selection.**

During the one year study period (1<sup>st</sup> August 2021 through to 31<sup>st</sup> July 2022), 10,857 deliveries occurred at RMBH-MTRH. The caesarean delivery rate was 30.5% (3309/10,845).

A total of 1,953 emergency primary caesarean deliveries were performed; 84 of which were in the second-stage of labour. Among the women who underwent caesarean delivery during the second-stage of labour, 13 were excluded from the study: 4 had high risk pregnancies, 3 had a history of prior caesarean delivery, 3 had pregnancies in non-vertex presentation, 2 had multiple pregnancy and, 1 had a pre-term pregnancy. There were no exclusions in the first-stage caesarean delivery group.

Analysis was performed on 222 primary emergency caesarean deliveries: 73 (32.8%) second-stage caesarean deliveries and 149 (67.2%) first-stage caesarean deliveries. There were neither participants who declined enrolment into the study nor participant drop outs.

The selection of cases is shown in **Figure 3**.

#### **4.1 Baseline sociodemographic and pregnancy characteristics**

Maternal sociodemographic characteristics and pregnancy care shown in **Table 4**.

Age of participants ranged from 18 to 44 years. No significant differences were observed in mean maternal age ( $24.8 \pm 6$  in the second-stage caesarean delivery group vs  $25.7 \pm 5.1$  in the first-stage group caesarean delivery), or mean gestational age at delivery between the groups ( $40.2 \pm 1.4$  vs  $39.6 \pm 1.3$ ). Parity, occupation and marital status were also comparable between the first-stage caesarean delivery and second-stage caesarean delivery groups.

Women who underwent caesarean delivery in the second-stage of labour had less antenatal care clinic (mean) attendance compared with women in the first-stage of labour caesarean delivery group ( $4.7 \pm 1.3$  vs  $5.3 \pm 1.4$ ,  $P = 0.002$ ). One woman (in the first-stage of labour caesarean delivery group) did not attend ANC. The highest number of ANC visits was 10. Only 5 women met the 2016 WHO ANC recommended 8 contacts – all of whom were in the first-stage of labour caesarean delivery group.

The proportion of women who underwent caesarean delivery in the second-stage of labour, admitted as referrals from peripheral facilities (rather than admissions from home) was higher than women having caesarean delivery in the first-stage of labour ( $67.1\%$  vs  $22.8\%$ ,  $P < 0.001$ ).

Majority of participants were 157 (70.7%) were unemployed, 135 (60.8%) were married and 54.5% had a post-secondary education. There was a statistically significant difference in the level of education between groups.

#### **4.2 The proportion of second-stage caesarean delivery at MTRH.**

Against all births during the study period, the proportion of second-stage caesarean deliveries was 0.75% [95% CI: 0.5% - 0.8%] (84/11181). Among women who underwent primary caesarean deliveries, the proportion of second-stage caesarean deliveries was 4.3% [95% CI: 2.9% - 4.7%] (84/1953).

**Table 4: Maternal sociodemographic characteristics and pregnancy care in primary caesarean deliveries according to stage of labour.**

Maternal characteristics	First-stage of labour (n=149)				Second-stage of labour (n=73)				P
	M	SD	n	%	M	SD	n	%	
<b>Maternal age(yrs)</b>	25.7	5.1			24.8	6			0.234
<b>Antenatal care clinic attendance</b>	5.3	1.4			4.7	1.3			0.002
<b>Gestational age</b>	39.6	1.3			40.2	1.4			0.142
<b>Birth weight (g)</b>	3335	444			3309	343			0.643
<b>Referral from peripheral facility</b>									<0.001
No			115	77.2			24	32.9	
Yes			34	22.8			49	67.1	
<b>Education</b>									0.019
Primary			10	6.7			7	9.6	
Secondary			48	32.2			36	49.3	
Tertiary			91	61.1			30	41.1	
<b>Parity</b>									0.168
0			100	67.1			54	74	
1-2			42	28.2			13	17.8	
>2			7	4.7			6	8.2	
<b>Occupation</b>									0.673
Employed			18	12.1			7	9.6	
Self-employed			29	19.5			11	15.1	
Student			32	21.5			20	27.4	
Unemployed			70	47			35	47.9	
<b>Marital status</b>									0.638
Married			89	59.7			46	63	
Single			60	40.3			27	37	
<b>History of pregnancy loss</b>									0.345
No			139	93.3			71	97.3	
Yes			10	6.7			2	2.7	

*M: Mean*

*SD: Standard deviation*

### 4.3 Intrapartum characteristics

Average dilatation at caesarean delivery in the first-stage of labour group was 6.7  $\pm$ 1.4cm. There was no difference in oxytocin administration for augmentation of labour between groups (94.6% vs 94.5%). Non-progressive labour and foetal distress were the most common reasons for caesarean delivery in the second-stage of labour (89% and 11%, respectively) as well as in the first-stage of labour (89.9% and 10.1%, respectively).

Women who underwent caesarean delivery in the second-stage had the procedure done commonly at night (64.6%), similar to the first-stage group (67.8%). The Median skin incision to delivery time was 4 minutes in both groups. However, the total operation time was significantly longer in caesarean deliveries performed in the second-stage of labour (46 minutes vs 40 minutes,  $P = 0.002$ ). The absolute difference in surgical time were, conversely, small.

In both second-stage and first-stage caesarean delivery groups, majority of the parturients received spinal anaesthesia (100% and 97.3%).

The majority of caesarean deliveries, were performed by junior registrars i.e. post graduate year 1 and year 2 (49.3% and 53.7%).

Selected study intrapartum characteristics are shown in **Table 5**.

**Table 5: Intrapartum characteristics in primary caesarean deliveries according to stage of labour.**

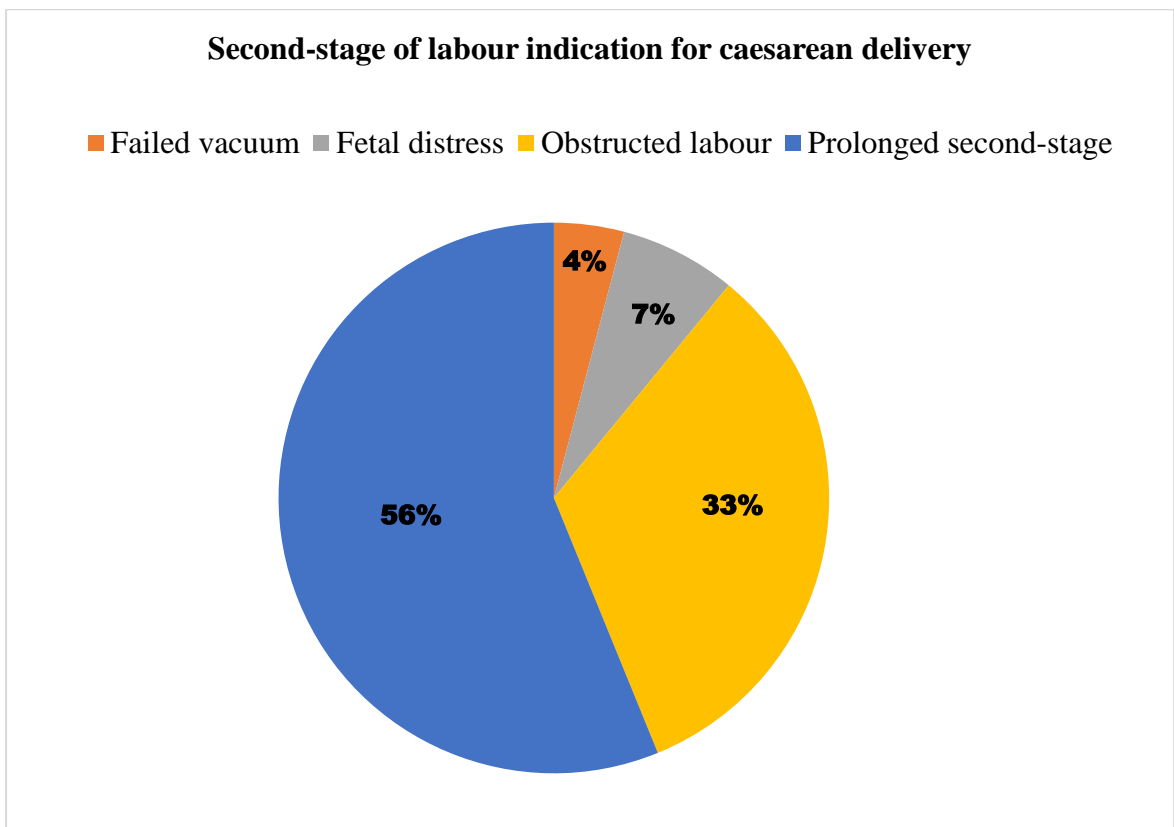
Intrapartum characteristics	First-stage of labour (n=149)				Second-stage of labour (n=73)				P
	<i>m</i>	<i>IQR</i>	<i>n</i>	%	<i>m</i>	<i>IQR</i>	<i>N</i>	%	
<b>Oxytocin augmentation</b>									
No			8	5.4			4	5.5	>0.99
Yes			141	94.6			69	94.5	
<b>Indication for caesarean delivery</b>									
Group 1: Non Progressive labour			134	89.9			65	89	0.838
Group 2: Foetal distress			15	10.1			8	11	
<b>Timing of operation</b>									
Day (08.00 to 17.59)			48	32.2			26	35.6	0.613
Night (18.00 to 07.59)			101	67.8			47	64.4	
<b>Skin incision to delivery time (min)</b>	4	3,5			4	3,6			0.823
<b>Total operation time (min)</b>	40	32,49			46	37,55			0.002
<b>Spinal anaesthesia</b>									
GA			4	2.7			0		0.305
Spinal			145	97.3			73	100	
<b>Delivery surgeon</b>									
Junior registrar (Y1/2)			80	53.7			36	49.3	0.657
Senior registrar (Y≥3)			68	45.6			36	49.3	
Consultant obstetrician			1	0.7			1	1.4	



#### 4.4 Indications for second-stage primary caesarean delivery.

Indications for caesarean delivery among second-stage of labour study participants are outlined in **figure 5**.

Seventy three parturient women were operated on in the second-stage of labour. The most common indication for caesarean delivery was prolonged second-stage of labour (56%), obstructed labour (33%), foetal distress (7%) and failed vacuum extraction (4%).



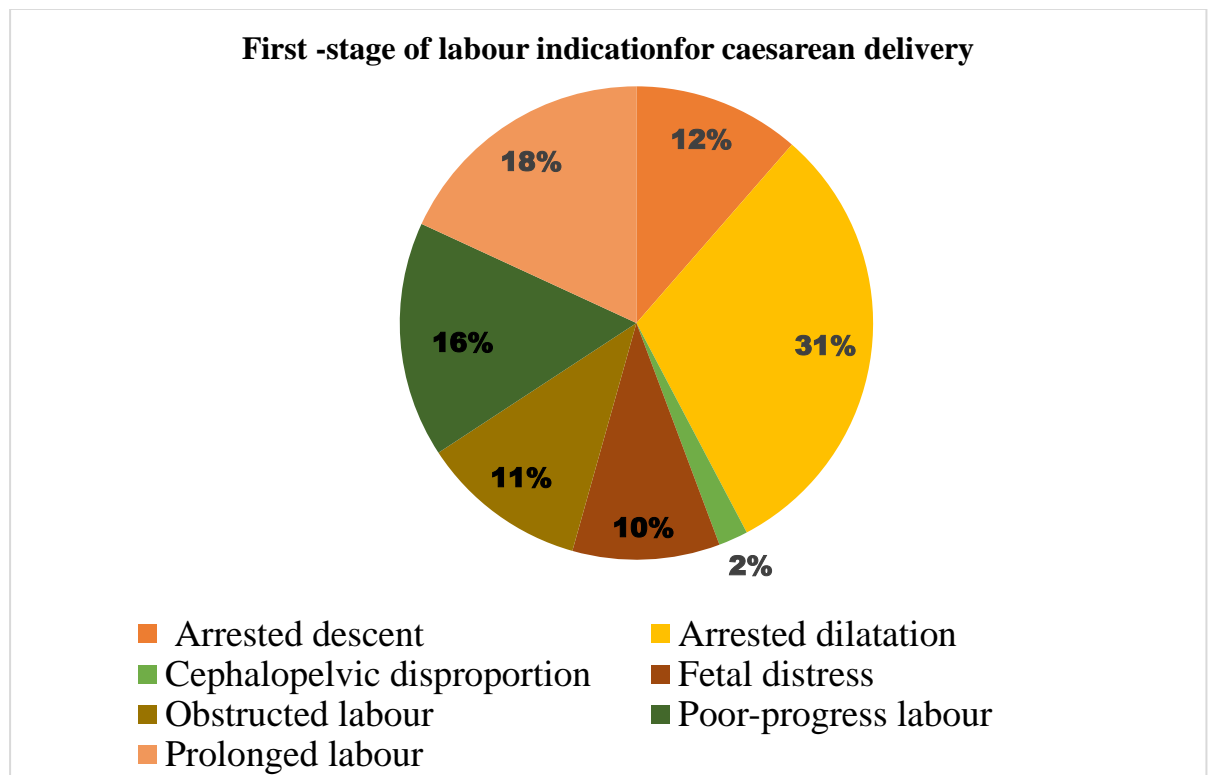
**Figure 5: Indications for emergency primary caesarean delivery among second-stage of labour study participants (n=73).**

#### 4.5 Indications for first-stage primary caesarean delivery.

Indications for caesarean delivery among second-stage of labour study participants are outlined in **figure 6**.

The selection of cases in the first-stage of labour was done in comparison to the second-stage of labour indication i.e group classification based on their similarities (as outlined in the methodology section).

One hundred and forty nine parturient women operated on in the first-stage of labour were selected for the study. The indications for caesarean delivery within this group were; arrested dilatation (31%), prolonged labour (18%), poor progress labour (16%), arrested descent (12%), obstructed labour (11%), foetal distress (10%) and cephalopelvic disproportion (2%).



**Figure 6 : Indications for emergency primary caesarean delivery among second-stage of labour study participants (n=149).**

#### **4.6 Adverse maternal outcomes in first and second-stage caesarean deliveries.**

Compared to caesarean delivery in the first-stage of labour, women who underwent second-stage caesarean delivery were 3.3 times more likely to experience adverse composite maternal outcome (RR 3.272, 95% CI 2.45–4.50,  $P < 0.001$ ).

There were no cases of in-hospital maternal mortality in either group within the study. Bladder injury occurred in 1.4% of caesarean deliveries in the second-stage of labour and, none in the first-stage of labour.

Overall, intraoperative complications resulting in hysterectomy was low; 2.7% in the second-stage caesarean delivery group and none in the first-stage caesarean delivery group.

Primary PPH occurred in 9.6% of cases in the second-stage of labour.

Eight cases of extension of uterine incision (T or J) resulted, all within the second-stage caesarean delivery group (11%).

Second-stage caesarean delivery had associated increased rates of uterine atony compared to caesarean delivery during the first-stage of labour (15.0% vs 3.4%, RR 2.13, 95% CI 1.99–3.98). Caesarean delivery in the second-stage of labour resulted in prolonged stay ( $>3$ days) in the hospital (20.5% vs 0.1%, RR 5.65, 95% CI 1.29–7.77).

The risk of receiving blood transfusion was 2.4 times higher among women who underwent second-stage caesarean delivery compared to those who underwent caesarean delivery while at first-stage of labour (9.6% vs 0.1%, RR 2.44, 95% CI 1.86–4.44).

These maternal complications are compared in **Table 6**.

**Table 6: Comparison of adverse maternal outcomes among women who have undergone primary caesarean delivery (n=222).**

Complications	Total no. of events	First-stage of labour n=149		Second-stage of labour n=73		RR	(95% CI)
		n	(%)	n	(%)		
<b>Atony</b>	16	5	3.4	11	15.0	2.13	1.99 - 3.98
<b>Adjacent tissue injury</b>	9	2	1.4	7	9.6	0.99	0.03 – 1.44
<b>Hysterectomy</b>	2	0	0	2	2.7	-	-
<b>Extension of uterine incision (T or J)</b>	8	0	0	8	11	-	-
<b>Bladder injury</b>	1	0	0	1	1.4	-	-
<b>Blood transfusion</b>	8	1	0.1	7	9.6	2.44	1.86 – 4.44
<b>Primary PPH</b>	7	0	0	7	9.6	-	-
<b>Length of post-operative stay &gt; 3 days</b>	16	1	0.1	15	20.5	5.65	1.29 – 7.77
<b>Urethral catheterization longer than 24 hours</b>	46	16	10.7	30	41.1	4.44	2.00 – 6.31
<b>Maternal death</b>	0	0	0	0	0	-	-
<b>Composite*</b>		7	15.4	26	35.6	3.272	2.28-4.71

\*Atony, adjacent tissue injury, hysterectomy, bladder injury, uterine incision extension, primary postpartum hemorrhage, blood transfusion, intensive care unit admission, length of post-operative hospital stay >3 days or in-hospital maternal death

#### **4.7 Adverse perinatal outcomes in first and second-stage caesarean deliveries.**

Women who underwent caesarean delivery during the second-stage of labour were 2.7 times more likely to experience adverse perinatal outcomes compared to those who underwent caesarean delivery while at first-stage of labour (RR 2.748, 95% CI 1.97–3.84 ,  $P < 0.001$ ).

Neonatal trauma occurred in 1.4% of caesarean deliveries in the second-stage of labour and, none in the first-stage of labour.

Second-stage caesarean delivery was associated with a reduced 5 min APGAR ( $\leq 3$ ) score among new-borns compared with babies born by first-stage caesarean delivery (26% vs 9.4%; RR 2.64, 95% CI 1.87–3.72). However, this may be likely as a result of increasing foetal compromise with prolonged duration of delivery, not necessarily a result of the procedure.

A further evaluation of neonatal morbidity examined caesarean delivery in the second-stage of labour and new-born admission into NBU. The study showed that caesarean delivery in the second-stage of labour was associated with more admissions into NBU (RR 2.015, 95% CI 1.39–2.92).

Compared with caesarean delivery in the first-stage of labour, women who underwent caesarean delivery in the second-stage of labour were 2.05 times more likely to have deliveries resulting in neonatal death (95% CI 1.29– 3.27) **Table 7.**

**Table 7: Comparison of neonatal morbidity among women who have undergone primary caesarean delivery (n=222).**

Complications	Total no. of events	First-stage of labour n=149		Second-stage of labour n=73		RR	(95% CI)
		n	(%)	n	(%)		
<b>5 min APGAR (<math>\leq 3</math>)</b>	14	3	2	11	15.1	2.636	1.87 - 3.72
<b>Neonatal trauma</b>	1	0	0	1	1.4	-	-
<b>Baby admitted into New Born Unit</b>	33	14	9.4	19	26	2.015	1.39 - 2.92
<b>Neonatal death</b>	15	6	4	9	12.3	2.054	1.29 - 3.27
<b>Composite*</b>		16	10.7	31	42.5	2.748	1.97-3.27

\* Neonatal trauma, new born unit admission and Apgar score  $\leq 3$  at 5min or, death within 24 hours of caesarean delivery.

#### **4.8 Adverse maternal and perinatal composite outcomes between second-stage and first-stage of labour caesarean delivery.**

Caesarean delivery in the first-stage of labour was associated with 15.4% maternal composite outcome compared to 35.6% in the second-stage of labour (RR 3.272, 95% CI 2.45– 4.50,  $P < 0.001$ ). Similarly perinatal composite outcome was identified in 16 (10.7%) caesarean deliveries in the first stage of labour as compared to 31 (42.5%) caesarean deliveries in the first-stage of labour (RR 2.748, 95% CI 1.97– 3.84 ,  $P < 0.001$ ).

**Table 8** shows the unadjusted and adjusted relative risks for the adverse maternal and perinatal composite outcomes.

The adverse maternal composite index was significantly increased in women undergoing caesarean delivery in the second-stage of labour compared to the first-stage of labour.

Adjustment was made for maternal age at delivery, parity, gestational age, foetal weight, caesarean delivery indication and surgeon years of obstetric practice (junior vs senior) and baseline characteristics that were significantly different between the comparison groups .

The adjusted adverse maternal composite outcome remained significantly increased with caesarean delivery in the second stage, as did the adjusted adverse perinatal composite outcome.

**Table 8: Adverse maternal and perinatal composite outcomes (n=222).**

	<b>Relative Risk</b>	<b>95% Confidence Interval</b>
<b>Maternal composite outcome</b>		
<b>Unadjusted</b>	3.272	2.28 – 4.71
<b>Adjusted</b>	3.556	2.35 – 5.37
<b>Perinatal composite outcome</b>		
<b>Unadjusted</b>	2.748	2.45 – 4.50
<b>Adjusted</b>	3.998	2.35 – 6.79



## CHAPTER FIVE

### 5.0 DISCUSSION

The present study examined the proportion of primary caesarean deliveries in the second-stage of labour. The study also assessed potential differences in adverse maternal and perinatal outcomes following primary caesarean delivery between the first and second stages of labour.

#### **5.1 Proportion of second-stage caesarean delivery among women who underwent primary caesarean delivery**

The proportion of primary caesarean deliveries in the second-stage of labour was 4.3%. This figure is in keeping with data from the UK, 4.8% (J Unterscheider et al., 2011). It is, however, a proportion lower than that found in studies in Turkey, 7.8% (Asıcioglu et al., 2014), and South Africa, 10.6% (Govender et al., 2010) which may be due to inclusion of women with prior caesarean deliveries by these studies. Women with prior caesarean deliveries were excluded in this study. One study in Nepal found that primary caesarean deliveries in the second-stage of labour among nullipara comprised 1.9% of all primary caesarean deliveries (Gurung et al., 2017), the proportion of a figure much lower than our study, which was 2.9% (54/1953). This may be because our study included women referred from peripheral facilities for second-stage caesarean delivery. Most women who underwent caesarean delivery in the second-stage of labour were nulliparous, 74% (54/73). An observation similar to a study done in India, 74% (Babre et al., 2017) and the USA, 84% (Alexander et al., 2007). This supports a pattern of primary caesarean delivery in the second-stage of labour being more frequent in nulliparous women, without any associated improved neonatal outcome (Fitzwater et al., 2015).

Although this study did not address caesarean delivery in the second-stage of labour trends; literature demonstrates that with increasing rates of caesarean deliveries, there is an associated increase in caesarean deliveries in the second-stage of labour (Vousden et al., 2014b). This may be as a result of multiple reasons, such as the growing perceived safety of caesarean deliveries, coupled with a decrease in instrumental delivery experience of junior trainees (Davis et al., 2015). The effect of this is a reluctance to attempt anticipated difficult assisted deliveries. The rising medico-legal mind set in current obstetrics and concerns over maternal and neonatal morbidity associated with complicated or failed assisted delivery techniques may also contribute to this trend.

## **5.2 Adverse maternal outcomes between second-stage and first-stage of labour caesarean delivery.**

In this cohort study, women who underwent caesarean delivery in the second-stage of labour had a 3.6 fold risk of maternal composite morbidity compared to women operated in the first-stage of the labour. Caesarean delivery in the second-stage of labour can present an intra-operative challenge due to foetal head impaction into the maternal pelvis, and an often oedematous lower uterine segment (in prolonged labour). In vertex presentation, a common method of delivery of the foetal head requires the surgeon to slip his or her hand into the uterine cavity and, then raise the foetal head using fingers and palm through the uterine incision. A higher maternal morbidity may result from tearing of the lower uterine segment while delivering the engaged head, including extension of the uterine incision injury as well as uterine vessel injury. This study demonstrated a slightly lesser magnitude of maternal morbidity risk compared to a similar study in Turkey, RR 4.26,  $p < 0.001$  (Asıcıoğlu et al., 2014), which may be explained by the inclusion of two maternal morbidities

(i.e. post-partum endometriosis and wound infection) that were not investigated in our study. A similar study done in the USA by James M Alexander et al found that caesarean delivery in the second-stage of labour was associated with slightly increased maternal morbidity (OR 1.30) compared to the first-stage of labour (Alexander et al., 2007). Increased maternal morbidity was also demonstrated in a study in South Africa; where the number of maternal complications were significantly higher in second-stage of labour caesarean deliveries compared to the first-stage of labour, 84 vs 37 (Govender et al., 2010).

During this study, extension of uterine incision was noted in 8 (11% vs 0% ) women with caesarean delivery in the second-stage of labour. This percentage was less, compared to a study done in South Africa, 22.4% vs 1.8%, RR 15.4,  $p < 0.001$  (Govender et al., 2010) and Israel, 17.1% vs 4.6%,  $p < 0.001$  (Lurie et al., 2014). However, in a USA study by James M Alexander et al, extension of uterine incision seen in only 0.4% vs 0.2%,  $P=0.03$  of women who had caesarean delivery in the second-stage of labour. These differences may be explained by inherent variances in operative techniques. Caesarean deliveries in the USA being carried out by consultant obstetricians or by residents under direct consultant supervision.

Almost all caesarean deliveries within the study were done by registrars (obstetrician gynaecologist in-training), with 49.3% of caesarean deliveries in the second-stage of labour being performed by junior registrars. Although this study did not look at the significance of the level of obstetrics and gynaecology training on caesarean delivery outcomes; A survey conducted in the UK (of 150 obstetric trainees) revealed that 86% of registrars and 94% of senior house officers agreed that training on how to perform second-stage caesarean deliveries would be beneficial. Moreover, two-thirds of these registrars reported that this training would increase confidence in managing a deeply

impacted foetal head (Sethuram et al., 2010). Currently, there is no protocol on second-stage caesarean delivery at institution or national level.

Within this study, bladder injury occurred in 1.4% of caesarean deliveries in the second-stage of labour and in none of the caesarean deliveries in the first-stage. This suggests that caesarean delivery performed in the second-stage of labour may be slightly more technically difficult. Engagement and impaction of the foetal head in the maternal pelvis likely results in a thinned out lower uterine segment; and subsequent difficulty in delineation of the bladder. Visualization of surgical planes may be less than optimal. Similar studies in Turkey, 2.6% vs 0.3%, RR 7.26, P=0.019 (Asicioglu et al., 2014) and in South Africa, 3.5% vs 0.41%, OR 8.7, P < 0.001 (Govender et al., 2010) demonstrated a larger proportion of bladder injury within caesarean deliveries in the second-stage of labour compared to the first-stage of labour. This could be explained by inclusion of repeat caesarean deliveries in some of these studies; bladder injury is more likely to occur during repeat caesarean delivery (Schneid-Kofman, 2012).

The risk of uterine atony following delivery was 2.13 fold higher in second-stage caesarean compared to first-stage caesarean delivery (15% vs 3.4%, RR 2.13, 95% CI 1.99–3.98). The longer duration of myometrium distension, subsequent desensitization of oxytocin receptors and uterine muscle fatigue may explain this finding. The proportion of atony was in concordance with a study in the USA by James M Alexander et al, 9% vs 7%, P=0.002 (Alexander et al., 2007). It however contrasted with a study done in Israel which showed a lesser percentage of atony with caesarean deliveries in the second-stage of labour, 3% vs 9.2%; In that study, uterine atony was more frequent among parturient women who underwent caesarean delivery for non-progressive labour (Lurie et al., 2014).

PPH ( $\geq 1000$  ml) occurred in 9.6% of caesarean deliveries in the second-stage of labour and in none of the first-stage caesarean deliveries; All 7 of these women (who had PPH) required blood transfusion (9.6% vs 0.1%, RR 2.44, 95% CI 1.86–4.44). PPH associated with caesarean delivery is mainly attributed to uterine atony and injury to uterine blood vessels (Sheiner, 2012). The findings of this study were similar to a study by Davis et al in New Zealand, which demonstrated PPH in 10.1% of second-stage of labour caesarean deliveries (Davis et al., 2015), but more than a study by Govender et al in South Africa (4.6% vs 0.72%, OR 6.2,  $p < 0.001$ ). The difference may have been due to differences in estimation of blood loss between studies.

### **5.3 Adverse perinatal outcome characteristics in second-stage caesarean delivery.**

The overall proportion of neonatal trauma following caesarean delivery in the second-stage of labour compared to the first-stage of labour was low (1.4% vs 0%).

These results compare to a study done in Canada, 0.2% vs 0% (V. M. Allen et al., 2005) and a similar study done in South Africa: which reported one occurrence of neonatal trauma in a participant having had caesarean delivery in the second-stage of labour (L. Cebekulu & E. Buchmann, 2006). Asıcıoglu et al demonstrated significant increased risk of foetal injury following caesarean delivery in the second-stage of labour compared to the first-stage of labour, 6.7% vs 0.4%, RR 17.7,  $P < 0.01$  (Asıcıoglu et al., 2014), this could be explained by a larger study population and longer study period.

Caesarean delivery in the second-stage of labour resulted in 2.015 fold higher risk of admissions to NBU. This could be attributed to a larger proportion of new-borns with reduced Apgar score ( $\leq 3$ ) among this group. Uterine contractions during the second-stage of labour increase in intensity (Hofmeyr & Singata-Madliki, 2020) . Intense

uterine contractions in the second-stage of labour are associated with decreased foetal blood oxygen saturation (McNamara & Johnson, 1995); Intrapartum foetal hypoxia can therefore occur as a complication with second-stage caesarean delivery.

In previous studies, neonatal outcome has been controversial, particularly with regard to the risk of foetal asphyxia. A UK study by Selo-Ojeme et al demonstrated no difference in the risk of foetal asphyxia between caesarean deliveries in the second and first stage of labour (Selo-Ojeme et al., 2008). However, Asıcıoglu et al reported a 2.96 fold risk (95% CI 0.64 – 13.53) of 5 min Apgar  $\leq$  3, as well as a 6.10 fold risk of admission into NICU among new-borns delivered via caesarean delivery in the second-stage of labour (Asıcıoglu et al., 2014). Allen et al also found that compared with caesarean deliveries in the first-stage of labour, women who underwent caesarean delivery in the second-stage of labour were 1.50 times more likely to deliver infants with perinatal asphyxia (95% CI 1.06– 2.14,  $P < 0.05$ ) (Victoria M Allen et al., 2005).

The increased risk of asphyxia and subsequent admission into NBU could be from increased foetal compromise with prolonged labour and delivery duration, not necessarily due to the caesarean procedure alone.

Neonatal death was increased among neonates born by caesarean delivery in the second-stage of labour, compared to the first-stage of labour (RR 2.05, 95% CI 1.29– 3.27). This may be due to the increased incidence of new-born low APGAR score and admission into NBU within this group. In Turkey, Asıcıoglu et al reported an 11.80 fold increased risk (95% CI 21.67 – 83.43) of neonatal death among neonates born by caesarean delivery in the second-stage of labour (Asıcıoglu et al., 2014).

These results contrast Selo-Ojeme et al study that had no foetal death in either study group (Selo-Ojeme et al., 2008). This may reflect the advanced labour and neonatal care in the UK.

#### **5.4 Study strengths and limitations**

A limitation of this study is that most of the outcomes were determined retrospectively.

There is a possibility of bias in the recorded outcomes, potentially stemming from incomplete or insufficient information contained in surgical notes. However, determining the direction of this bias is challenging. Consequently, it is difficult to dismiss the possibility of misclassification, particularly concerning the outcomes of interest. Any such misclassification is likely to be non-differential in nature, which could attenuate the strength of the observed associations. However, the calculation of relative risk would remain unaffected by this potential bias.

There was missing data regarding the technique used to deliver the foetus, documented in only 10% of the operation notes. Evaluation of outcomes based on foetal delivery techniques was therefore not possible. The abdominal palpation findings, asynclitism, caput, and moulding assessments in the second-stage of labour, were also infrequently documented. Inference on the possible reasons for prolonged second-stage could also not be made.

Cases with high-risk pregnancies (such as diabetes mellitus, preeclampsia and HELLP syndrome) were also excluded. Including all second-stage caesarean deliveries in the study period, similar demographic variables across the study population, and the performance of the surgery at a single institution increases the validity and mitigates these weaknesses.

Finally, long-term outcomes, such as the risk of preterm labour in subsequent deliveries associated with second-stage caesarean delivery were also not evaluated by this study (Williams et al., 2021). It is, therefore, not possible to conclude if caesarean delivery performed during the second-stage of labour may have adverse effects beyond what is observed until hospital discharge. Nonetheless, these questions can provide the impetus for future studies within this area of continuing interest.

The study strengths included a well matched first-stage of labour caesarean delivery comparison group. The inclusion of all second-stage primary caesarean deliveries within the study period reduced sampling errors.

Additionally, this was the first local study comparing morbidity and mortality in second-stage of labour caesarean delivery versus first-stage of labour caesarean delivery.



## CHAPTER SIX

### 6.0 CONCLUSIONS AND RECOMMENDATIONS

#### 6.1 Conclusions

Caesarean deliveries performed in the second-stage of labour accounted for 4.3% of all primary caesarean deliveries at MTRH-RMBH.

In evaluating adverse maternal outcomes with caesarean delivery in labour, women who underwent caesarean delivery in the second-stage of labour had a 3.6 fold higher risk of maternal morbidity than those who underwent caesarean delivery in the first-stage of labour. This included maternal intraoperative trauma, atony, blood transfusion, and post-operative hospital stay longer than 3 days.

This study result also suggests that women who underwent caesarean delivery in the second-stage of labour had almost four times higher risk of adverse perinatal outcomes compared to women who underwent caesarean delivery in the first-stage of labour. The associated perinatal complications included an increased risk of a 5min APGAR  $\leq 3$ , admission into NBU, and neonatal death.

## 6.2 Recommendations

- i. The labour ward team, including obstetricians, registrars and midwives should be aware of the increased risk of adverse outcomes with caesarean delivery in the second-stage of labour and reduce the need for these deliveries.

In daily practice, early identification of scenarios that may result in second-stage caesarean delivery, such as obstructed labour, could be beneficial in decreasing the associated maternal and perinatal morbidity. Timely identification of the presence of moulding and caput is essential in considering the possibility of obstructed labour before the second-stage of labour. This could be achieved through adoption of the 2018 WHO Labour Care Guide, which follow updated global recommendations for intrapartum care.

- ii. The surgical team, including anaesthesiologists, should be aware of the increased risk of PPH with caesarean delivery in the second-stage of labour. This increased risk of blood loss > 1000mls and subsequent need for blood transfusion should be anticipated and included during the preoperative surgical safety checklist as good practice.
- iii. As majority of second-stage caesarean deliveries in the study were conducted by junior registrars, who are obstetrician-gynecologists in training, we recommend the presence of a senior obstetrician during second-stage caesarean delivery. The involvement of experienced senior obstetricians can provide guidance and expertise, during these complex or challenging deliveries, enhancing the overall quality of care provided.
- iv. Due to an increased risk of a 5min APGAR  $\leq 3$  and admission into NBU, we recommend the neonatal resuscitation personnel (NBU team) be alerted before

caesarean delivery in the second-stage of labour, to aid in any resuscitation that may be required and prompt expert care for these neonates.

- v. Further research is recommended to understand how to reduce adverse maternal and neonatal outcomes with second-stage caesarean delivery. This could include evaluating second-stage caesarean delivery techniques practised at MTRH. The choice of manoeuvres includes the pull technique (reverse breech extraction), push technique from below and the Patwardhan method (as described in literature review). In a single centre RCT, the ‘push’ method was associated with significantly greater extension of the uterine incision (30% vs 11%,  $P < 0.05$ ) and operative blood loss (1257 ml vs 898 ml,  $P < 0.01$ ) compared to the ‘pull’ method (Fasubaa et al., 2002).

## REFERENCES

- Abalos, E., Addo, V., Brocklehurst, P., El Sheikh, M., Farrell, B., Gray, S., Hardy, P., Juszczak, E., Mathews, J., & Naz Masood, S. (2016). Caesarean section surgical techniques: 3 year follow-up of the CORONIS fractional, factorial, unmasked, randomised controlled trial. *Lancet*, *388*(10039).
- ACOG Practice Bulletin Number 49, December 2003: Dystocia and augmentation of labour. (2003). *Obstet Gynecol*, *102*(6), 1445-1454.  
<https://doi.org/10.1016/j.obstetgynecol.2003.10.011>
- Ahmed, R., Mosa, H., Sultan, M., Helill, S. E., Assefa, B., Abdu, M., Ahmed, U., Abose, S., Nuramo, A., & Alemu, A. (2021). Prevalence and risk factors associated with birth asphyxia among neonates delivered in Ethiopia: a systematic review and meta-analysis. *PloS One*, *16*(8), e0255488.
- Alexander, J. M., Leveno, K. J., Hauth, J., Landon, M. B., Thom, E., Spong, C. Y., Varner, M. W., Moawad, A. H., Caritis, S. N., Harper, M., Wapner, R. J., Sorokin, Y., Miodovnik, M., O'Sullivan, M. J., Sibai, B. M., Langer, O., & Gabbe, S. G. (2006). Foetal injury associated with cesarean delivery. *Obstet Gynecol*, *108*(4), 885-890.  
<https://doi.org/10.1097/01.AOG.0000237116.72011.f3>
- Allen, V. M., O'Connell, C. M., & Baskett, T. F. (2005). Maternal and perinatal morbidity of caesarean delivery at full cervical dilatation compared with caesarean delivery in the first stage of labour. *BJOG: An International Journal of Obstetrics and Gynaecology*, *112*(7), 986-990.
- Antonucci, R., Porcella, A., & Pilloni, M. D. (2014). Perinatal asphyxia in the term newborn. *Journal of Pediatric and Neonatal Individualized Medicine (JPNIM)*, *3*(2), e030269-e030269.
- Ascioglu, O., Gungorduk, K., Yildirim, G., Ascioglu, B. B., Gungorduk, O. C., Ark, C., Gunay, T., & Yenigul, N. (2014). Second-stage vs first-stage caesarean delivery: comparison of maternal and perinatal outcomes. *J Obstet Gynaecol*, *34*(7), 598-604. <https://doi.org/10.3109/01443615.2014.920790>
- Babre, V. M., Bendre, K. R., & Niyogi, G. (2017). Review of caesarean sections at full dilatation. *International Journal of Reproduction, Contraception, Obstetrics and Gynecology*, *6*(6), 2491-2494.
- Bergholt, T., Stenderup, J. K., Vedsted-Jakobsen, A., Helm, P., & Lenstrup, C. (2003). Intraoperative surgical complication during cesarean section: an observational study of the incidence and risk factors. *Acta Obstetrica et Gynecologica Scandinavica*, *82*(3), 251-256.
- Biccard, B. M., Madiba, T. E., Kluyts, H.-L., Munlemvo, D. M., Madzimbamuto, F. D., Basenero, A., Gordon, C. S., Youssouf, C., Rakotoarison, S. R., & Gobin, V. (2018). Perioperative patient outcomes in the African Surgical Outcomes Study: a 7-day prospective observational cohort study. *The Lancet*, *391*(10130), 1589-1598.

- Boley, J. (1991). The history of caesarean section. 1935. *CMAJ: Canadian Medical Association Journal*, 145(4), 319.
- Casey, B. M., McIntire, D. D., & Leveno, K. J. (2001). The continuing value of the Apgar score for the assessment of newborn infants. *New England Journal of Medicine*, 344(7), 467-471.
- Caughey, A. B., Sharshiner, R., & Cheng, Y. W. (2015). Foetal malposition: impact and management. *Clinical Obstetrics and Gynecology*, 58(2), 241-245.
- Cebekulu, L., & Buchmann, E. J. (2006). Complications associated with cesarean section in the second stage of labour. *Int J Gynaecol Obstet*, 95(2), 110-114. <https://doi.org/10.1016/j.ijgo.2006.06.026>
- Cheng, Y. W., & Caughey, A. B. (2017). Defining and Managing Normal and Abnormal Second Stage of Labour. *Obstet Gynecol Clin North Am*, 44(4), 547-566. <https://doi.org/10.1016/j.ogc.2017.08.009>
- Clark, S. L., Belfort, M. A., Dildy, G. A., Herbst, M. A., Meyers, J. A., & Hankins, G. D. (2008). Maternal death in the 21st century: causes, prevention, and relationship to cesarean delivery. *American Journal of Obstetrics and Gynecology*, 199(1), 36.e31-35; discussion 91-32. e37-11. <https://doi.org/10.1016/j.ajog.2008.03.007>
- Davis, G., Fleming, T., Ford, K., Mouawad, M. R., & Ludlow, J. (2015). Caesarean section at full cervical dilatation. *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 55(6), 565-571.
- de Souza, A. L. S., de Souza, N. L., de França, D. F., de Oliveira, S. I. M., Araújo, A. K. C., & Dantas, D. N. A. (2016). Risk factors for perinatal asphyxia in newborns delivered at term. *Open Journal of Nursing*, 6(7), 558-564.
- El-Sayed, Y. Y. (2012). Diagnosis and management of arrest disorders: duration to wait. *Seminars in Perinatology*,
- Fasubaa, O., Ezechi, O., Orji, E., Ogunniyi, S., Akindele, S., Loto, O., & Okogbo, F. (2002). Delivery of the impacted head of the fetus at caesarean section after prolonged obstructed labour: a randomised comparative study of two methods. *Journal of obstetrics and Gynaecology*, 22(4), 375-378.
- Ferrari, A., Frigerio, L., Candotti, G., Buscaglia, M., Petrone, M., Taglioretti, A., & Calori, G. (2001). Can Joel-Cohen incision and single layer reconstruction reduce cesarean section morbidity? *International Journal of Gynecology & Obstetrics*, 72(2), 135-143.
- Fitzwater, J. L., Owen, J., Ankumah, N. A., Campbell, S. B., Biggio, J. R., Szychowski, J. M., & Edwards, R. K. (2015). Nulliparous Women in the Second Stage of Labour: Changes in Delivery Outcomes Between Two Cohorts From 2000 and 2011. *Obstet Gynecol*, 126(1), 81-86. <https://doi.org/10.1097/aog.0000000000000872>

- Friedman, E. A. (1955). Primigravid labour; a graphicostatistical analysis. *Obstet Gynecol*, 6(6), 567-589. <https://doi.org/10.1097/00006250-195512000-00001>
- Gabel, K. T., & Weeber, T. A. (2012). Measuring and communicating blood loss during obstetric hemorrhage. *Journal of Obstetric, Gynecologic & Neonatal Nursing*, 41(4), 551-558.
- Gedefaw, G., Demis, A., Alemnew, B., Wondmieneh, A., Getie, A., & Waltengus, F. (2020). Prevalence, indications, and outcomes of caesarean section deliveries in Ethiopia: a systematic review and meta-analysis. *Patient Safety in Surgery*, 14(1), 11. <https://doi.org/10.1186/s13037-020-00236-8>
- Gibbons, L., Belizán, J. M., Lauer, J. A., Betrán, A. P., Merialdi, M., & Althabe, F. (2010). The global numbers and costs of additionally needed and unnecessary caesarean sections performed per year: overuse as a barrier to universal coverage. *World health report*, 30(1), 1-31.
- Govender, V., Panday, M., & Moodley, J. (2010). Second stage caesarean section at a tertiary hospital in South Africa. *The Journal of Maternal-Foetal & Neonatal Medicine*, 23(10), 1151-1155.
- Gregory, K. D., Jackson, S., Korst, L., & Fridman, M. (2012). Cesarean versus vaginal delivery: whose risks? Whose benefits? *American journal of perinatology*, 29(01), 07-18.
- Gurung, P., Malla, S., Lama, S., Malla, A., & Singh, A. (2017). Caesarean section during second stage of labour in a tertiary centre. *Journal of Nepal Health Research Council*, 15(2), 178-181.
- Häger, R. M., Daltveit, A. K., Hofoss, D., Nilsen, S. T., Kolaas, T., Øian, P., & Henriksen, T. (2004). Complications of cesarean deliveries: rates and risk factors. *American journal of obstetrics and gynecology*, 190(2), 428-434.
- Hammad, I. A., Chauhan, S. P., Magann, E. F., & Abuhamad, A. Z. (2014). Peripartum complications with cesarean delivery: a review of Maternal-Foetal Medicine Units Network publications. *Journal of Maternal-Foetal & Neonatal Medicine*, 27(5), 463-474. <https://doi.org/10.3109/14767058.2013.818970>
- Herstad, L., Klungsøyr, K., Skjærven, R., Tanbo, T., Forsén, L., Åbyholm, T., & Vangen, S. (2016). Elective cesarean section or not? Maternal age and risk of adverse outcomes at term: a population-based registry study of low-risk primiparous women. *BMC pregnancy and childbirth*, 16(1), 230.
- Hofmeyr, G., & Singata-Madliki, M. (2020). The second stage of labour. *Best Practice & Research Clinical Obstetrics & Gynaecology*, 67, 53-64.
- Hofmeyr, G. J., Mathai, M., Shah, A. N., & Novikova, N. (2008). Techniques for caesarean section. *Cochrane database of systematic reviews*(1).
- ICD-10. ( 2010). <http://www.who.int/classifications/icd/icdonlineversions/en>

- Ijaiya, M., & Aboyeji, P. (2001). Caesarean Delivery: The trend over a Ten-year period at Ilorin, Nigeria. *Nigerian Journal of Surgical Research*, 3(1), 11-18.
- James, D. (2001). Caesarean section for foetal distress. *BMJ (Clinical research ed.)*, 322(7298), 1316-1317. <https://doi.org/10.1136/bmj.322.7298.1316>
- Jeve, Y., Navti, O., & Konje, J. (2016). Comparison of techniques used to deliver a deeply impacted foetal head at full dilation: a systematic review and meta-analysis. *BJOG: An International Journal of Obstetrics and Gynaecology*, 123(3), 337-345. <https://doi.org/https://doi.org/10.1111/1471-0528.13593>
- Kagoni, S. E., Mwangi, A., & Chelagat, D. (2017). INDICATION AND OUTCOMES OF CAESAERIAN SECTION AT MOI TEACHING & REFERRAL HOSPITAL, ELDORET, KENYA. *Kenyan Journal of Nursing & Midwifery*, 2(2), 114-123.
- Kelsey, J. L., Whittemore, A. S., Evans, A. S., & Thompson, W. D. (1996). *Methods in observational epidemiology* (Vol. 10). Monographs in Epidemiology and.
- Khasawneh, W., Obeidat, N., Yusef, D., & Alsulaiman, J. W. (2020). The impact of cesarean section on neonatal outcomes at a university-based tertiary hospital in Jordan. *BMC Pregnancy and Childbirth*, 20, 1-9.
- Larsson, C., Saltvedt, S., Wiklund, I., Pahlen, S., & Andolf, E. (2006). Estimation of blood loss after cesarean section and vaginal delivery has low validity with a tendency to exaggeration. *Acta Obstetrica et Gynecologica Scandinavica*, 85(12), 1448-1452.
- Lavoie, A., & Toledo, P. (2013). Multimodal postcesarean delivery analgesia. *Clinics in perinatology*, 40(3), 443-455.
- Loudon, J. A. Z., Groom, K. M., Hinkson, L., Harrington, D., & Paterson-Brown, S. (2010). Changing trends in operative delivery performed at full dilatation over a 10-year period. *Journal of Obstetrics and Gynaecology*, 30(4), 370-375. <https://doi.org/10.3109/01443611003628411>
- Low, J. (2009). Caesarean section—past and present. *Journal of obstetrics and gynaecology Canada*, 31(12), 1131-1136.
- Lurie, S. (2005). The changing motives of cesarean section: from the ancient world to the twenty-first century. *Arch Gynecol Obstet*, 271(4), 281-285. <https://doi.org/10.1007/s00404-005-0724-4>
- Lurie, S., Raz, N., Boaz, M., Sadan, O., & Golan, A. (2014). Comparison of maternal outcomes from primary cesarean section during the second compared with first stage of labour by indication for the operation. *Eur J Obstet Gynecol Reprod Biol*, 182, 43-47. <https://doi.org/10.1016/j.ejogrb.2014.08.025>
- Majoko, F., & Gardener, G. (2012). Trial of instrumental delivery in theatre versus immediate caesarean section for anticipated difficult assisted births. *Cochrane Database Syst Rev*, 10(10), Cd005545. <https://doi.org/10.1002/14651858.CD005545.pub3>

- Marshall, N. E., Fu, R., & Guise, J.-M. (2011). Impact of multiple cesarean deliveries on maternal morbidity: a systematic review. *American journal of obstetrics and gynecology*, 205(3), 262. e261-262. e268.
- McKenna, S. P., & Heaney, A. (2020). Composite outcome measurement in clinical research: the triumph of illusion over reality? *Journal of Medical Economics*, 23(10), 1196-1204. <https://doi.org/10.1080/13696998.2020.1797755>
- McNamara, H., & Johnson, N. (1995). The effect of uterine contractions on foetal oxygen saturation. *BJOG: An International Journal of Obstetrics and Gynaecology*, 102(8), 644-647.
- Menacker, F. (2010). *Recent trends in cesarean delivery in the United States*. US Department of Health and Human Services, Centers for Disease Control and ....
- MoH. (2018). *Kenya Health Information System*.
- Moodley, J., Devjee, J., Khedun, S. M., & Esterhuizen, T. (2009). Second-stage primary Caesarean deliveries: Are maternal complications increased? *South African Family Practice*, 51(4).
- Morales, P., Bustamante, D., Espina-Marchant, P., Neira-Peña, T., Gutiérrez-Hernández, M. A., Allende-Castro, C., & Rojas-Mancilla, E. (2011). Pathophysiology of perinatal asphyxia: can we predict and improve individual outcomes? *Epma j*, 2(2), 211-230. <https://doi.org/10.1007/s13167-011-0100-3>
- MTRH. (2016). *Hospital Background*
- Oliphant, S. S., Bochenska, K., Tolge, M. E., Catov, J. M., & Zyczynski, H. M. (2014). Maternal lower urinary tract injury at the time of Cesarean delivery. *International Urogynecology Journal*, 25(12), 1709-1714. <https://doi.org/10.1007/s00192-014-2446-2>
- Organization, W. H. (2015). *WHO statement on caesarean section rates*.
- Patwardhan, B., & Motashaw, N. (1957). Caesarean section. *J Obstet Gynecol India*, 8, 1-15.
- Pitsawong, C., & Panichkul, P. (2011). Risk factors associated with birth asphyxia in Phramongkutklao Hospital. *Thai Journal of Obstetrics and Gynaecology*, 165-171.
- Rada, M. P., Ciortea, R., Măluțan, A. M., Prundeanu, I., Doumouchsis, S. K., Bucuri, C. E., Blaga, L. D., & Mișu, D. (2022). Maternal and neonatal outcomes associated with delivery techniques for impacted foetal head at cesarean section: a systematic review and meta-analysis. *Journal of Perinatal Medicine*, 50(4), 446-456. <https://doi.org/doi:10.1515/jpm-2021-0572>



- Rainaldi, M. A., & Perlman, J. M. (2016). Pathophysiology of Birth Asphyxia. *Clinics in Perinatology*, 43(3), 409-422. <https://doi.org/10.1016/j.clp.2016.04.002>
- Richards, M. (1977). The induction and acceleration of labour: some benefits and complications. *Early human development*, 1(1), 3-17.
- Robson, M. S. (2001). Classification of caesarean sections. *Foetal and maternal medicine review*, 12(1), 23-39.
- Sacre, H., Bird, A., Clement-Jones, M., & Sharp, A. (2021). Effectiveness of the foetal pillow to prevent adverse maternal and foetal outcomes at full dilatation cesarean section in routine practice. *Acta Obstetrica et Gynecologica Scandinavica*, 100(5), 949-954. <https://doi.org/https://doi.org/10.1111/aogs.14038>
- Safa, H., & Beckmann, M. (2016). Comparison of maternal and neonatal outcomes from full-dilatation cesarean deliveries using the Foetal Pillow or hand-push method. *International Journal of Gynecology & Obstetrics*, 135(3), 281-284.
- Schiff, E., Friedman, S. A., Zolti, M., Avraham, A., Kayam, Z., Mashiach, S., & Carp, H. (2001). A matched controlled study of Kielland's forceps for transverse arrest of the foetal vertex. *J Obstet Gynaecol*, 21(6), 576-579. <https://doi.org/10.1080/01443610120085500>
- Schneid-Kofman. (2012). *Maternal complications of cesarean delivery*. (Sheiner E, Ed.). Nova Science Publishers.
- Schorn, M. N. (2010). Measurement of blood loss: review of the literature. *Journal of midwifery & women's health*, 55(1), 20-27.
- Seal, S. L., Dey, A., Barman, S. C., Kamilya, G., Mukherji, J., & Onwude, J. L. (2016). Randomized controlled trial of elevation of the foetal head with a foetal pillow during cesarean delivery at full cervical dilatation. *International Journal of Gynaecology and Obstetrics*, 133(2), 178-182. <https://doi.org/10.1016/j.ijgo.2015.09.019>
- Seal, S. L., Kamilya, G., Mukherji, J., Bhattacharyya, S. K., De, A., & Hazra, A. (2010). Outcome in second- versus first-stage cesarean delivery in a teaching institution in eastern India. *Am J Perinatol*, 27(6), 507-512. <https://doi.org/10.1055/s-0030-1248936>
- Selo-Ojeme, D., Sathiyathan, S., & Fayyaz, M. (2008). Caesarean delivery at full cervical dilatation versus caesarean delivery in the first stage of labour: comparison of maternal and perinatal morbidity. *Archives of Gynecology and Obstetrics*, 278(3), 245-249.
- Sethuram, R., Jamjute, P., & Kevelighan, E. (2010). Delivery of the deeply engaged head: a lacuna in training. *Journal of Obstetrics and Gynaecology*, 30(6), 545-549.
- Sheiner, E. (2012). *Cesarean section: Procedures, complications and recovery*. Nova Science Publishers, Inc.

- Sobhy, S., Arroyo-Manzano, D., Murugesu, N., Karthikeyan, G., Kumar, V., Kaur, I., Fernandez, E., Gundabattula, S. R., Betran, A. P., Khan, K., Zamora, J., & Thangaratinam, S. (2019). Maternal and perinatal mortality and complications associated with caesarean section in low-income and middle-income countries: a systematic review and meta-analysis. *Lancet*, *393*(10184), 1973-1982. [https://doi.org/10.1016/s0140-6736\(18\)32386-9](https://doi.org/10.1016/s0140-6736(18)32386-9)
- Stanton, C. K., & Holtz, S. A. (2006). Levels and trends in cesarean birth in the developing world. *Studies in family planning*, *37*(1), 41-48.
- Stark, M., Chavkin, Y., Kupfersztain, C., Guedj, P., & Finkel, A. (1995). Evaluation of combinations of procedures in cesarean section. *International Journal of Gynecology & Obstetrics*, *48*(3), 273-276.
- [Record #118 is using a reference type undefined in this output style.]
- Timor-Tritsch, I. E., & Monteagudo, A. (2012). Unforeseen consequences of the increasing rate of cesarean deliveries: early placenta accreta and cesarean scar pregnancy. A review. *American journal of obstetrics and gynecology*, *207*(1), 14-29.
- Tita, A. T. N. (2012). When is primary cesarean appropriate: maternal and obstetrical indications. *Seminars in perinatology*,
- Todman, D. (2007). A history of caesarean section: from ancient world to the modern era. *Aust N Z J Obstet Gynaecol*, *47*(5), 357-361. <https://doi.org/10.1111/j.1479-828X.2007.00757.x>
- Torloni, M. R., Betran, A. P., Souza, J. P., Widmer, M., Allen, T., Gulmezoglu, M., & Meriardi, M. (2011). Classifications for cesarean section: a systematic review. *PloS one*, *6*(1), e14566.
- Unterscheider, J., McMenamin, M., & Cullinane, F. (2011). Rising rates of caesarean deliveries at full cervical dilatation: a concerning trend. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, *157*(2), 141-144.
- Unterscheider, J., McMenamin, M., & Cullinane, F. (2011). Rising rates of caesarean deliveries at full cervical dilatation: a concerning trend. *Eur J Obstet Gynecol Reprod Biol*, *157*(2), 141-144. <https://doi.org/10.1016/j.ejogrb.2011.03.008>
- Van Der Spek, L., Sanglier, S., Mabeya, H. M., Van Den Akker, T., Mertens, P. L., & Houweling, T. A. (2020). Socioeconomic differences in caesarean section—are they explained by medical need? An analysis of patient record data of a large Kenyan hospital. *International journal for equity in health*, *19*(1), 1-14.
- Van Dongen, P. W. (2009). Caesarean section—etymology and early history. *South african journal of obstetrics and gynaecology*, *15*(2).
- Van Ham, M. A., Van Dongen, P. W., & Mulder, J. (1997). Maternal consequences of caesarean section. A retrospective study of intra-operative and postoperative maternal complications of caesarean section during a 10-year period.

*European Journal of Obstetrics & Gynecology and Reproductive Biology*, 74(1), 1-6.

- Vintzileos, A. M., Nochimson, D. J., Guzman, E. R., Knuppel, R. A., Lake, M., & Schifrin, B. S. (1995). Intrapartum electronic foetal heart rate monitoring versus intermittent auscultation: a meta-analysis. *Obstetrics & Gynecology*, 85(1), 149-155.
- Vousden, N., Cargill, Z., Briley, A., Tydeman, G., & Shennan, A. H. (2014a). Caesarean section at full dilatation: incidence, impact and current management. *The Obstetrician & Gynaecologist*, 16(3), 199-205. <https://doi.org/https://doi.org/10.1111/tog.12112>
- Vousden, N., Cargill, Z., Briley, A., Tydeman, G., & Shennan, A. H. (2014b). Caesarean section at full dilatation: incidence, impact and current management. *Obstet Gynaecol*, 16(3), 199-205.
- Vousden, N., Tydeman, G., Briley, A., Seed, P. T., & Shennan, A. H. (2017). Assessment of a vaginal device for delivery of the impacted foetal head at caesarean section. *Journal of Obstetrics and Gynaecology*, 37(2), 157-161.
- Wanyonyi, S., Sequeira, E., & Obura, T. (2006). Caesarian section rates and perinatal outcome at the Aga Khan University Hospital, Nairobi. *East African medical journal*, 83, 651-658. <https://doi.org/10.4314/eamj.v83i12.9495>
- WHO. (2012). *Guidelines on basic newborn resuscitation*
- Williams, C., Fong, R., Murray, S. M., & Stock, S. J. (2021). Caesarean birth and risk of subsequent preterm birth: a retrospective cohort study. *BJOG: An International Journal of Obstetrics and Gynaecology*, 128(6), 1020-1028.
- Women's, N. C. C. f., & Health, C. s. (2011). Caesarean section.
- Yaya, S., Uthman, O. A., Amouzou, A., & Bishwajit, G. (2018). Disparities in caesarean section prevalence and determinants across sub-Saharan Africa countries. *Global health research and policy*, 3(1), 19.
- Zhang, J., Landy, H. J., Branch, D. W., Burkman, R., Haberman, S., Gregory, K. D., Hatjis, C. G., Ramirez, M. M., Bailit, J. L., & Gonzalez-Quintero, V. H. (2010). Contemporary patterns of spontaneous labour with normal neonatal outcomes. *Obstetrics and gynecology*, 116(6), 1281.

## APPENDICES

### APPENDIX 1: INFORMED CONSENT FORM



**MOI TEACHING & REFERRAL HOSPITAL / MOI UNIVERSITY  
COLLEGE OF HEALTH SCIENCES -INSTITUTIONAL RESEARCH AND  
ETHICS COMMITTEE (MTRH/MU-IREC) INFORMED CONSENT FORM**  
**Study Title: ADVERSE MATERNAL AND PERINATAL OUTCOMES IN  
SECOND-STAGE VERSUS FIRST-STAGE OF LABOUR PRIMARY  
CAESAREAN DELIVERIES AT MOI TEACHING AND REFERRAL  
HOSPITAL, KENYA.**

**Name of Principal Investigator(s):** Asaso Kimbley Omwodo (Moi University).

**Name of Organization:** Moi University.

**Address:** P.O Box 4606-030100, Eldoret, Kenya.

**Telephone Number:** 254 53 2061562, 254 53 2060958/9

**Name of Sponsor/Funding Agency:** None

**Informed Consent Form for:**

Women post caesarean delivery.

**This Informed Consent Form has two parts:**

- Part I: Information Sheet [to share information about the study with you]
- Part II: Certificate of Consent [for signatures if you choose to participate]

#### **PART I: INFORMATION SHEET**

##### **Introduction:**

You are being asked to take part in a research study. This information is provided to tell you about the study. Please read this form carefully. You will be given a chance to ask questions.

Taking part in this research study is voluntary. Saying no will not affect your rights to health care or any other services. Your treatment/payment or enrollment in any health plans or eligibility for benefits will not be affected if you decide not to take part. You are also free to withdraw from this study at any time. If after data collection you choose to quit, you can request that information provided by you be destroyed under supervision. This would be before data is de-identified and aggregated. You will be notified if new

information becomes available about the risks or benefits of this research. You will receive a copy of this form after it is signed

**Purpose of the study:** Compare maternal and perinatal adverse outcomes between second-stage and first-stage of labour primary caesarean delivery at Moi Teaching and Referral hospital (MTRH), Eldoret.

**Study site:** The study was conducted at the Moi Teaching and Referral Hospital– Riley Mother and Baby Hospital (RMBH).

**Study population:**

Women who had undergone emergency primary caesarean delivery at Moi Teaching and Referral Hospital– Riley Mother and Baby Hospital (RMBH).

**Study procedures:**

The hospital obstetric procedure register was examined daily for caesarean deliveries performed in the preceding 24 hours. The inpatient numbers of parturients to be enrolled will then be traced to the postnatal ward. Recruitment was post-delivery, within 24hrs participant admission into the postnatal ward. The medical records of eligible participants will be retrospectively reviewed from respective files in the postnatal ward records department. Data will be collected with respect to age, parity, antenatal clinic attendance, gestation, referral/non-referral, full dilatation–delivery interval, clinical management (oxytocin use and vacuum delivery attempt), intra-operative details, perinatal and maternal outcomes. The prospective aspect will be the maternal post-operative length of hospital stay outcome. All participants was followed up until discharge from the postnatal ward. The study period will be between 1<sup>st</sup> August 2021 and 31<sup>st</sup> July 2022

**If you agree you will do the following:**

Your medical records will be reviewed for outcome data and you was followed up until hospital discharge to ascertain your duration of stay at the hospital post caesarean delivery procedure.

**Benefits:**

The outcome of this study will help improve our practice to be at par with the current international standards. The feedback will also help in shaping policies that will ultimately guide enhancement of your knowledge in caesarean delivery in the second-stage of labour.

**Risks/Discomforts:**

There are no risks associated with your participation in this study.

**Payments and Reimbursements:**

You will not be reimbursed or paid for participation in this study.

**Confidentiality:**

All reasonable efforts will be made to keep your protected information (private and confidential). Using or sharing (“disclosure”) of such information will follow National privacy guidelines. By signing the consent document for this study, you are giving permission (“authorization”) for the use and disclosure of your study information. We may need to share your protected information with the community advisory board, MTRH//MU-IREC, NACOSTI or the healthcare team. We will retain your research records for at least six years after the study is completed. At that time, the research information is destroyed [Inform the participant how the records will be destroyed]. If you decide to withdraw your permission for use of your personal data, contact the [PI] in writing and let them know your decision. At that time, we will stop further collection of any information about you. However, the health information collected before this withdrawal may continue to be used for the purposes of reporting and research quality.

[OPTIONAL]: For studies involving biological materials, specify the storage location and procedures and duration for handling specimens.

[OPTIONAL]: For studies involving patients, explain that their information will be added to their medical record and that any research information entered into their medical record will be kept indefinitely.

[OPTIONAL]: You have the right to see and copy your personal information related to the research study for as long as the study team holds this information

**Compensation for injury:**

There is no anticipated injury that may result from participation in the study. In the event of any form of injury resulting from participating in this study, no compensation was awarded.

**PART II: CONSENT OF PATICIPANT:**

I have read or have had someone read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all the questions I have at this time. I have been told of the potential risks, discomfort, and possible benefits (if any) of the study. I freely volunteer to take part in this study.

[This section must be written in the first person. If the participant is illiterate, or for some reason is unable to write, they should provide a thumbprint and a competent witness must be engaged during the consent process]

\_\_\_\_\_

Name of Participant \_\_\_\_\_ Signature of participant/Thumbprint  
Date & Time

\_\_\_\_\_

Name of Witness [Optional] \_\_\_\_\_ Signature of Witness \_\_\_\_\_ Date &  
Time

\_\_\_\_\_

Name of the person obtaining consent \_\_\_\_\_ Signature of person \_\_\_\_\_ Date &  
Time  
obtaining consent

\_\_\_\_\_

Printed name of the investigator \_\_\_\_\_ Signature of Investigator \_\_\_\_\_ Date

### **Contacts for questions about the study**

Questions about the study: Please contact the Principal investigator

Name: Omwodo Kimbley Asaso

Phone: 0705557929

Email: kimbleyasaso@yahoo.com

Questions about your rights as a participant: You may contact the Institutional Ethics and Research Committee (MTRH//MU-IREC) 0787723677 or email [irec@mtrh.go.ke](mailto:irec@mtrh.go.ke) or [irecoffice@gmail.com](mailto:irecoffice@gmail.com). The MTRH//MU-IREC is a group of people that review studies for safety and to protect the rights of participants.

**APPENDIX 2: DATA ABSTRACTION FORM**

Completed by (investigators name):

Study ID No [ ]

Date of collection: YEAR / MONTH / DAY

**SECTION A: DEMOGRAPHIC CHARACTERISTICS**

Date of birth (dd/mm/yyyy) \_\_\_\_\_

Age \_\_\_\_\_

**Occupation:**

- a. Employed [ ] b. Self-employed [ ] c. Unemployed [ ] d. Student [ ]

**Marital status:**

- a. Married [ ] b. Widowed [ ] c. Divorced [ ] d. Single [ ]

**Highest level of education:**

- a. Tertiary [ ] b. Secondary [ ] c. Primary [ ] d. None [ ]

Current smoking status: a Yes [ ] b No [ ]

Weight (kg) \_\_\_\_\_ Height (m) \_\_\_\_\_ BMI (kg/m2) \_\_\_\_\_

**SECTION B: OBSTETRICS HISTORY**

Parity [ ]

LMP (dd/mm/yyyy) \_\_\_\_\_

Gestational age at delivery in weeks [ ]

Date of delivery EDD [ ]

Admission as referral [ ] Yes [ ] No

Reason for referral \_\_\_\_\_

Number of ANC visits: \_\_\_\_\_

History of Pregnancy Loss: a. No previous pregnancy loss [ ] b. Previous pregnancy loss [ ]



**SECTION C: MEDICAL COMORBIDITIES**

a. Yes [ ]      b. No [ ]

IF Yes,

- i. Hypertensive Disorder in pregnancy [ ]
- ii. Chronic hypertension [ ]
- iii. Thyroid disease [ ]
- iv. Venous thromboembolic disease [ ]
- v. Pre-gestational DM [ ]
- vi. Renal disease [ ]
- vii. Seizure disorder [ ]
- viii. Thyroid disease in pregnancy [ ]
- ix. None [ ]

Others (Specify) \_\_\_\_\_

**SECTION D: INDICATION FOR CAESAREAN DELIVERY**

- a. Poor-progress labour [ ]      b. Cephalopelvic disproportion [ ]
- c. Prolonged or obstructed labour [ ]      d. Failed vacuum delivery [ ]
- e. Foetal distress [ ]      f. Cord prolapse [ ]
- f. Non-reassuring foetal heart rate pattern [ ]
- g. Other [ ] Specify \_\_\_\_\_

**SECTION E: LABOUR DATA**Length of 1<sup>st</sup> Stage

- a. Commencement: Date \_\_\_\_\_ Time \_\_\_\_\_ (AM/PM)
- b. Full dilatation: Date \_\_\_\_\_ Time \_\_\_\_\_ (AM/PM)

Total [ ] Hours

Augmentation with Oxytocin a. Yes [ ]      b. No [ ]

**Instrument Use**

Indication for instrumental delivery a. None [ ] b. Ventouse [ ]

Number of pulls \_\_\_\_\_

Foetal head station at decision to operate: [ ] Not indicated [ ]

Cervical OS dilatation at decision to operate [ ] Centimetres

Time of operation: a. Day shift (8.00am to 5.59pm) [ ]  
b. Night shift (6.00pm to 7.59am) [ ]

**SECTION F: INTRAOPERATIVE DATA**

Surgeon: Postgraduate year:

a. PGY 1 [ ] b. PGY 2 [ ] c. PGY 3 and above [ ]

Anaesthesia:

a. GA [ ] b. Spinal/Epidural [ ]

Operation length

a. Skin incision: Date \_\_\_\_\_ Time \_\_\_\_\_ (AM/PM)

b. Delivery of foetus: Date \_\_\_\_\_ Time \_\_\_\_\_ (AM/PM)

Technique: \_\_\_\_\_

Date \_\_\_\_\_ Time \_\_\_\_\_ (AM/PM)

c. Skin Closure: Date \_\_\_\_\_ Time \_\_\_\_\_ (AM/PM)

Second registrar/ consultant assistance: a. Yes [ ] b. No [ ]

**SECTION G: MATERNAL OUTCOME**

Intraoperative complications a. Yes [ ] b. No [ ]

IF Yes:

- I. Uterine atony [ ]
- II. Adjacent tissue injury [ ]
- III. Hysterectomy [ ]
- IV. Bladder injury [ ]
- V. Uterine incision extension [ ]
- VI. Other. Specify \_\_\_\_\_

Estimated blood loss in mls \_\_\_\_\_

Intraoperative blood transfusion [ ]

Postoperative transfusion [ ]

No: of Blood products transfused: \_\_\_\_\_

If blood loss of 1000mls or more;

Cause of post-partum haemorrhage \_\_\_\_\_

Length of Hospital Stay in Days \_\_\_\_\_

Duration of urethral catheter placement \_\_\_\_\_ Hours

\_\_\_\_\_ Days

Maternal death a. Yes [ ] b. No [ ]

### **Neonatal outcomes**

Foetal weight in grams \_\_\_\_\_

Foetal sex: [ ] Male [ ] Female [ ] Other

Neonatal trauma (including scalp, facial bruising and fractures) [ ]

Neonatal trauma detail \_\_\_\_\_

APGAR scores [ ] 1min [ ] 5min [ ] 10min

Fresh still birth (FSB) a. Yes [ ] b. No [ ]

Baby stay in days New Born Unit [ ]

Neonatal death a. Yes [ ] b. No [ ]

**APPENDIX 3: BUDGET**

<b>Items</b>	<b>Quantity</b>	<b>Unit Price (Kshs)</b>	<b>Total (Kshs)</b>
<b><i>Stationery &amp; Equipment</i></b>			
Printing Papers	15 reams	500.00	7,500.00
Black Cartridges	4	2,000.00	8,000.00
Writing Pens	1 packet	500.00	500.00
Flash Discs	1	2,000.00	2,000.00
Box Files	2	200.00	400.00
Document Wallets	4	50.00	200.00
<b>Sub total</b>			<b>18,700.00</b>

<b><i>Thesis Development</i></b>			
Printing drafts & final Thesis	10 copies	500.00	5,000.00
Photocopies of final Thesis	6 copies	100.00	600.00
Binding of copies of Thesis	5 copies	100.00	500.00
<b>Sub total</b>			<b>6,100.00</b>
<b><i>Personnel</i></b>			

Biostatician	1	25,000.00	25,000.00
Research assistant	2	10,000	20,000.00
<b>Sub total</b>			<b>45,000.00</b>
<i>Thesis Development</i>			
Printing of drafts and final thesis	10 copies	800.00	8,000.00
Photocopy of final thesis	6 copies	200.00	1,200.00
Binding of thesis	6 copies	300.00	1,800.00
Publication	1	20,000	20,000.00
<b>Sub total</b>			<b>31,000.00</b>
<b>Total</b>			<b>119,300.00</b>
<b>Miscellaneous Expenditure</b>			<b>10,000.00</b>
<b>Grand Total</b>			<b>129,300.00</b>

### Appendix 4: Work Plan

	2021				2022			2023	
<b>ACTIVITY</b>	JAN- MAR	APR- JUN	JUL- AUG	SEPT- DEC	JAN- SEPT	OCT- NOV	DEC	JAN- FEB	MARCH -SEPT
<b>Thesis writing</b>									
<b>Ethical approval</b>									
<b>Data collection</b>									
<b>Data analysis</b>									
<b>Report writing</b>									
<b>Submission of thesis</b>									
<b>Presentation of thesis</b>									
<b>Publication of thesis</b>									

## Appendix 5: IREC

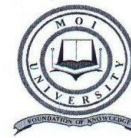


MOI TEACHING AND REFERRAL HOSPITAL  
P.O. BOX 3  
ELDORET  
Tel: 33471/2/3

Reference: IREC/2021/88

**Approval Number: 0003919**

Dr. Omwodo Kimbley Ahsaso,  
Moi University,  
School of Medicine,  
P.O. Box 4606-30100,  
**ELDORET-KENYA.**



MOI UNIVERSITY  
COLLEGE OF HEALTH SCIENCES  
P.O. BOX 4606  
ELDORET  
Tel: 33471/2/3  
13<sup>th</sup> July, 2021

Dear Dr. Kimbley,

**MATERNAL AND PERINATAL ADVERSE OUTCOMES IN SECOND STAGE VERSUS FIRST STAGE OF LABOUR CAESAREAN DELIVERIES AT MOI TEACHING AND REFERRAL HOSPITAL**

This is to inform you that **MTRH/MU-IREC** has reviewed and approved your above research proposal. Your application approval number is **FAN: 0003919**. The approval period is **13<sup>th</sup> July, 2021- 12<sup>th</sup> July, 2022**.

This approval is subject to compliance with the following requirements;

- i. Only approved documents including (informed consents, study instruments, Material Transfer Agreements (MTA) will be used.
- ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by **MTRH/MU-IREC**.
- iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to **MTRH/MU-IREC** within 72 hours of notification.
- iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to **MTRH/MU-IREC** within 72 hours.
- v. Clearance for export of biological specimens must be obtained from **MOH at the recommendation of NACOSTI** for each batch of shipment.
- vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
- vii. Submission of an executive summary report within 90 days upon completion of the study to **MTRH/MU-IREC**.

Prior to commencing your study; you will be required to obtain a research license from the National Commission for Science, Technology and Innovation (NACOSTI) <https://oris.nacosti.go.ke> and other relevant clearances from study sites including a written approval from the CEO-MTRH which is mandatory for studies to be undertaken within the jurisdiction of Moi Teaching & Referral Hospital (MTRH) and its satellites sites.

Sincerely,

**PROF. E. WERE**  
CHAIRMAN



**INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE**

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

Dean - SOM  
Dean - SOD

## Appendix 6: Hospital Approval (MTRH)



An ISO 9001:2015 Certified Hospital



### MOI TEACHING AND REFERRAL HOSPITAL

Telephone : (+254)053-2033471/2/3/4  
 Mobile: 722-201277/0722-209795/0734-600461/0734-683361  
 Fax: 053-2061749  
 Email: [ceo@mtrh.go.ke](mailto:ceo@mtrh.go.ke)/[directorsofficemtrh@gmail.com](mailto:directorsofficemtrh@gmail.com)

Nandi Road  
 P.O. Box 3 – 30100  
 ELDORET, KENYA

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

13<sup>th</sup> July, 2021

Dr. Omwodo Kimbley Ahsaso  
 Moi University  
 School of Medicine  
 P.O. Box 4606-30100  
 ELDORET-KENYA

#### MATERNAL AND PERINATAL ADVERSE OUTCOMES IN SECOND STAGE VERSUS FIRST STAGE OF LABOUR CAESAREAN DELIVERIES AT MOI TEACHING AND REFERRAL HOSPITAL

You have been authorised to conduct research within the jurisdiction of Moi Teaching and Referral Hospital (MTRH) and its satellites sites. You are required to strictly adhere to the regulations stated below in order to safeguard the safety and well-being of staff, patients and study participants seen at MTRH.

- 1 The study shall be under Moi Teaching and Referral Hospital regulations.
- 2 A copy of MTRH/MU-IREC approval shall be a prerequisite to conducting the study.
- 3 Studies intending to export human bio-specimens must provide a permit from MOH at the recommendation of NACOSTI for each shipment.
- 4 No data collection will be allowed without an approved consent form(s) to participants unless waiver of written consent has been granted by MTRH/MU-IREC.
- 5 Take note that **data** collected must be treated with due confidentiality and anonymity.

The continued permission to conduct research shall only be sustained subject to fulfilling all the requirements stated above.

*13/07/2021*  
 DR. WILSON K. ARUASA, *EBS*  
 CHIEF EXECUTIVE OFFICER  
 MOI TEACHING AND REFERRAL HOSPITAL



cc - Senior Director, Clinical Services  
 - Director of Nursing Services  
 - HOD, HRISM

*All correspondence should be addressed to the Chief Executive Officer*

*Visit our Website: [www.mtrh.go.ke](http://www.mtrh.go.ke)*

TO BE THE LEADING MULTI-SPECIALTY HOSPITAL FOR HEALTHCARE, TRAINING AND RESEARCH IN AFRICA