FETAL AND MATERNAL OUTCOMES OF VACUUM ASSISTED DELIVERIES AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

BY

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A THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE (REPRODUCTIVE HEALTH), MOI UNIVERSITY.

DECLARATION

Declaration by Student

This thesis is my original work and has not been presented for a degree in any other university. No part of this thesis may be reproduced without prior written permission of the author and/or Moi University.

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DEDICATION

This thesis is dedicated to my family which has supported me during my Postgraduate studies.

To the continued improvement of services provided to the mothers who deliver at MTRH.

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I would like to acknowledge my supervisors Dr. Kaihura and Dr. Itsura for their guidance during the process of doing my thesis. I would also like to thank the faculty and colleagues in the Department of Reproductive Health of Moi University who provided immense support.

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ABBREVIATIONS

AOR	Adjusted Odds Ratio
APGAR	Appearance, pulse, grimace, activity, respiration
AVD	Assisted Vaginal Delivery
CI	Confidence Interval
CS	Caesarean Section
MTRH	Moi Teaching and referral hospital
NYHA	New York Heart Association
OA	Occipito-anterior
OP	Occipito-posterior
OR	Odds Ratio
OT	occipito- transverse
PPH	Postpartum hemorrhage
RHD	Rheumatic Heart Disease
SPET	Severe Preeclampsia
SVD	Spontaneous Vertex Delivery
VAD	Vacuum Assisted Delivery
VE	Vacuum extraction

OPERATIONAL DEFINITION OF TERMS

Vacuum extraction – A procedure that is done to assist the delivery of the fetal head using a soft or a rigid cup attached to a vacuum device.

Second stage of labor – This is the time from full dilatation of the cervix (10 cm) to the delivery of the fetus

Caesarian section – It is the delivery of a fetus through an incision in the abdominal wall and uterus.

Postpartum hemorrhage – This is blood loss occurring after delivery of the fetus. The cut-off is 500ml after vaginal delivery and 1000ml after caesarian section.

Perineal tear – It is a spontaneous laceration of the soft tissue structures between the vagina and anus.

Cephalohematoma- It is a traumatic subperiosteal hematoma that occurs underneath the skin in the periosteum of the infant's skull bone.

ABSTRACT

Background: Vacuum assisted deliveries (VAD) are vaginal deliveries that are accomplished with the use of a vacuum device. This avoids caesarean section and its associated morbidity and implications on future pregnancies. Vacuum deliveries account for approximately 0.2 to1.2% of vaginal deliveries in sub- Saharan Africa. There has been a rise in the number of vacuum deliveries due to increased training in Kenya in the recent past.

Objectives: To determine the indications, labor and procedural characteristics and feto-maternal outcomes of vacuum deliveries at MTRH.

Methods: A hospital– based descriptive study on VAD of parturients of ≥ 37 weeks gestational age and their neonates followed up for 24 hours. A census was conducted in one year from 31st January 2018 to 28th February 2019. Data collection was done in labour ward from participant's file, observation of the procedure and questionnaires were filled by research assistants. Categorical variables were summarized with frequencies, median and their interquartile ranges and association assessed using Pearson's Chi Square test / Fisher's exact test. Continuous variables were summarized using the mean and their standard deviation. Results are presented using tables and graphs

Results: There were 188 participants with a mean age of 23 years. 58.5% were nulliparous. There were 180 successful and 8 failed VAD. Indications for VAD were prolonged second stage of labor, maternal exhaustion and non- reassuring fetal status at 42%, 36.2% and 11.7% respectively. Use of a rigid cup was associated with increased maternal injuries. (p=0.046). Failed VAD resulting in CS was associated with fetal caput succedaneum (p=0.025) and longer decision to delivery interval (p=0.034). The average fetal birth weight was 3200 grams. Admission to the Newborn Unit was 19.1% with birth asphyxia as the commonest diagnosis at 50%. Perinatal mortality occurred at 6.9 %. Genital injuries were the commonest maternal morbidity at 60.6%. Obstetric Anal Sphincter Injuries occurred in 23.7% of the participants. 18.6% of the participants had postpartum hemorrhage and the main cause was trauma.

Conclusion: The commonest indication of vacuum assisted delivery was prolonged second stage of labor. Presence of caput succedaneum and longer duration of vacuum extraction was associated with VAD failure. Superficial scalp injuries were the commonest morbidity due to this procedure. Genital tract injuries were the major maternal morbidity and main cause of PPH in this study.

Recommendations: There is need for proper assessment of parturients in order to reduce cases of failed vacuum extraction. Continuous training of the health-care provider in the art of vacuum extraction to improve fetal and maternal outcomes.

CHAPTER ONE: INTRODUCTION

1.1 Background Information

Assisted vaginal delivery or operative vaginal delivery is a technique used to accomplish delivery safely and avoids caesarean section and its implications for future pregnancy. It is done with the use of forceps or vacuum device. The overall incidence of assisted vaginal delivery is found to be 10% to 20%. The rates vary from 10 – 15% in the UK, 4.5% in the USA and rates under 1% in Sub – Saharan Africa (Martin et al, 2009).

The principle idea of the vacuum extractor is to use a cup device attached by tubing to a pump to create enough negative pressure to allow traction on the cup, thus transferring the traction to the fetal scalp which is thereby pulled along the birth canal axis during delivery. James Young Simpson, a professor of Obstetrics in Edinburgh, performed the first vacuum extraction (VE) in 1849. His device was metal syringe attached to a rubber cup that was placed on the fetal head and traction applied. Vacuum techniques became popular after the introduction of the stainless steel cup vacuum device introduced by Dr. Tage Malmstrom in 1956. It was a metal cup 40 to 60mm in diameter with a chain attached to the cup connecting it to a detachable handle to apply traction. A mechanical or electrical suction device was attached peripherally on the cup. The advantage of the metal cup included a higher success rate, easier cup placement in occipito – posterior position. The disadvantages included increased risk of fetal scalp injuries, difficulty in application and it is uncomfortable.

Forceps device consists of two mirror-image metal instruments that are articulated. The blades of the forceps are placed in the maternal pelvis to cradle the fetal head and traction is applied to effect delivery.

There has been a decline in AVD from 9.1% in 1990 to 3.2 % in 2014 in the United States of America (USA). (Hamilton et al 2015). Vacuum to forceps delivery ratio was found to be 5:1 in the USA. Osterman et al (2009) found a 0.8% vacuum extraction failure rate in his study in the USA.

Spong et al (2012), recommends medically indicated AVD as an acceptable birth method that can reduce the number of CS which comprise a third of all deliveries in the USA. With proper training, medical practitioners can prevent the first CS, its complications and its impact on future pregnancies by perfoming VE properly.

Prerequisites for Operative Vaginal Delivery by Unzila et al (2009) includes informed consent from the mother, clinical pelvimetry must be adequate, her bladder must be empty and have adequate analgesia. There must be full cervical dilatation, ruptured membranes and no placenta previa. The fetal head must be engaged in the pelvis, in vertex presentation, in station 0/5. The position, attitude and presence of caput succedaneum and/or molding of the fetal head should be noted. The estimated fetal weight must be between 2500g and 4500g.An experienced operator, ability to monitor fetal well – being and availability of caesarean section services are necessary.

Indications of VE include prolonged second stage of labor, non – reassuring fetal status, elective shortening of the second stage of labor in maternal cardiovascular or neurologic disease and maternal exhaustion. Prolonged second stage of labor may be due to incoordinate uterine contractions, malposition or malpresentation. After assessment of these time limits, oxytocin may be administered as long as maternal and

fetal condition is reassuring. Lack of progress in descent or a non-reassuring status will necessitate caesarian section.

Non – reassuring fetal status as detected with intermittent auscultation or electronic fetal monitoring may require expedited delivery with vacuum if appropriate. Common signs include persistent bradycardia and reduced variability with decelerations.

Elective shortening of the second stage of labor is sometimes necessary. Maternal conditions like cardiac disease NYHA class 3 & 4, cerebrovascular conditions e.g. hypertensive crises, proliferative retinopathy or neuromuscular diseasese.g. Myasthenia gravis and spinal cord injury with a risk of autonomic dysreflexia in which voluntary maternal expulsive efforts are contraindicated or impossible.

Maternal exhaustion or fatigue is a highly subjective indication. It may be due to prolonged labor or poor maternal psyche. It may respond to rest, encouragement, positional changes and rehydration. Adequate analgesia and augmentation with oxytocin may also alleviate the need for vacuum extraction.

Absolute Contraindications of vacuum extraction include failure to obtain informed consent from the patient, fetal bleeding disorders (e.g., hemophilia, alloimmune thrombocytopenia) due to an increased risk of bleeding and fetal demineralizing diseases (e.g., osteogenesis imperfecta) which predispose fetuses to fractures. Failure to fulfill all the prerequisites for VE, fetal malpresentation (e.g. breech, transverse lie, brow, and face) and suspected cephalopelvic disproportion are a contraindication. Estimated gestational age of less than 34 weeks poses a risk of cephalohematoma, intracranial and subgaleal hemorrhage and neonatal jaundice to the fetus. The safety of using vacuum extractor between 34+0 and 36+0 days is uncertain thus needs to be used with caution.It is an absolute contraindication too.

Relative Contraindications include suspected fetal macrosomia (defined as an estimated fetal weight of 4500 g)**,** uncertainty about fetal position, inadequate anesthesia and prior scalp sampling due to risk of bleeding. (RCOG Green Top Guideline No. 26, 2011).

The choice of instrument (forceps or vacuum extractor) during operative vaginal delivery is mainly influenced by tradition and training, comfort and experience of the operator with a specific instrument the degree of maternal analgesia, and knowledge of the risks and benefits of each of the individual instruments,. The vacuum extraction is widely used in developing countries as the instrument of first choice for operative vaginal delivery. In a meta - analysis by Johanson et al (2000**)** found out that vacuum extraction is easier to learn, has quicker delivery and less genital trauma, less maternal discomfort, less need for analgesia and fewer neonatal craniofacial injuries**.** However, vacuum deliveries are more likely to fail, though its CS rate is still lower than forceps. Vacuum devices were also associated with a reduced need for general and regional anesthesia, and with less postpartum pain than forceps. In the same review, the advantages of forceps deliveries included a lower risk of scalp injury and cephalohematoma than vacuum, they can be used safely in premature infants, they can be used to effect rotation of the fetal head (which is not true of vacuum), and they are less likely to detach from the fetal head.

Maternal complications including perineal pain at delivery, pain in the immediate postpartum period, perineal lacerations, hematomas, blood loss and anemia, urinary retention, and longterm problems with urinary and fecal incontinence.

Neonatal complications include scalp lacerations, cephalohematomas, subgaleal hematomas, intracranial hemorrhage, facial nerve palsies, hyperbilirubinemia, and

retinal hemorrhage. The risk of such complications in neonates is estimated at around 5%. ACOG Practice Bulletin NO. 17**.** In a retrospective cohort study of 913 vacuum extractions by Simonson et al *(*2007), scalp edema, cephalohematoma and skull fracture assessed by cranial radiography was present in 18.7%, 10.8% and 5 % respectively. Intracranial hemorrhage which includes subdural, subarachnoid, intraparenchymal and intraventricular occurred in 0.87% cases. Long-term sequelae from vacuum associated injuries such as intracranial hemorrhage and neuromuscular injury are uncommon**.**

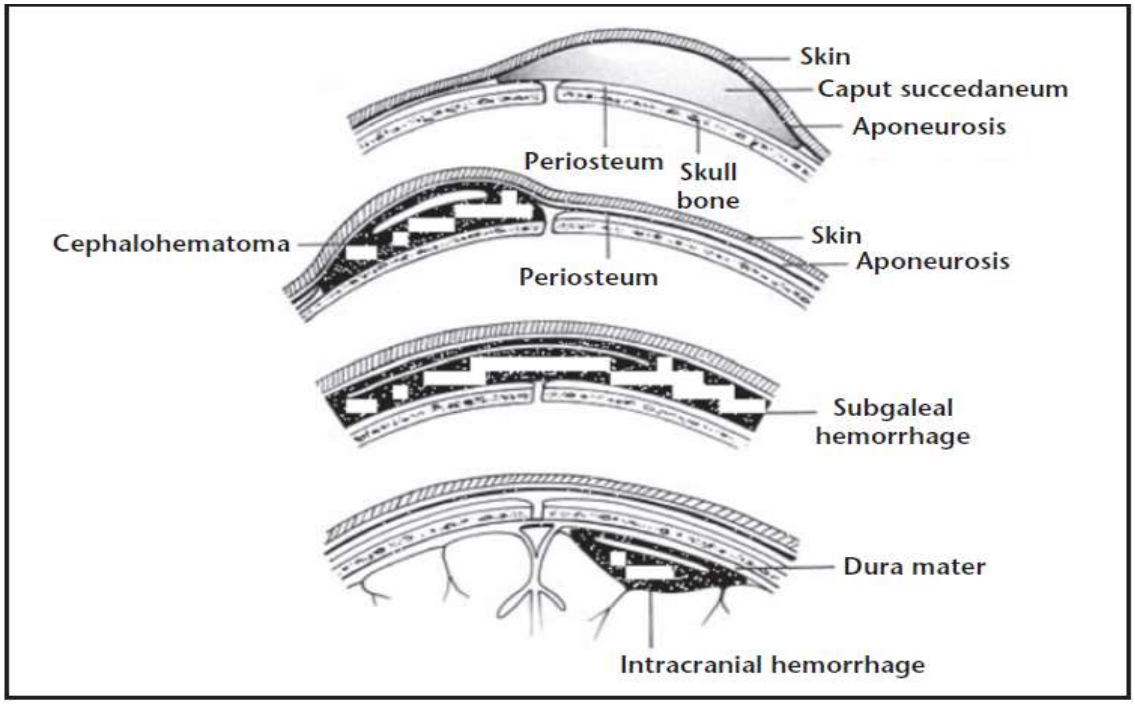

Figure 1: Fetal scalp injuries associated with vacuum extraction. Adapted from Unzila et al **(2009).**

1.2 Problem Statement

It is estimated that 5-20% deliveries are completed using operative vaginal delivery methods that include forceps and vacuum extraction in developed countries (Mahony et al 2010). AVD rates of less than 1% were found in developing countries (Martin et al 2009). The use of the vacuum device is more common in less developed countries due to increased training of medical students and practitioners on its use.

VAD is used to expedite vaginal delivery for the benefit of the baby, mother or both. The mother thus avoids CS which is the mode of delivery that is commonly used when difficulty is encountered during vaginal delivery. The number CS has been increasing worldwide.In developed countries like the United States of America, one in three deliveries is by CS. There has also been an increase in CS perfomed in developing countries. Some of the maternal risks associated with CS include complications of anesthesia, wound infection, hemorrhage and psychological trauma. A repeat CS is further complicated by increased rates of abnormal placentation, trauma to abdominal organs due to adhesions intraoperatively and uterine rupture. Neonatal complications include respiratory problems and intra-operative injuries like cuts.

The MTRH caesarian section rate has been above the recommended WHO rate of 10 - 15%. There were very few documented VAD cases as reported during departmental meetings at MTRH thus need to find the total number perfomed.

The maternal morbidity associated with VAD incudes perineal pain, genital injuries, PPH, failed VAD leading to CS and long term problems with fecal and urine incontinence.

Neonatal morbidities associated with VAD incude scalp injuries, intracranial hemorrhage, skull fracture, hyperbilirubinemia and admission to NBU.

The specific fetal and maternal outcomes of this practice at MTRH are undocumented. There is need to obtain data on these outcomes in our setting. This information will be used to to improve the neonatal and maternal outcomes in women undergoing VAD**.**

1.3 Justification of the Study

VAD is one of the evidence- based interventions that can prevent complications to the mother and fetus by shortening the second stage of labor and effect a vaginal delivery. Maternal complications associated with VAD include genital injuries, PPH, and failed attempt leading to CS and its associated complications. Neonatal complications after VAD include scalp injuries, skull fractures, intracranial hemorrhages, hyperbilirubinemia and admission to NBU.

Being a practice that is on the rise after countrywide training of medical practitioners by The Ministry of Health of Kenya in conjunction with other partners, there is need to find out local data. The findings of this study will aid in the improvement of the management of the mothers and fetus undergoing this intervention and ultimately their outcomes.

1.4 Research Questions

1. What are the common indications of vacuum assisted delivery at MTRH?
2. What are labor and procedural characteristics of vacuum assisted delivery at MTRH?
3. What are the fetal and maternal outcomes of vacuum assisted deliveries at MTRH?
4. What are the associations of variables involved in vacuum assisted deliveries at MTRH?

1.5 Objectives

1.5.1 Broad Objective

To establish fetal and maternal outcomes following vacuum assisted delivery at MTRH Eldoret.

1.5.2 Specific Objectives

1. To identify the indications of vacuum assisted deliveries at MTRH.
2. To describe the labor and procedural characteristics of vacuum assisted deliveries at MTRH.
3. To establish the fetal and maternal outcomes of vacuum assisted deliveries at MTRH.
4. To determine the factors associated with outcomes of vacuum assisted deliveries at MTRH.

1.6 Conceptual Framework

The conceptual framework seeks to illustrate the interplay of demographic, obstetric and procedural factors that affect the fetal and maternal outcomes in vacuum assisted deliveries.

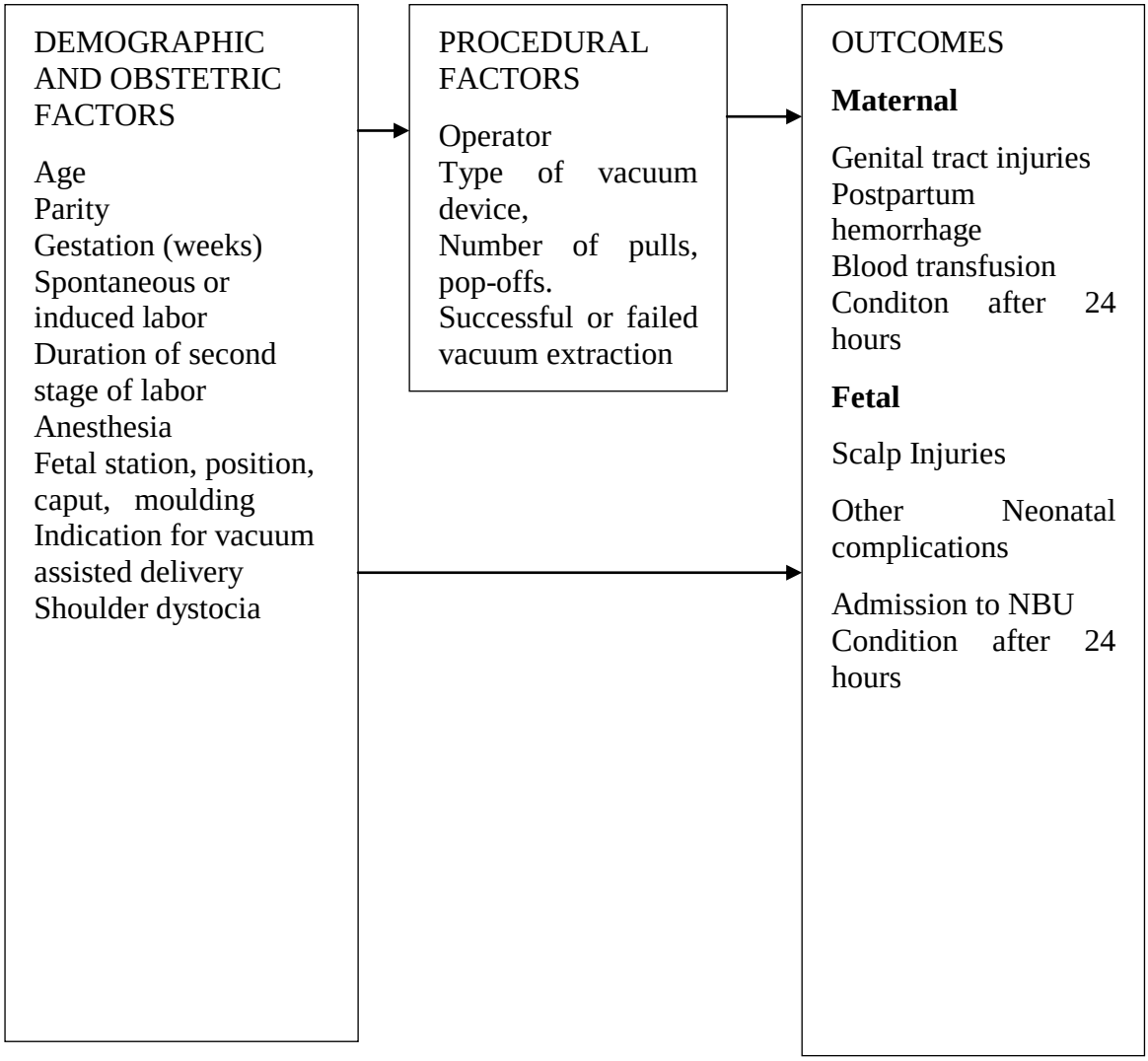

Figure 2: Conceptual framework of the study

CHAPTER TWO: LITERATURE REVIEW

2.1 Indications of Vacuum Delivery

Prolonged second stage of labor is defined according to parity and the presence or absence of epidural anesthesia. In nullipara, it is 2 hours without and 3 hours with epidural analgesia. In multipara, it is 1 hour without and 2 hours with epidural analgesia. Duration of greater than 4 hours in second stage of labor is associated with PPH, chorioamnionitis, perineal injury, less likelihood of SVD and increased rates of instrumental delivery without affecting fetal status in nulliparous women (Cheung et al 2004**).** A specific maximum length of the second stage of labour beyond which all women should be considered for AVD has not been determined (ACOG 2016).

Yakasai et al (2015) in a retrospective study of 210 women in a Nigeria Hospital who had vacuum deliveries had prolonged second stage of labour in 45.2% of cases. Shortening of the second stage of labor for maternal disease conditions was done in 36.7%, and fetal distress accounted for 18.1**%.** In a study by Gachiri et al (1991) at the Kenyatta National Hospital in Kenya, prolonged 2nd stage (59.3%) and eclampsia (23.9%) were the commonest indications. Hafeez et al (2013) conducted a prospective study in Pakistan on 1149 mothers who had vaginal deliveries. Amongst them 67 (5.83%) women had vacuum deliveries. The common indications included fetal distress at 44.7%, prolonged 2nd stage of labor at 25.37% and poor maternal effort at 16.4%.

2.2 Labor characteristics

In a case control study of vacuum deliveries of 87 women in Lithuania, 20 received epidural anesthesia while 67 did not. The cases needed labor induction with oxytocin more often than controls though there was no significant association between epidural

anesthesia and increased vacuum extraction rate OR 0.81; 95 % CI 0.6 – 1.09.(Kestutis et al 2015).

In a Cochrane Database System Review, Anim – Somuah M. et al (2005) found that epidural analgesia compared with non – epidural methods was associated with an increased incidence of operative vaginal deliveries, low neonatal APGAR scores at 5 minutes but mothers had satisfaction with pain relief. Epidural analgesia may lead to a slowly progressing labor increasing the risk of instrumental delivery. In a case – control study by Hasegawa et al (2013) of 350 women cases vs. 1400 without epidural anesthesia, the rate of vacuum extraction was 6.5% in cases vs. 2.9% in controls.

Fetal engagement is defined as the passage of the biparietal diameter of the fetal head through the plane of the pelvic inlet. Confirmation of fetal station (defined as the leading bony edge of the fetal presenting part relative to the maternal ischial spines) of more than 0/5 on transvaginal examination can also be used to document engagement. However, in a case of prolonged second stage of labor in which the fetal skull may be elongated and molded, resulting in the caput descending below the +2 cm station, whereas the skull itself is much higher. Station zero does not prove engagement, especially with a posterior presentation or a large degree of molding. Physicians can improve their clinical estimate of engagement by using the abdominal hand to feel how much of the fetal head is above the upper level of the pubic symphysis using the Leopold'smaneuvers. A large fetus, excessive molding of the fetal skull bones, a deflexed attitude (extension) of the fetal head, and asynclitism (lateral flexion of the fetal head) can make it appear as though the vertex is engaged when the leading bony edge is actually above the level of the ischial spines.

The type of operative vaginal delivery is classified according to the station and the degree of rotation of the fetal head within the pelvis due to the difficulties of clinically estimating engagement in the table below. ACOG Operative Vaginal Delivery Technical Bulletin 196 (1994). Delivery instruments should never be applied to an unengaged fetal head.

Classification of operative vaginal deliveries

Table 1: Classification of Operative Vaginal Deliveries adapted from American college of Obstetricians and Gynecologists.

Type of procedure	Criteria
Outlet	Scalp is visible at the introitus without separating the labia. Fetal skull has reached the level of the pelvic floor. Sagittal suture is in the direct anteroposterior diameter or in the right or left occiput anterior or posterior position. Fetal head is at or on the perineum. Rotation is $\leq 45^{\circ}$
Low	Leading point of the fetal skull (station) is station +2/ +5 or more but has not yet reached the pelvic floor. Rotation is $\leq 45^{\circ}$ Rotation is $> 45^{\circ}$
Midpelvic	The head is engaged in the pelvis but the presenting part is above +2 station.
High	Not indicated in this classification

The denominator is a bony landmark on the fetal presenting part used to denote the fetal position. In vertex presentation, it is the occiput. It can be occipito – anterior or occipito –posterior. Damrom et al (2004) found that there was less likelihood of delivery if vacuum or forceps was used in occipitoposterior position. Additionally, the rates of anal sphincter lacerations with forceps and vacuum delivery were 72% and 33% for occipito – posterior position compared to 54% and 27% for occipito - anterior position respectively.

Episiotomy refers to a surgical incision in the perineum designed to enlarge the vagina and assist in childbirth. De Leeuw et al (2008), found out that mediolateral episiotomy protected significantly for anal sphincter damage in both vacuum extraction (OR 0.11, 95% CI 0.09–0.13) and forceps delivery (OR 0.08, 95% CI 0.07–0.11) in Netherlands and recommended its routine use. However, recent evidence suggests that routine use of episiotomy with vacuum extraction is associated with an increased rather than decreased risk of perineal trauma and rectal injuries. Among vacuum extraction deliveries an increased rate of such trauma was noted when episiotomy was used (34.9% vs. 9. 4%; relative risk, 3.7; 95% confidence interval, 1.2-11.2). (Robinson et al 1999). Murphy et al (2008), could not conclusively recommend routine use of episiotomies after a randomized controlled study in Scotland of women undergoing operative vaginal deliveries.

Episiotomy during operative vaginal delivery also increases the incidence of postpartum hemorrhage and perineal infection, the need for stronger analgesia, and neonatal birth trauma. Moreover, pressure exerted by the intact soft tissues of the pelvic floor promotes flexion and rotation of the fetal head as it descends through the birth canal. Taken together, these data suggest that routine episiotomy during vacuum extraction should be discouraged *(*Kudish et al

2006).

Demissie et al (2004), found vacuum delivery is a risk factor for shoulder dystocia as compared to forceps delivery OR 2, 95%CI 1.62 to 2.48 in a retrospective study in the U.S. There is need to confirm this finding locally.

2.3 Procedural characteristics

There are two types of vacuum extractors, those with metal cups and those with disposable cups. The disposable cups can be soft or rigid. The soft cup is pliable funnel / bell – shaped. The rigid cup is a firm mushroom shaped cup (M- cup) and is available in size 40, 50, 60mm.

A meta –analysis of 1375 women in 9 trials by Johanson et al (2000), showed that soft cups were more likely to fail due to more frequent detachments / pop offs OR 1.65; 995% CI, 1.19 to 2.29 and had less fetal scalp injuries OR 0.45; 95% CI 0.15 to 0.6.There was no difference between the soft and rigid cups in terms of maternal injury. Several studies have also concluded that rigid cups are better for large infants with significant caput succedaneum, occipito – posterior position or asynctilism.

Groom et al (2006) conducted a randomized control studies if Kiwi Omnicup vs. conventional vacuum cups in London, the failure rate of Kiwi Omnicup was 30.1% vs. 19.2% and was associated with more detachments.

In MTRH, the disposable (soft and rigid) cups are commonly used and thus number of pulls needed to deliver and how effective they are in vacuum extraction of fetuses needs to be determined.

Murphy et al (2003) in UK found out that more than three pulls at attempted vacuum extraction was associated with neonatal trauma for successful deliveries AOR 4.2, 95% CI 1.6 to 9.5 and failed deliveries AOR7.2, 95 % CI 2.1 to 2.4. Delivery after failed vacuum extraction via CS after more than 3 pulls was also associated with increased admission to the newborn unit. This study is aimed to find out if this finding still applies.

2.4 Fetal Outcomes

Vaidya et al (2003) studied 100 vacuum deliveries in India and 20% of the babies had an APGAR score of <7 at 5 minutes of life and this was associated with the application of cup to delivery time of >10 minutes; more than 2 applications and > 3 pulls.

Gachiri et al (1991), in Kenya found that intrauterine asphyxia was the commonest cause of neonatal deaths at 4.8% and perinatal morbidity at 16.2%.

Cephalohematoma is bleeding into fetal scalp due to separation from the underlying structures.Cephalohematomas are more commonly associated with vacuum deliveries compared to forceps. They typically resolve within 4 weeks but can result in hyperbilirubinemia in some cases. In a retrospective study by Yakasai et al (2015) in Nigeria, the rate of fetal complications was 31% of vacuum deliveries. 18.1% had cephalohematoma; scalp bruising in 4.3%; 4.8% had asphyxia and 3.8% deaths occurred. However, the deaths and asphyxia may not have been due to the procedure rather the indication of the vacuum extraction in the first place.

Wen et al (2001) did a retrospective study in Canada on forceps and vacuum assisted deliveries. He found that compared with delivery by forceps, the adjusted risk ratios for third-/fourth-degree perineal laceration was 0.48 (95% CI: 0.45, 0.50); intracranial hemorrhage, subdural or cerebral hemorrhage 1.28 (95% CI: 0.73, 2.25); intraventricular hemorrhage 0.97 (95% CI: 0.49, 1.93); subarachnoid hemorrhage 0.99 (95% CI: 0.16, 5.97); cephalohematoma 5.44 (CI: 1.26, 23.43) and neonatal in-hospital death 0.93 (95% CI: 0.32, 2.70). The authors concluded that vacuum extraction causes less maternal trauma but may increase the risk of cephalhematoma and certain types of intracranial hemorrhage (e.g., subarachnoid hemorrhage).

2.5 Maternal Outcomes

A review of over 50,000 vaginal deliveries at the University of Miami reported that the rates of third and fourth degree perineal lacerations were higher in vacuum-assisted (10%) and forceps deliveries (20%) compared with spontaneous vaginal deliveries (2%) (Angioli et al 2000**).**

Räisänen et al (2012) in retrospective study in Finland, found that nulliparous women who delivered by vacuum extraction had an increased risk of obstetric anal sphincter injury than multiparous women. This study recommended routine use of episiotomy since it was associated with a 46% reduction of obstetric anal sphincter injuries (3rd and fourth degree perineal tears).

A retrospective study by Yakasai et al (2015***)*** found PPH at 9.5% to be the commonest maternal complication in Nigeria over a 5 year period. Gachiri et al (1991) in Kenya also found that PPH was the most common complication at 8.4% followed by lacerations at 7.8%. This study will help establish the complications in our setting.

Johnson et al (2004) conducted a population based historical cohort study in Canada between 1991- 1996. He found that periurethral lacerations were common with vacuum extractions compared to forceps delivery (p=0.026). Caput succadeneum, moulding (p=0.03) and cephalohematomas (p=<0.01) were associated with vacuum assisted delivery. There is need to find if there will be similar characteristics in our study population.

Nolens et al (2018) found that blood loss of at least 500ml was more frequent in second stage CS compared to vacuum extraction (p=<0.001). However, the number of blood transfusions in the two groups was similar. There is need to determine the risk of hemorrhage associated with vacuum assisted delivery so as to plan better on how to manage it.

CHAPTER THREE: METHODOLOGY

3.1 Setting of the Study

The study was conducted at Riley Mother and Baby Hospital (RMBH), a maternity unit at the Moi Teaching and Referral Hospital (MTRH). MTRH is the second largest teaching and referral hospital in Kenya. The hospital is located at Eldoret, Uasin Gishu County. MTRH is a teaching hospital for Moi University School of Medicine. The hospital has a bed capacity of 800; the RMBH has a bed capacity of 160. Of this, 17 beds are allocated for labor and delivery. The hospital serves a catchment population of 16.24 million people, drawn from Nyanza, North Rift and Western parts of Kenya. The RMBH is composed of antenatal, postnatal and labour Wards. Within the same building are two operating theatres dedicated to obstetric patients for emergencies. A neonatal/ New Born Unit is also housed in the same building to take care of babies needing treatment. VAD are done in the labour ward by midwives, residents and consultants according to the MTRH protocol on Assisted Vaginal Delivery.

3.2 Study Population and Target Population

Study population was mothers admitted at the RMBH labor ward. Mothers at ≥37 weeks gestation, with singleton pregnancy; in cephalic presentation.The target population was mothers in second stage of labor needing vacuum assisted delivery as deemed necessary by the consultant, registrar or midwife attending to her.

3.3 Study Design

It was a descriptive study done in MTRH, Eldoret. This was a clinical audit of all cases of Vacuum assisted deliveries that occurred from 31st January 2018 to 28th February 2019.

3.4 Sampling

A census of all VAD cases was done during the study period. This was to ensure that the exact number of VAD and their outcomes are collected. Prior records had reported extremely low numbers due to poor documentation.

3.5 Study Procedure

The expectant women who were admitted in RMBH labor ward were considered for participation in the study. The recruitment into the study was done by a trained research assistants who were present in labor ward but were not part of the care team. When a vacuum assisted delivery was deemed necessary to complete second stage of labor as of the opinion of the Consultant, Registrar or Midwife, the research assistant was informed.Verbal consent was sought from the parturient or her guardian if it is a minor to take part in the study by the research assistant. The inclusion criteria was a singleton pregnancy of more than or equal to 37 weeks gestational age; cephalic presentation. Gestational age was determined from the date of last menstrual period and whenever possible, it was confirmed by the first trimester dating ultrasonography. The labor and procedural characteristics and fetal and maternal outcomes were recorded from the participant's file and observation of the procedure (any information that was not recorded, especially on procedural aspects like number of pulls, pop-offs) in a questionnaire.

A written consent form was filled by the participant after the delivery and the third stage of labor had been conducted or casaerian section for those who had failed vacuum assisted delivery.

The client was managed according to the MTRH protocol for management of assisted vaginal delivery by a Consultant, Registrar or Midwife. A vacuum device with a soft

or rigid cup with a vacuum pressure of 0.6 to 0.8 kg/cm2 (500-600 mm Hg) was used and are illustrated below.

The client was followed up by the research assistant for documentation of maternal and fetal outcomes upto 24 hours after delivery.

Figure 3: Kiwi Omni-Cup – rigid cup

Figure 4: Mystic II Vacuum- Assisted Device system – soft cup

3.6 Description of Determination of Outcomes

The maternal outcomes of interest were the presence of cervical and vaginal lacerations and 3rd and 4th degree perineal tears, PPH and need for blood transfusion. The fetal outcomes included APGAR score at 5 minutes, neonatal trauma: - scalp lacerations, cephalohematoma and admission to the Newborn Unit for further management and fetal death.

Postpartum hemorrhage (PPH) was determined when blood loss after vacuum assisted vaginal delivery of the fetus was estimated to be more than 500ml or 1000ml after CS. Blood loss was estimated by:-

1. Counting number of gauzes and drapes used during delivery and estimating amount of blood absorbed by each. The amount of blood in suction machine during CS was recorded.
2. Need for blood transfusion regardless of amount of blood lost after delivery.
3. Hemoglobin (Hb) drop of 3 g/dl [difference between pre-VAD (Hb level within a 24-h interval prior the delivery) and post-VAD.

3rd degree perineal tear was defined as laceration of the fourchette, perineal skin, vaginal mucosa, muscles and anal sphincter.

4th degree perineal tear was defined as laceration of the fourchette, perineal skin, vaginal mucosa, muscles anal sphincter and rectal mucosa.

Scalp lacerations were wounds found in the area bordered by the face at the front and by the neck at the sides and back and are caused by the vacuum device.

Cephalohematoma was defined as bleeding into fetal scalp that is located in the subperiosteal space and is limited by the suture lines.

APGAR score is a fast method to summarize the health of a newborn baby and the need for resuscitation. It is determined by evaluating five criteria:- skin color, pulse rate, grimace, activity and respiratory effort. Each is graded on a scale of zero to two and the score ranges from zero to ten. It was determined by the operator at one minute and five minutes.

Table 2: The APGAR Scoring System

THE APGAR SCORE				
	Sign	0 POINTS	1 POINTS	2 POINTS
A	Appearance	blue or pale	blue extremities pink body	body & extremities pink, no cyanosis
P	Pulse	absent	<100 beats per minute	>100 beats per minute
G	Grimace	no response to stimulation, floppy	grimace on suction or aggressive stimulation	cry on stimulation
A	Activity	none	some flexion of arms and legs	active flexion against resistance
R	Respirations	absent	weak, irregular and slow	strong crying

Birth asphyxia is the condition resulting from oxygen deprivation to a newborn that lasted long enough to cause physical harm to the fetus' organs especially the brain which has a major impact neurologically later in life. Cyanosis, poor responsiveness, activity, muscle tone and respiratory effort as reflected by a poor APGAR score at five minutes. APGAR scores of 1 to 3, 4 to 5 and 6 to 7 represent severe, moderate and mild birth asphyxia respectively.

Fresh still birth is any baby born without signs of life i.e. no heartbeat and no respiration at greater than 28 weeks gestation. Death usually occurred intrapartum and there are no changes on the baby's skin.

Macerated stillbirth is a fetus born with skin and soft –tissue changes (skin discoloration or darkening, redness, peeling and breakdown) suggesting that death was well before labour.

Successful vacuum delivery was delivery by vacuum extraction irrespective of fetal or maternal complications.

Failed vacuum extraction was whereby the procedure was abandoned and CS done after either of the following criteria was met:-

- 3 pulls over 3 contractions with no progress
- 3 pop-offs
- After 20 minutes of application with no progress

Decision to delivery interval was time between the healthcare provider's decision to do a vacuum extraction (as noted in the file) and time of birth.

Neonatal sepsis-It is a clinical syndrome of bacterial infection characterized by signs and symptoms of systemic involvement during the first month of life. There are no specific signs and symptoms of neonatal sepsis. Isolation of the causative microorganisms by using blood culture has been the golden standard method for its diagnosis, the result is ready after 24-72 hours. It is necessary to treat the suspicious infants for sepsis with antibiotics on the basis of history.

Transient Tachypnea of the Newborn (TTN) - Transient tachypnea of the newborn (TTN) is a benign, self-limited condition that can present in infants of any gestational age, shortly after birth. It is caused due to delay in clearance of fetal lung fluid after birth which leads to ineffective gas exchange, respiratory distress, and tachypnea.

3.7 Eligibility Criteria

3.7.1 Inclusion Criteria

Mothers at ≥37 weeks' gestation, with singleton pregnancy; in cephalic presentation; in second stage of labor requiring vacuum assisted delivery. All successful vacuum deliveries and those who deliver via CS after failed attempts were included in the study.

3.7.2 Exclusion Criteria

Vacuum Assisted deliveries that resulted in a Macerated stillbirth.

3.8 Data Management

3.8.1 Data Collection

Data was collected using a semi-structured interviewer - administered questionnaire. The questionnaire was administered by trained research assistants. The data collected included:-

Maternal characteristics

Age

Parity

Gestational age

Labor characteristics

Induction of labor vs. spontaneous

Duration of 2^{nd} stage of labor

Oxytocin augmentation

Fetal position

Fetal Station

Caput, moulding

Shoulder dystocia

Indication for assisted vaginal delivery

Episiotomy

Procedural Factors

The operator: - midwife, registrar, consultant

Number of pulls of extractor

The decision to delivery time of infant

Number of CS after failed instrumentation

3.8.2 Data Processing and Storage

There was adequate staff capacity with supervision in data collection. Routine cross-checking to ensure consistency and completeness of questionnaires was done daily. Any missing data was retrieved from the participant's file.

The data collected using questionnaires was entered into an electronic database created using Microsoft Excel. The data was de-identified prior to entry into the database to ensure that confidentiality of the participants was maintained. Data entered into the database was encrypted to enhance confidentiality of the data and the password kept by the principal investigator. The databases were backed-up using flash drives and external drives to cushion against data loss. The questionnaires were kept in a safe storage cabinet under a lock and the key kept by the principal investigator. The questionnaires will be destroyed after seven years from the date of presentation of the results.

3.6.3 Data Analysis and Presentation

Descriptive statistics such as frequencies were used to summarize categorical variables such as the level of education, marital status and parity among others. Continuous variables such as mother's age, birth weight, and duration of second stage labor among others were assessed for Gaussian (or normality) assumptions using histograms, box plots and Shapiro-Wilk test for normality. The variables that had the Gaussian assumptions holding were summarized using the mean and the corresponding standard deviation (SD). The continuous variables that violated the

Gaussian assumptions were summarized using the median and the corresponding inter- quartile range (IQR).

Association between categorical variables such as success or failure of vacuum extraction and number of presence of caput succedaneum, presence of moulding among others were assessed using Pearson's Chi Square test. Fisher's exact test was used whenever the Chi Square assumptions were violated. The level of significance was a p-value of <0.05.

Results were presented using tables and graphs.

Data analysis was done using STATA version 13 SE (College Station, Texas 77845 USA).

3.9 Ethical Considerations

The approval to undertake the study was obtained from the Institutional Research and Ethics Committee (IREC) before the study was conducted (FAN: IREC 2009).

Permission to undertake the study at MTRH was sought from the hospital administration.

Individual informed consent was sought from clients before enrollment into the study. The clients were informed that failure to give consent did not in any way affect their care.

Participants who developed complications in the course of the study period received standard treatment in accordance with the hospital guidelines.

The data obtained was stored in a computer and secured with a password restricting access only to the principal investigator. The filled questionnaires were kept in a cabinet under lock and key.

There was no financial benefit to research participants. The clients who participated in the study were managed according to the MTRH protocol on Assisted Vaginal Delivery.

The results of the study were presented to MTRH, the Department of Reproductive Health Moi University and are to be published in a medical journal.

3.10 Study Limitations

The study focused on the immediate fetal and maternal outcomes of VAD as follow – up of the participants and their babies was for only 24 hours after delivery. Long term fetal and maternal sequelae of vacuum assisted delivery were not studied. This study did not evaluate technique of the operators. The vacuum extractors were re-used after sterilization.

CHAPTER FOUR: RESULTS

4.1 Study execution

Data was collected for a period of one year from (31st January 2018 to 28TH February 2019).

During that period, 192 expectant mothers admitted in RMBH labor ward were identified to be in need of vacuum-assisted delivery. 2 of them did not give consent. 2 expectant mothers who had the procedure done were excluded from the study because they had macerated stillbirth which was the exclusion criteria.188 participants were approached, informed consent taken and they were recruited into the study. 188 women and their neonates were then followed up to the completion of the study, 24 hours later. There were 180 successful VAD and 8 failed (CS) was done. Thus VAD represented 1.4% of the deliveries during the study period.

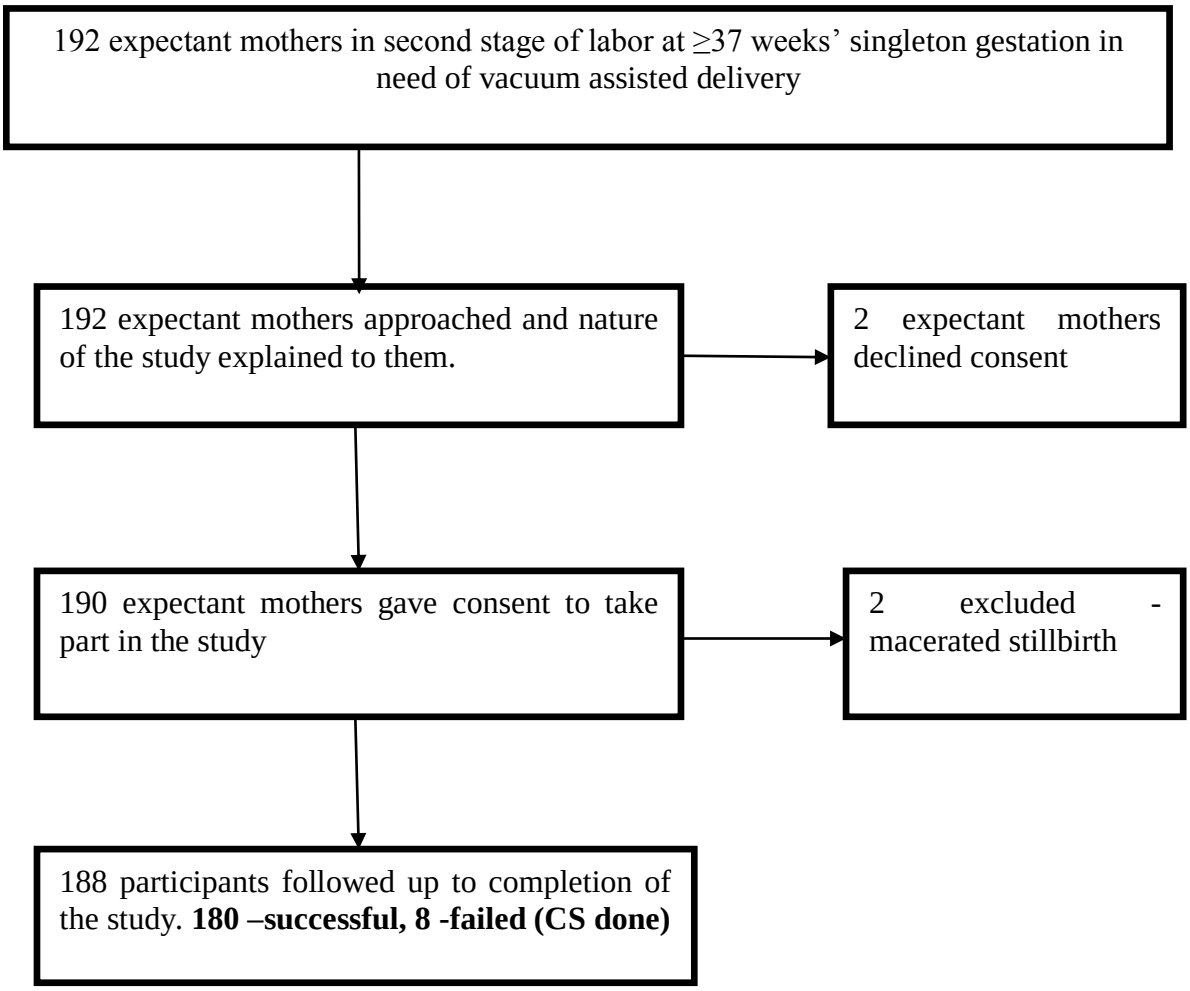

Figure 5: Study Flow Diagram

4.2 Socio-demographic Characteristics

The median age was 23.0 (IQR: 20.0, 27.0) years with a minimum and a maximum of 14.0 and 44.0 years respectively

Up to 158 (84.1%) of the participants had at least a secondary level of education, and 141 (75%) were married.

Over half of the participants were nulliparous 110(58.5%).75 (39.9%) were multipara and 3 (1.6%) were grand multipara.

The median gestation was 40.0 (IQR: 39.0, 41.0) weeks with a range of 37.0 to 45.0 weeks.

Table 2: Socio-demographic characteristics

Variable	N	n (%) or Median (IQR)
Age(Years), Median(IQR)	188	23.0 (20.0, 27.0)
Range (Min. - Max.)		14.0 - 44.0
Education Level, n (%)		
No formal education		3 (1.6%)
Primary	188	27 (14.3%)
Secondary		78 (41.5%)
Tertiary		80 (42.6%)
Marital Status, n (%)		
Married		141 (75%)
Single	188	47 (25%)
Parity, n (%)		
Nulliparous		110 (58.5%)
Multipara		75 (39.9%)
Grand Multipara		3 (1.6%)
Gestation (Weeks), Median(IQR)	188	40.0 (39.0, 41.0)
Range (Min. - Max.)		37.0 - 45.0

4.3 Indications for Vacuum-Assisted Deliveries

The main indications for labor were prolonged second stage of labor 79(42.0%), maternal exhaustion 68 (36.2%), and non-reassuring fetal status 22(11.7%). Rheumatic Heart Disease (RHD) 10(5.3%) and eclampsia was 5(2.7%).

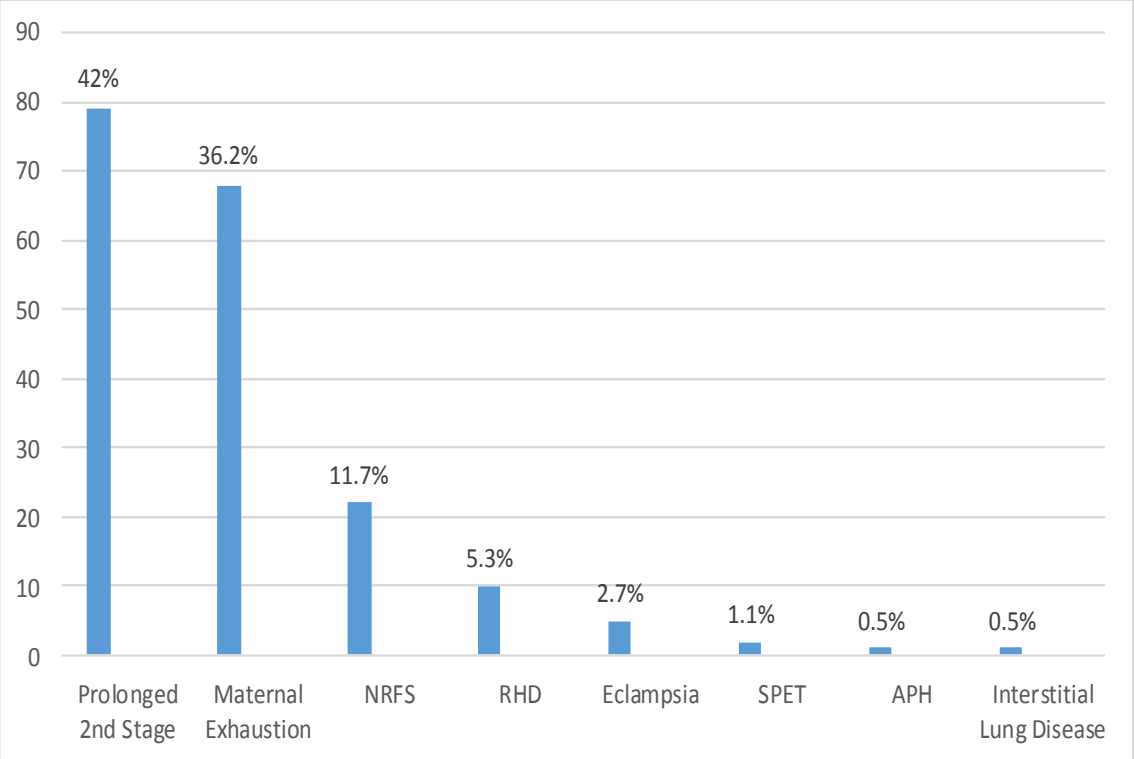

Figure 6: Indications of vacuum assisted deliveries

4.4 Labor Characteristics

156 (83%) of the participants went into spontaneous labor. Induction of labor was done for 32(17.0%) of the participants. Of those induced, 23 (71.9%) received misoprostol. Oxytocin was given to 124 (66.0%), of the participants for the augmentation of labor. Only 10 participants received analgesia during labor. Parenteral analgesia (tramadol, morphine) was given to 10 (5.3%) of the participants during labor who had Rheumatic Heart Disease (RHD) or intrauterine fetal death. Caput succedaneum was present in 86 (45.7%) of the fetuses. Moulding was present in 29 (15.4%) of the fetuses in the second stage of labor. Of those who had moulding, 18 (62.1%) were Grade 1 and 11 (37.9%) were Grade 2.

Table 3: Labor characteristics

Variable	N	n (%) or Median (IQR)
Onset of Labor, n (%)	188	
Spontaneous		156(83%)
Induced		32 (17%)
Method of Induction, n (%)	32	
Misoprostol		23 (71.9%)
Foley's Catheter		7(21.8%)
Both		2(6.3%)
Oxytocin Use, n (%)	188	
Present		124 (66.0%)
Absent		64 (34.0%)
Analgesia, n (%)	188	
Present(parenteral)		10 (5.3%)
Absent		178 (94.7%)
Fetal Position, n (%)	188	
Occipitoanterior		165 (87.8%)
Occipitoposterior		18 (9.6%)
Occipitotransverse		5 (2.7%)
Fetal Station, n (%)	188	
-1		1 (0.5%)
0		54 (28.7%)
+1		78 (41.5%)
+ 2		54 (28.7%)
+ 3		1 (0.5%)
Caput Succedaneum, n (%)	188	
Present		86 (45.7%)
Absent		102 (54.3%)
Moulding, n (%)	188	
Present		29 (15.4%)
Absent		159 (84.6%)
Grade of Moulding, n (%)	29	
Grade 1		18 (62.1%)
Grade 2		11 (37.9%)

Figure 7: Classification of vacuum delivery by station

Majority of the vacuum-assisted deliveries were mid-pelvic 70.21% (132). Low and High vacuum –assisted deliveries were 29.28% (55) and 0.53% (1) respectively.

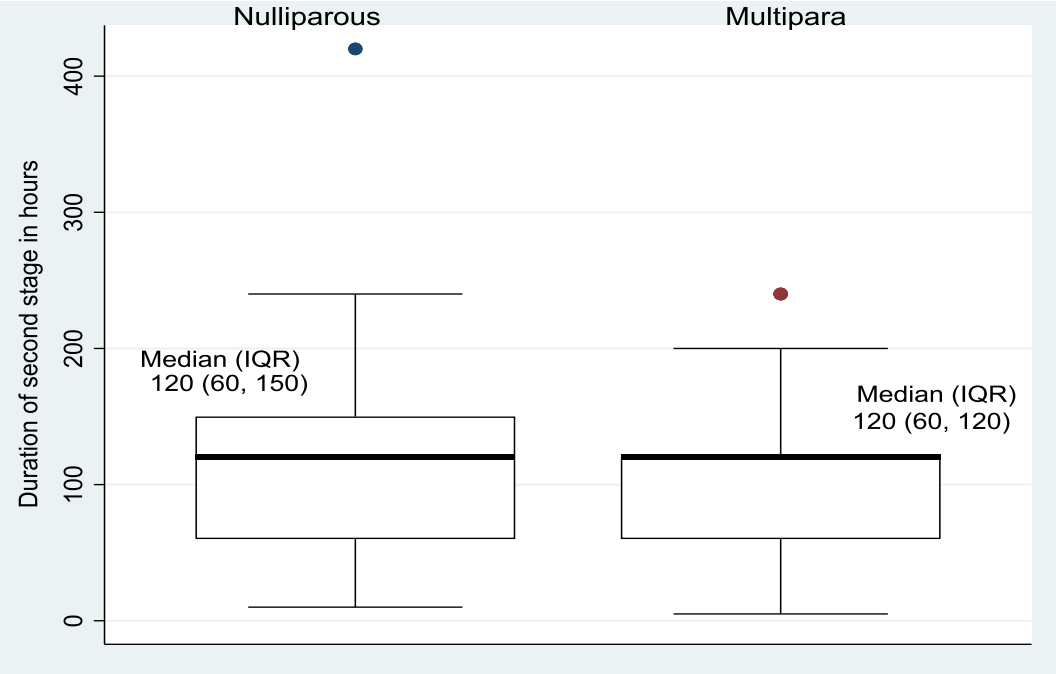

Figure 8: Duration of second stage of labor

median duration of second stage of labor was similar for the primigravida and the multipara at 120 minutes. Overall, the median duration was 120.0 (IQR: 60.0, 150.0) minutes with a minimum of 5 minutes and a maximum of 420.0 minutes.

Table 4: Other Maternal Diagnosis

Variable	N	n (%)
Other Diagnosis, n%)		
None		115 (61.2%)
Post-term		19 (10.1%)
Hypertension		17 (9.0%)
Previous Caesarean section scar		13 (6.9%)
RHD		10(5.3%)
Rhesus Negative	188	4 (2.1%)
Prolonged Labor		2 (1.1%)
Antepartum Hemorrhage (placenta abruption)		1(0.5%)
Term Premature rupture of membranes		1 (0.5%)
Gestational Diabetes Mellitus		1 (0.5%)
Anemia		1 (0.5%)
Fibroids		2 (1.1%)
Chorioamnionitis		1 (0.5%)
Hemiparesis		1 (0.5%)

Up to 73 (38.8%) of the participants had other diagnosis made. Post-term pregnancy, hypertension, PSC, RHD and rhesus negative were reported for 17 (10.1%), 13 (9.0%), 8 (6.9%), 10(5.3%) and 4 (2.1%) respectively.

4.5 Procedural Characteristics

Table 5: Procedural Characteristics

Variable	N	n (%) or Median (IQR)
Operator, n(%)		
Midwife		90 (47.9%)
Registrar	188	93 (49.5%)
Consultant		5 (2.7%)
Type Of Cup, n(%)		
Rigid		168 (89.4%)
Soft	188	20 (10.6%)
No. Of Pulls, n(%)		
1		47 (25.0%)
2		95 (50.5%)
3	188	41 (21.8%)
>/=4		5 (2.7%)
Number of pop-offs, n(%)		
0		143 (76.1%)
1	188	39 (20.7%)
2		4 (2.1%)
3		2 (1.1%)
Successful Vacuum assisted delivery, n(%)		
Successful		180 (95.7%)
Failed C/S	188	8 (4.3%)
Decision to delivery interval (Minutes), Median(IQR)	188	7.0 (5.0, 10.0)
Range (Min. - Max.)		1.0 - 35.0
Episiotomy given, n(%)		
Yes		37 (19.7%)
No	188	151 (80.3%)
Episiotomy Analgesia, n(%)		
With local Anesthesia		10 (27.0%)
Without Local Anesthesia	37	27 (73.0%)
Shoulder Dystocia present, n(%)		
Yes		7 (3.7%)
No	188	181 (96.3%)

Up to 90 (47.9%) of the participants had vacuum assisted delivery was done by midwives and 93 (49.5%) was operated by the registrars. The vacuum extractor with a

rigid cup, Kiwi, was used for168 (89.4%). While the rest were done using a soft cup – Mystic II Vacuum-Assisted Delivery system, 20 (10.6%).

Half of the participants had two pulls, and 24.5% had more than two pulls to deliver the fetal head.

Pop-offs (cup detachments) were reported for 45 (23.9%) of the participants.

Vacuum assisted delivery was successful in 180 (95.7%) of the participants. The median decision to delivery of the infant was 7.0 (IQR: 5.0, 10.0) minutes with a minimum and a maximum of 1.0 and 35.0 minutes respectively.

Episiotomy was given to 37(19.7%) of the participants. It was given with a local anesthetic to 10 (2 7.0%) of those who had episiotomy. Shoulder dystocia was present for 7 (3.7%) of the participants

4.6 Fetal Outcomes

Table 6: Fetal outcomes

Variable	N	n (%) or Median (IQR)
Sex, n(%)		
Male		121 (64.4%)
Female	188	67 (35.6%)
Birth weight (Grams), Median(IQR)		3200.0 (2900.0, 3500.0)
Range (Min. - Max.)	188	2100.0 - 4500.0
< 2500		4 (2.1%)
≥ 2500		184 (97.8%)
Apgar Score At 5 Minutes, Median (IQR)	188	9.0 (8.0, 10.0)
Range (Min. - Max.)		0.0 - 10.0
0	188	12 (6.4%)
1 to 7		15(9.0%)
≥ 7		161 (85.6%)
Neonatal Resuscitation		
Yes		53 (28.2%)
No	188	135 (71.8%)
Person Resuscitating		
Nurse		42 (79.3%)
Obs/Gyn Registrar	53	10 (18.8%)
Registrar Paediatrics		1 (1.9%)

The median birth weight was 3200.0 (IQR: 2900.0, 3500.0) grams, and 64.4% of the neonates were male. The median Apgar score was 9.0 (IQR: 8.0, 10.0) with a minimum of 0.0 and a maximum of 10.0.

Neonatal resuscitation was done for 53 (28.2%) of the neonates, mainly by nurses, 42 (79.3%). Perinatal mortality was13 (6.9%) after 24 hours. There were 12 fresh stillbirths (6 due to SPET, 3 eclampsia & 3 NRFS in post-term pregnancy) and 1 neonatal death in NBU due to severe birth asphyxia.

Table 7: Neonatal Complications

Variable	N	n (%)
Fetal Scalp Injuries, n(%)		
Yes		161 (85.6%)
No	188	27 (14.4%)
Type of Scalp Injuries, n(%)		
Chignon		124 (77.0%)
Scalp Lacerations		34 (21.1%)
Cephalohematoma	161	3 (1.8%)
Admission To NBU, n(%)		
Yes		36 (19.1%)
No	188	152 (80.9%)
Diagnosis at NBU		
Birth asphyxia		18 (50.0%)
Transient Tachypnea of the Newborn (TTN)		11 (30.6%)
Neonatal sepsis	36	2 (5.5%)
Congenital anomaly		1 (2.8%)
Neonatal jaundice		2 (5.5%)
Facial Laceration		1 (2.8%)
Shoulder dislocation		1 (2.8%)
Fetal Condition At 24Hrs, n (%)		
Discharged		149(79.3%)
To stay	188	26 (13.8%)
Dead		13 (6.9%)

Up to 85.6% of the neonates had scalp injuries. The main type of scalp injury was chignon (77.0%). The second most common injury reported was scalp lacerations suffered by 19.9%.

Of all the neonates, 19.1% were admitted to NBU. The leading diagnosis at NBU was birth asphyxia 18 (50.0%) then TTN 11(30.6%). 2 (5.5%) neonates who had neonatal sepsis and another 2 (5.5%) had neonatal jaundice.

At 24 hours, 13 (6.9%) neonates had died, and 26 (13.8%) neonates were to continue receiving care at the facility.

4.7 Maternal outcomes

Table 8: Maternal Outcomes

Variable	N	n (%)
PPH, n(%)		
Yes		35 (18.6%)
No	188	153(81.3%)
Cause Of PPH, n(%)		
Atony		13 (37.1%)
Trauma	35	20 (57.1%)
Tissue		2 (5.8%)
Coagulopathy		0 (0.0%)
Blood Transfusion, n(%)		
Yes		8 (4.3%)
No	188	180 (95.7%)
Maternal Genital Injuries, n(%)		
Yes		114 (60.6%)
No	188	74 (39.4%)
Type Of Maternal Genital Injuries, n(%)		
1st Degree Perineal Tear		47 (41.2%)
2nd Degree Perineal Tear	114	37 (32.5%)
3rd Degree Perineal Tear		22 (19.3%)
4th Degree Perineal Tear		5 (4.4%)
Cervical Tear		3 (2.6%)
Maternal Condition at 24 Hours, n (%)		
Discharged		135(71.8%)
To Stay In Hospital	188	52 (27.7%)
Dead		1 (0.5%)

Post-partum hemorrhage was reported for 35 (18.6%) of the participants. The main cause of PPH was trauma 20 (57.1%).

Of all the participants 8 (4.3%) were transfused, and 60.6% had genital injuries. Of those who had perineal tears, 23.7% had third or fourth degree tears and 2.6% had cervical tears. One participant died at the hospital due to eclampsia and 52 (27.7%) were still admitted after 24 hours in order to receive treatment for different conditions.

4.8 Factors Associated with Outcomes of Vacuum Assisted Deliveries

Table 9: Comparison of the characteristics of successful and failed Vacuum assisted Deliveries

Variables	N	Successful VAD	Failed VAD (CS)	P-value
Age (median, IQR)	188	23.5 (20, 27)	22 (19, 24.5)	0.233[w]
Parity	188			
Nulliparity		104 (94.5%)	6 (5.5%)	
Multiparity		76 (97.4%)	2 (2.6%)	0.473[f]
Gestational age		40 (39, 41)	39.5 (39, 40)	0.319[w]
Indication of VAD	188			
Prolonged 2nd stage		73 (92.4%)	6 (7.6%)	0.208[f]
Maternal exhaustion		67 (98.5%)	1 (1.5%)	
Others		40 (97.6%)	1 (2.4%)	
Malposition	188			
OA		159 (96.4%)	6 (3.6%)	0.254[f]
OT/OP		21 (91.3%)	2 (8.7%)	
Caput succedaneum	188			
Absent		101 (99%)	1 (1%)	0.025[f]
Present		79 (91.9%)	7 (8.1%)	
Moulding	188			
1		27 (93.1%)	2 (6.9%)	0.357[f]
2		153 (96.2%)	6 (3.8%)	
Episiotomy	188			
Absent		145 (96%)	6 (4%)	0.657[f]
Present		35 (94.6%)	2 (5.4%)	
Duration of second stage of labour (minutes)	188	120 (60 , 150)	135 (97.5, 165)	0.136[w]
Decision to delivery interval (minutes), Median (IQR)	188	7.0 (5.0, 10.0)	15.0 (7.5, 20.0)	0.034[w]

[f] Fisher's Exact Test, [w] Wilcoxon Rank-Sum Test

Fetuses with caput succedaneum were more likely to have failed vacuum extraction, 87.5% vs. 43.9%, p = 0.025.

Median decision to delivery interval for successful vacuum extraction was 7.0 (IQR: 5.0, 10.0) minutes compared to 15.0 (IQR: 7.5, 20.0) minutes among those who had a failed vacuum extraction. The data demonstrate that the failed vacuum extraction took twice as long the duration compared to successful vacuum extraction, p = 0.034.

Maternal age, parity, gestational age, the indication of VAD, Fetal position, moulding, duration of second stage of labour and giving an episiotomy was not associated with failed VAD ($p > 0.05$).

Table 10: Comparison of outcomes by type of cup used

Outcome	N	Type of cup: Rigid, n(%) (N = 168)	Type of cup: Soft, n(%) (N = 20)	P value
Outcome of vacuum extraction, n(%)				
Success		160 (95.2%)	20 (100.0%)	
Failed	188	8 (4.8%)	0 (0.0%)	>0.999[f]
Maternal injuries, n(%)				
Yes		106 (63.1%)	8 (40.0%)	
No	188	62 (36.9%)	12 (60.0%)	0.046[c]
Fetal scalp injuries, (%)				
Yes		142 (84.5%)	19 (95.0%)	
No	188	26 (15.5%)	1 (5.0%)	0.317[f]

[c] Pearson's Chi Square test, [f] Fisher's Exact test

All of the deliveries where a soft cup was used were successful compared to 95.2% among those that had the rigid cup used. However, there was no evidence that this was a statistically significant difference ($p>0.999$).

A significantly higher proportion of mothers (63.1%) who had the rigid cup used reported some form of maternal injury compared to 40% of those who had a soft cup used ($p = 0.046$).

There was no sufficient evidence from the data to demonstrate a difference in the proportion of fetal scalp injuries among those who had a rigid cup used compared to those who had a soft cup used ($p=0.317$).

Table 11: Factors associated with Apgar score at 5 minutes

Variable	Category	Apgar score at 5 minutes		P value
		<7, (n=27) N (%)	**≥ 7, (n=161) n (%)**	
Maternal comorbidity	Hypertension	5(29.4)	12(70.6)	0.228[f]
	Post term	3(15.8)	16(84.2)	
	Others	6(16.2)	31(83.8)	
	None	13(11.3)	102(88.7)	
Fetal station	+1 & above	20(15.0)	113(85.0)	0.681[c]
	+2 & below	7(12.7)	48(87.3)	
Number of pulls, n (%)				
< 3		17 (63.0%)	125 (77.6%)	
≥ 3		10 (37.0%)	36 (22.4%)	0.101[c]
Number of Pop-offs, n (%)				
< 2		27 (100.0%)	155 (96.3%)	
≥ 2		0 (0.0%)	6 (3.7%)	0.596[f]

[c] Pearson's Chi Square test, [f] Fisher's Exact test

There was no statistically significant association between the presence of maternal comorbidity and fetal APGAR score at 5 minutes (p=0.228).

The fetal station was not found to have substantial effect on the APGAR at 5 minutes (p =0.681).

There was no evidence that the number of pulls needed to effect a vacuum delivery affected its APGAR score at 5 minutes (p=0.101).

All the neonates that had an APGAR score of <7 at 5 minutes had less than 2 pop-offs. Further analysis of data showed that the number of pop-offs did not affect the APGAR score at 5 minutes (p=0.596).

Table 12: Factors associated with PPH

Variables	Absent, n=153 N (%)	Present, n=35 N (%)	P-value
Parity			
Nullipara	88 (80%)	22 (20%)	0.563[c]
Multipara	65 (83.3%)	13 (16.7%)	
Indication for VAD			
Prolonged 2nd stage	63 (79.8%)	16 (20.2%)	0.807 [c]
Maternal exhaustion	57 (83.8%)	11 (16.2%)	
Others	33 (80.5%)	8 (19.5%)	
Induction of labor			
Spontaneous	124 (79.5%)	32 (20.5%)	0.140 [c]
Induced	29 (90.6%)	3 (9.4%)	
Episiotomy			
Absent	124 (82.1%)	27 (17.9%)	0.600 [c]
Present	29 (78.4%)	8 (21.6%)	
OASIS(3rd & 4th degree perineal tear)			
Absent	138 (85.7%)	23 (14.3%)	<0.001 [c]
Present	15 (55.6%)	12 (44.4%)	
Birth weight			
<2500g	3 (75%)	1 (25%)	
≥2500g	150 (81.5%)	34 (18.5%)	0.565 [f]

[f] Fisher's Exact Test, [c] Chi Square Test

The number of participants with OASIS who had PPH was 12(44.4%) versus 15 (55.6%) who did not have PPH. Presence of OASIS was associated with occurrence of PPH (p=<0.001). The parity of the participant, indication for vacuum delivery, episiotomy use, fetal birthweight and induction of labor were not associated with PPH (p=>0.05).

Table 13: Factors associated with OASIS (3rd & 4th degree)

Variable	Category	OASIS (3rd & 4th degree)		P value
		Present, (n=27) n (%)	**Absent, (n=161) n (%)**	
Foetal Position	Occipitoanterior (OA)	25(15.2)	140(84.8)	<0.539[f]
	Malposition (OP/OT)	2(8.7)	21(91.3)	
Birth weight	<2500g	0	4(100	>0.99[f]
	≥2500g	27(14.7)	157(85.3)	
Oxytocin augmentation	Present	22(17.7)	102(82.3)	0.066[c]
	Absent	5(7.8)	59(92.2)	
Parity	Nulliparous	21(19.1)	89(80.9)	0.028[c]
	Multipara	6(7.7)	72(92.3)	
2nd stage duration	Median (IQR)	120 (70, 150)	120 (60, 120)	0.353[w]

[c] Pearson's Chi Square test, [f] Fisher's Exact test, [w] Wilcoxon rank-sum test

Nulliparous participants who had OASIS were 21 (19.1%) versus multipara 6 (7.7%) who had OASIS. There is a statistically significant association between parity and OASIS (p=0.028).

There was no evidence that showed fetal position, birth weight, oxytocin augmentation and duration of second stage of labor were associated with OASIS (p=>0.05).

CHAPTER FIVE: DISCUSSION

5.1 Indications for vacuum assisted delivery

The main indications for labor were prolonged second stage of labor 42.0% (79), maternal exhaustion 36.2% (68), and non-reassuring fetal status 11.7% (22).RHD 5.3% (10) and eclampsia 2.7% (5). This was to shorten the second stage of labor in order to mitigate possible adverse fetal outcome like birth asphyxia. Yakasai et al (2015) in Nigeria had a similar rate of Prolonged 2nd stage of labor at 45% as an indication of vacuum extraction in a study population that was similar in age and parity.

Singh et al (2011) had prolonged 2^{nd} stage as the commonest indication at 31% followed by preeclampsia by 20% in a prospective study that women were randomized to ventouse or forceps. Salman et al (2017) had an incidence of prolonged second stage at 64%, NRFS 36% which were higher rates than those found in our study.

Maiimona et al (2013) had a higher rate of non- reassuring fetal status as an indication at 44.7%, prolonged 2^{nd} stage at 25.37%, and maternal exhaustion at 16.4%. Adaji et al (2009), found a similar rate of maternal exhaustion of 35.7% as an indication of vacuum extraction with much higher rates of delayed 2^{nd} stage and non- reassuring fetal status at 50% and 42.9% respectively.

5.2 Labor and Procedural Characteristics of Vacuum Assisted Deliveries

The median age was 23.0 IQR (20.0, 27.0) in this study. This was a fairly young population that is within the reproductive age in Kenya. There were 58.5% primigravidas and 41.5% multipara. Yakasai et al (2015) had a mean age of 23.5 ± 7 years with 42.9% primigravida. Hubena et al (2018) had a mean age of 24.7 years +/-

5 years SD with 69.4 % (168) being primigravida. Mutihir et al (2007) had a mean age of 25.6 years. Nolens et al (2018) had a similar rate of primigravidas of 57.1%.

The average gestational age was 40 weeks in this study. This is similar to Prapas et al (2009) who found a mean gestational age 39±1.2 weeks in Greece.

In this study, onset of labor was spontaneous in 83% and it was induced in 17%. Some of the participants were induced because they were post-term or had hypertensive disorder in pregnancy. Merriam et al (2004) had a 5.8% rate of induction of labor which was lower than in my study that was 17%. Augmentation of labor with oxytocin was done in 6.2% unlike my study that was much higher at 66%.

Analgesia was given to only 10 participants (5.3%) who were mostly RHD patients. 94.7% (178) had no analgesia in labor. No epidural anaesthesia was given in the unit due to the logistics involved for example staff. Analgesia (parenteral) was not prescribed in majority of the parturients due to the possibility of neonatal respiratory depression if administered within 4 hours of delivery. In a study by Ahlberg et al (2013), 83.8% were found to have VAD without potent pain relief such as epidural blockade, spinal blockade or pudendal nerve block. When infiltration of the perineum was added as a method of pain relief, 18% were delivered without pain relief.

The commonest position was occipitoanterior 87.8% (165), occipito-posterior (OP) 9.6% (18), and occipito-transverse (OT) 2.7% (5). Ashwal et al (2016) found a lower rate of occipito-anterior (OA) of 77.9% while OP was much higher at 22.1%. Shihadeh et al (2001) had a lower OA rate of 77.3%. Kabiru et al (2001) had a similar rate of OA position of 85.6%. Sharmila et al (2016) had OA at a much lower rate of 17.38% and a similar OT rate of 2%.

Majority of the vacuum extractions, 70.2 % (132) were mid- pelvic in this study. Unlike my study, Sharmila et al (2016) had a much higher incidence of low vacuum extractions at 96% and midpelvic extractions at 4%.

Caput succedaneum was present in 45.7% (86). Sharmila et al (2016) found a similar rate of caput succedaneum on 42% of the fetuses. This may be attributed to the high number of participants with prolonged second stage of labor as the indication of AVD.

Moulding was present in 15.4% (29) of the fetuses. Sau et al (2004) had an incidence of ≥ grade 2 moulding at 4% while it was higher in this study at 37.9% (11) of grade 2 moulding only.

19.7% (37) mothers had a medio-lateral episiotomy prior to the vacuum delivery. There was restrictive use of episiotomy. 73% of them were nulliparous and had 73% of the fetuses in occipito-anterior position. All the episiotomies given were mediolateral. Out of the 37, only 27% (10) received local anaesthesia during the procedure. There was a 2.7% (1) episiotomy extension to a 4^{th} degree perineal tear. In a study by Aliya et al (2008), there was a 91% rate of episiotomy and 15% of extension of episiotomy. Routine episiotomies were given thus higher number of extensions. Shinde et al (2007) had a 3.93% extension of episiotomy to 3^{rd} and 4^{th} degree perineal tears. Norwitz et al (2015), found a 64.5% incidence of episiotomy with 58.7% being primipara. The OASIS rate was 8.5% with median episiotomy being a risk factor in both nulliparous and multipara. De Vogel et al (2012), OASIS rate was 5.7 % and those with a mediolateral episiotomy compared to those without having(AOR ,0.17;95% CI, 0.12-0.De Leew et al (2007) had a much higher episiotomy rate at 79.5% with primiparity, occipito-posterior position and fetal birth

weight being its risk factors. The mediolateral episiotomy which was mainly given in his study, significantly protected for anal sphincter damage (OR 0.11, 95% CI 0.09-0.13).

The rate of shoulder dystocia was 3.7% (7) in this study. There was only one admission to NBU with shoulder dislocation as a complication of shoulder dystocia. This is similar to a study by Caughey et al (2005), who found an incidence of shoulder dystocia of 3.5%. Bofill et al (1997), found a similar rate of shoulder dystocia of 3.3%. Use of vacuum extraction, large fetal size and longer time to delivery were associated with shoulder dystocia in his study.

The midwives and registrars who performed the vacuum extractions were 47.9% (90) and 49.5 % (93) respectively. This was because they are more in numbers and are always with the patients on the labor ward floor. The consultants performed only 2.7% (5) which were the more complicated cases but were successful. Sau et al (2004) had 92% of the vacuum extractions performed by registrars while 4% by consultants. Mesleh et al (2002), consultants 84.9% residents 15.1%. No midwives performed vacuum assisted deliveries in these studies and consultants were more involved as per their institutional protocols.

In 89.4% (168) of the participants, the rigid cup vacuum extractor was used. There was no association between the type of cup used with fetal scalp injuries and vacuum extraction success. More maternal injuries were seen in cases that the rigid cup was used, p-value 0.046. Hoffmeyer et al (1990) found that rigid cups could sustain more traction than soft cups thus lower failure rates. However, all the failed vacuum extractions were with the rigid cup which was used more oftenly in my study.Unlike my study, a Cochrane Review by Johanson et al (2000), vacuum extractions using

soft cup were more likely to fail 22% vs 10% for rigid cup to achieve a vaginal delivery (OR 1.65, 95% CI 1.19-2.29) .They were however associated with less scalp injury (OR 0.45, 95% CI 0.15 TO 0.60). In this study, there was no association between occurrence of fetal scalp injuries and the type of cup used.

2 pulls were needed to complete 50.5% (95) of the vacuum extractions. Only 2.7 % (4) needed more than 3 pulls to effect the delivery. This is similar to the findings in a study by Sharmila et al (2016) who had a mean number of pulls of 1.98.

The median mean decision to delivery interval of the fetus was 7.0 (IQR: 5.0, 10.0) minutes with a minimum and a maximum of 1.0 and 35.0 minutes respectively. Longer time intervals were associated failed vacuum extraction thus CS and more neonatal complications. In a study by Okunwobi – Smith et al (2005) the decision to delivery interval was 34.4 minutes .Singh et al (2011)and Lurie et al (2006) an average of 13.8 ±6.2 minutes and 13.8 minutes respectively

There were 95.7% (180) successful and 4.3% (8) failed vacuum extractions. Of the failed 87.5% VE, (n=7) were primigravida. All of the mothers had prolonged 2^{nd} stage. 25 % (2) had malposition (1 occipito- posterior and 1 occipito-transverse). On further data analysis, presence of caput succedaneum and longer decision to delivery time, were shown to be associated with failed vacuum extraction. Edgar et al (2012) had a high failure rate of 16.3 % with majority, 82.3% occurring in primigravida and labor dystocia being the commonest indication for vacuum extraction as in my study. Shinde et al (2017) had a higher failure rate of 5.5%. Increased birth weight, longer duration of second stage of labor and rotational delivery (malposition) were the associated factors in his study. Popowski et al (2012), had a failure rate of 12.8% and the risk factors were nulliparity and malposition. Sheiner et al (2001), found a failure

rate of 5.4% and it was associated with neonates weighing >4000g and Apgar scores less than 7 at one and five minutes. Shekhar et al (2013), had a failure rate was 10%, double the incidence in this study.

5.3 Fetal Outcomes

The median birth weight was 3200 grams (g). Prapas et al (2009) found a mean birth weight of 3343±379g. Mesleh (2002) had a mean birth weight 3330±440g. Singh et al (2011) found a much lower mean birth weight of 2800 ±390g.

The median Apgar score at 5 minutes was 9. This may be explained by the fact that the commonest indication for vacuum extraction was not non-reassuring fetal status. This similar to findings by Prapas et al (2009) whose mean was also 9. 85.6% (161) had Apgar score at 5 minutes of ≥7/10 in this study. Adefuye et al (2004) had a lower incidence rate of 68.2% of Apgar score at 5 minutes of ≥7/10. Aliya et al (2008), found that 96% of the neonates had an Apgar score at 5 minutes of ≥7/10.

28.2% (53) neonates that had resuscitation done. This may be explained by the indications of VE and other maternal diagnoses that may compromise fetal status like hypertension. 79.3% (42) of the neonatal resuscitation was done by midwives/ nurses in labor ward or theatre. Obstetrics & Gynecology registrars did 18.9% (19) and the Paediatrics registrar did 1.9% (1) of the neonatal resuscitations. This is because the pediatric team was not informed prior to commencing vacuum assisted delivery in labor ward in many instances. In the operating theatre (after failed vacuum extraction), it was due to the inability of the pediatric registrar to arrive before the delivery or resuscitation was not anticipated thus he was not called. However, once the neonates were taken to the Newborn Unit, the Pediatric team was always prompt

to attend to them. Unlike my study, Hubena et al (2018) found that 19.4% of neonates needed resuscitation after vacuum extraction.

Fetal scalp injuries were the commonest morbidity in the neonates. Almost all were mild and superficial. Chignon was the commonest at 77.6% (125). This is a mild complication that occurs at the point of cup application due to edema and is expected to resolve after 2 hours to 2 weeks. This is similar to the findings of Iyoke et al (2006) that had a rate of chignon at 78.2%. Simonson et al (2007) found a much lower rate of scalp edema (chignon) at 18.7%. In my study cephalohematoma was at 1.2% (2). Higher rates of cephalohematoma were found the studies done by Vacca et al (2007) and Shrestha et al (2016) at 8.4% and 48% respectively.

19.1% (36) of the neonates were admitted to NBU. The commonest diagnosis being birth asphyxia 50% (18), Transient Tachypnea of the Newborn 30.6% (11), neonatal sepsis (suspected) 5.6% (2). Birth asphyxia may be explained by presence of maternal comorbid conditions like hypertension and prolonged labor. Gumanga et al (2012) had a lower rate of admission to NBU at 9.7%. Prapas et al (2007) had 11% admissions to NICU with his commonest complication being respiratory distress at 19% which was lower than rate in my study of 30.6%. Shinde et al (2017) found a lower rate of birth asphyxia at 19.5%. A study by Ramachandra et al (2016) found birth asphyxia at 8% and TTN 24% which differed with my study.

VAD being a safe procedure, 79.2% of the neonates were discharged home within 24 hours.

13.8% (26) were to stay in the NBU due to various conditions mentioned above that needed treatment.

The perinatal mortality rate was 6.9% (13). This is similar to a study by Aliyu et al (2011) who had a mortality rate of 6.7%. In my study, 12 were fresh stillbirths. 3 mothers had eclampsia, 6 had SPET and 3 had post-term pregnancy. These conditions may have adversely affected fetal well-being and may have led to the stillbirths. 1 fetus had prolonged 2nd stage as an indication of VAD and died after a few hours in NBU with a diagnosis of severe birth asphyxia. Thus, the procedure of vacuum extraction did not lead to the fetal deaths.

5.4 Maternal Outcomes

The main maternal morbidity was genital tract injuries 60.6% (114). The rate of OASIS (third and fourth degree perineal tears) in this study was 23.7% (27). FitzPatrick et al (2003), found an OASIS rate in VAD of 3.7%. Bourgon et al (2016) had an OASIS rate of 1.21% in a target population of primigravidas who had vacuum delivery. In a study by Johnson et al (2008), OASIS rate was 27.9%, similar to the one found in my study.

Post-partum hemorrhage (PPH) was reported for 18.6% (35) of the participants. The main cause of PPH was trauma 57.1%. 4.3% (8) needed blood transfusion in this study. For those needing blood transfusion, 62.5% (5) were due to trauma (4 OASIS and 1 cervical tear), 2(25%) were due to anemia in pregnancy and 1(12.5%) was due to atony. Mesleh et al (2002) and Ramachandra et al (2016) had a much lower rate of PPH at 8.5% and 8% respectively. These were mainly due the prolonged duration of the second stage of labor that predisposed them to atony. Gachiri et al (1991) in Kenya had a PPH rate of 8.4%. A study by Nolens et al (2018) in Mulago had a lower rate of PPH at 8.2 % with fewer mothers 0.8% needing blood transfusion.

71.8% (135) of the mothers who underwent vacuum deliveries were discharged within 24 hours, thus it is a fairly safe procedure and since most mothers were of good health. This is similar to a study by Nolens et al (2018) whose average length of stay was 0 to 2 days at 80.5%. Similarly, Singh et al (2011), found an average length of stay of 24 hours of mothers after vacuum assisted deliveries. The ones who remained in hospital were 27.7% (52), mainly post- operative or had other conditions like hypertension, cardiac disease, anemia that needed further treatment. One participant (0.5%) died due to eclampsia.

5.5 Factors associated with Outcomes of Vacuum Assisted Deliveries

Longer decision to delivery interval was associated with failed VE. In contrast, a retrospective study by Sikolia et al (2011) in Kenya, fetal malposition contributed to failed vacuum extraction (OR 12.7, 95% CI 1.5 – 14.8). The participants matched my study in terms of age and parity. Ahlberg et al (2016) also had different findings. Occipitoposterior position, mid- pelvic station, high birth weight, short maternal stature, induction of labor were risk factors for failed vacuum extraction. Neonates had higher risk of subgaleal hemorrhage OR 7.3 CI (5.5 -9.7): convulsions OR 2.6 CI (2.3 – 3.0) but not of intracranial hemorrhage.

Sheiner et al (2001) found risk factors for failed vacuum extraction to include birth weight >4000g. Women who had failed vacuum had higher rates of cervical and uterine tears, postpartum anemia, intrapartum and postpartum fetal deaths.

Nulliparity was associated with occurrence of OASIS in my study. Similar findings were observed by Segal et al (2018) that showed a strong association between nulliparity and OASIS (OR 3.34; 95% CI 1.93-5.78; $p<0.001$) in a study at a large tertiary hospital of 9116 women who delivered by vacuum extraction.

In my study, episiotomy, birth weight, fetal position, oxytocin augmentation and duration of second stage were not associated with occurrence of OASIS. In contrast, Jango et al (2014) found that vacuum extraction without episiotomy was a significant risk factor of OASIS (aOR, 2.99; 95% CI, 2.86-3.12; P < .0001), and episiotomy was protective in vacuum assisted deliveries compared with vacuum-assisted deliveries without episiotomy (aOR, 0.60; 95% CI, 0.56-0.65; P < .0001). In addition, birth weight was found to be an important risk factor (aOR, 2.76; 95% CI, 2.62-2.90; P < .0001).

Bourgon et al (2016) in a retrospective study of 1056 vacuum extractions found that vacuum extraction was a risk factor for OASIS ($p < 0.0001$): OR = 4.5 CI 95% [1.91–10.29]. His other findings that differed from my study included birth weight (>4000 g) OR = 8 CI 95% [2.87–22.32], maternal age (>30 years) OR = 2.67 CI 95% [1.1–6.64], and duration of expulsion (>20 min) OR = 3.2 CI 95% [1.32–7.75.

My study showed that PPH was associated with presence of OASIS. These findings differed from those of Hiersch et al (2016) that showed risk factors for PPH after vacuum extraction included nulliparity, hypertensive disorders, episiotomy, induction of labor and longer second and 3rd stages of labor.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

1. The common indications of vacuum assisted delivery were prolonged second stage of labor, maternal exhaustion, non-reassuring fetal status and Rheumatic Heart Disease in that order.

2. Majority of the vacuum extractions were mid-pelvic and the rigid cup (Kiwi OmniCup) was used in 89.4% of the vacuum extractions. There was restrictive use of medio-lateral episiotomy.

3. Mild Superficial scalp injuries were the commonest morbidity due to vacuum extraction.

4. Genital tract injuries were the commonest maternal morbidity and the main cause of PPH in this study.

5. Failed vacuum extractions (4.3%) were associated with the presence of caput succedaneum and longer decision to delivery time.

6.2 Recommendations

1. There is need for proper assessment of parturients in order to reduce cases of failed vacuum extraction.

2. Continuous training of the health-care provider in the art of vacuum extraction to improve the fetal and maternal outcomes.

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APPENDICES

APPENDIX 1: CONSENT FORM

CONSENT FORM MOI UNIVERSITY COLLEGE OF HEALTH SCIENCES / MOI TEACHING AND REFERRAL HOSPITAL
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC) INFORMED CONSENT FORM (ICF)
STUDY TITLE: FETAL AND MATERNAL OUTCOMES OF VACUUM ASSISTED DELIVERIES AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

Name of Principal Investigator(s)

Dr. Sitti Harriet Nabalayo

Co Investigators:

Dr. Kaihura

Dr. Itsura

Name of Organization:

Moi University School of Medicine,

Department of Reproductive Health

P.O Box 4606 – 30100 Eldoret

Name of Sponsor: Self

Informed Consent Form for: Women admitted at Moi Teaching and Referral Hospital labour ward in need of vacuum assisted delivery in second stage of labour at >37 weeks gestation.

This Informed Consent Form has two parts:

• Information Sheet (to share information about the study with you)

• 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 educate you about the study and you will be allowed to ask questions if any. Please read this form carefully. If you decide to be in the study, you will be given a copy of this consent form for your records.

Taking part in this research study is voluntary. You may choose not to take part in the study. You could still receive other treatments. Saying no will not affect your rights to health care or services. You are also free to withdraw from this study at any time. If after data collection you choose to quit, you can request that the information provided by you be destroyed under supervision- and thus not used in the research study. You will be notified if new information becomes available about the risks or benefits of this research. Then you can decide if you want to stay in the study

Purpose of the study:

The purpose of the study is to find out outcomes among mothers admitted at Moi Teaching and Referral Hospital deliver by use of a vacuum device. This study entails identifying mothers in need of vacuum assisted delivery in second stage of labor at >37 weeks gestation, conducting the vacuum extraction and noting down fetal and maternal complications and treating them accordingly.

Type of Research Project/Intervention:

This study will involve obtaining of demographic and obstetric information from mothers and from their hospital records (patient's file). The procedure of vacuum extraction, maternal and fetal complications will be documented by the operator (midwife, registrar, medical officer intern) in patient's chart. The mother will be

treated according to standard procedures and the neonates will be observed for 24 hours after delivery.

Why have I been identified to Participate in this study?

You have been identified to participate in the study primarily because you are in second stage of labor and need a vacuum extractor to assist you to deliver.

How long will the study last?

The total duration of the study will be one year. The duration of your participation in this study will last from the second stage of labor to 24 hours after delivery.

What will happen to me during the study?

We are requesting you to help us learn more about what happens to pregnant women and their babies when they vacuum assisted delivery is conducted. If you accept to take part in the study, you will be requested by the research assistant to give a formal consent. After you have voluntarily given the consent, your demographic and obstetric information will be obtained from the file, and if not available you will be requested to give the information. This information will include your age, the number of pregnancies you have had and the details of the current pregnancy. You will receive treatment in accordance with the hospital guidelines, just like any other patient with a similar condition. You will then be followed up by the research assistants who will document your progress and observe you for any complications. The research assistants may examine you in the course of follow up. In case you develop any complications, the research assistants will inform you about it and you will be treated in accordance with the hospital guidelines. Your baby will also be followed up for 24 hours after delivery to observe for complications. Your baby will also be treated in accordance with the hospital guidelines.

The information obtained will be entered in a questionnaire. Some of the information that will be obtained include:

Your age, parity, gestational age

The time taken between decision to do vacuum extraction and delivery

The procedure of vacuum assisted delivery and who did it

The maternal complications that you may develop after delivery, including perineal injuries and PPH.

The gestation and weight of the baby

Your baby's admission to new born unit or new born intensive care unit

Your baby's complications including asphyxia, cephalohematoma, scalp lacerations and even death

What side effects or risks I can expect from being in the study?

During your participation in the study, you will be treated in accordance with the hospital guidelines and your participation will not influence the care that you receive in the hospital. Previous studies have shown that women undergoing a procedure like yours are subject to some complications genital injuries and bleeding. You may also deliver through caesarean section if this procedure fails. Some complications may occur to your baby that are associated with this procedure include lacerations of the scalp, bleeding under the scalp, admission to new born unit or newborn intensive care unit and asphyxia and even death.

Are there benefits to taking part in the study?

The possible benefits to you and your baby includes the close monitoring and follow up while in the hospital thus early detection and treatment of any complications. The study will enable health care providers to provide better care to patients with a similar condition in future.

Reimbursements:

The participants will not receive any financial benefits and reimbursements in the course of the study. The treatment offered will be covered under the free maternity programme.

Who do I call if I have questions about the study?

In case you have any questions concerning the study, please contact the principal investigator on using the following contacts:

Cell phone number: 0713 876556

Email Address: harnab2014@gmail.com

Questions about your rights as a research subject

You may contact Institutional Review Ethics Committee (IREC) 053 33471 Ext.3008. IREC is a group of people that reviews studies for safety and to protect the rights of study subjects.

Will the information I provide be kept private?

All reasonable efforts will be made to keep your protected information private and confidential. Protected Informationis information that is, or has been, collected or maintained and can be linked back to you. Using or sharing ("disclosure") of such information must follow National privacy guidelines. By signing the consent document for this study, you are giving permission ("authorization") for the uses and disclosures of your personal information. A decision to take part in this research means that you agree to let the research team use and share your Protected Information as described below.

As part of the study, Dr. Harriet Nabalayo Sitti and her study team may share your demographic and obstetric information, details of the complications that you may

encounter, and the laboratory results of any tests that may be carried out in the course of the study.

These may be study or non-study related. They may also share portions of your medical record, with the groups named below:

The National Bioethics Committee

The Institutional Review and Ethics Committee

National privacy regulations may not apply to these groups; however, they have their own policies and guidelines to assure that all reasonable efforts will be made to keep your personal information private and confidential.

The study results will be retained in your research record for at least six years after the study is completed. At that time, the research information not already in your medical record will be destroyed by burning. Any research information entered into your medical record will be kept indefinitely.

Unless otherwise indicated, this permission to use or share your Personal Information does not have an expiration date. If you decide to withdraw your permission, we ask that you contact Dr. Harriet Nabalayo Sitti in writing and let her know that you are withdrawing your permission. The mailing address is P.O. Box 4606 - 30100, Eldoret. 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.

You have the right to see and copy your personal information related to the research study for as long as the study doctor or research institution holds this information. However, to ensure the scientific quality of the research study, you will not be able to review some of your research information until after the research study has been completed.

Your treatment, payment or enrollment in any health plans or eligibility for benefits will not be affected if you decide not to take part.

Part II: Consent of Subject:

I have read or have had 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 of the questions I have at this time. I have been told of the potential risks, discomforts and side effects as well as the possible benefits (if any) of the study. I freely volunteer to take part in this study.

_____ mobile number _____

_____

Name of Participant Signature of subject/thumbprint Date & Time

(Witness to print if the subject is unable to write

_____ _____

Name of Representative/Witness Relationship to Subject

_____ _____ _____

Name of person Obtaining Consent Signature of person Obtaining Consent Date

_____ _____ _____

Printed name of Investigator Signature of Investigator Date

CHUO KIKUU CHA MOI, CHUO CHA USOMI WA SAYANSI YA AFYA/ HOSPITALI YA MAFUNZO NA RUFAA YA MOI

KAMITI YA MAADILI NA UTAFITI (IREC) CHETI YA HIARI (ICF)

KICHWA CHA UTAFITI: MATOKEO YA MIMBA KWA MAMA NA MWANAWE, WAKATI KIFYONZA KINAPOTUMIWA KUZALISHA MAMA

Jina La Mtafiti Mkuu/ Watafiti Wakuu:

Dkt. Harriet Nabalayo Sitti

Watafiti Wenza:

1. Dkt. Kaihura

2. Dkt. Itsura

Jina la Shirika:

Chuo Kikuu Cha Moi,

Shule ya Mafunzo ya Udaktari,

Idara ya Afya ya Uzazi,

Sanduku La Posta **4606 – 30100,** Eldoret.

Jina la Mfadhili: Mtafiti mwenyewe

Cheti ya Hiari ya: Akina Mama wajawazito wanaohitaji kifyonza kuwasaidia kujifungua baada ya njia ya uzazi kufunguka kabisa iwapo mimba hiyo ni wiki thelathini na saba au zaidi.

Cheti hiki cha Hiari kina sehemu mbili:

Hati ya Maelezo (ya kukueleza habari juu ya utafiti)

Cheti cha Kutoa Ridhaa kwa Hiari (cha kutia sahihi ukiamua kushiriki)

Sehemu ya I: Hati ya Maelezo

Utangulizi:

Unaombwa kushiriki kwenye utafiti. Habari hii ni kukueleza zaidi juu ya utafiti huu. Tafadhali isome hati hii kwa taratibu. Utapewa fursa ya kuuliza maswali. Ikiwa utaridhia kushiriki utafiti huu, utapewa nakala ya hati hii uiweke. Kushiriki kwenye utafiti huu utakuwa kwa kupenda mwenyewe (hiari yako). Unaweza kuamua kutoshiriki, na hapo utaendelea kupewa matibabu kwa kawaida. Kukataa kwako hakutaadhiri haki yako ya kupewa huduma za kiafya. Waweza pia kujiondoa wakati wowote. Ikiwa utaamua kujiondoa baada ya taarifa kuchukuliwa kwako, unaweza ukatoa ombi la kuangamizwa kwa taarifa hiyo ukishuhudia ili isitumiwe kwa utafiti. Utajulishwa ikiwa kutagunduliwa madhara ama faida mpya ya utafiti huu ili ufanye uamuzi wa kuendelea kushiriki kwenye utafiti au la.

Lengo la utafiti:

Utafiti huu unalenga kuchunguza matokeo ya mimba kwa mama na mwanawe wakati kifyonza kinapotuniwa kuzalisha mama.

Aina ya Utafiti/Hatua:

Utafiti huu utahusisha akina mama wanaohitaji kutumia kifyonza kuwasaidia kujifungua wakati njia ya uzazi imefunguka kabisa katika hospitali kuu ya rufaa ya Moi. Watafuatiliwa na wachunguzwe iwapo watapata madhara yoyote kutokana na mbinu hii ya kujifungua. Mtoto aliyezaliwa kutumia mbinu hii pia atachunguzwa na kufuatiliwa kwa muda wa siku moja ili kutathmini iwapo atapata madhara yoyote yanayotokana na mbinu hii.

Mbona nimechaguliwa kushiriki kwenye utafiti huu?

Umechaguliwa kushiriki utafiti huu kwa sababu unahitaji kujifungua kwa kutumia kifyonza.

Utafiti huu utadumu muda gani?

Utafiti wote kwa jumla utachukua mwaka mmoja. Muda ambao wewe utashiriki kwa utafiti huu utakuwa tangu wakati ambapo njia ya uzazi imefunguka kabisa mpaka msaa ishirini na nne baada ya kujifungua.

Ni nini itakayonifanyikia wakati wa utafiti?

Tunakuomba ushiriki kwa utafiti huu utakaosaidia madaktari kujua mengi kuhusu mbinu hii ya kujifungua kutumia kifyonza. Baada ya kutoa ruhusa ya kuhusika kwa utafiti huu, mtafiti msaidizi atakuchukua historia yako kutoka kwa rekodi zako za hosipitali. Utaulizwa habari nyingiye yoyote ambao haitapatika kwa rekodi zako za hospitali. Baada ya kutathmini kuwa unahitaji mbinu hii ya kujifungua, utahudumiwa na madaktari kama mgonjwa mwingine yeyote, kulingana na kanuni za hosipitali ya rufaa ya Moi. Kisha mtafiti msaidizi atakukfwatilia kutathmini iwapo utapata athari zozote zinazotokana na mbinu hii. Ukipata athari zozote utatibiwa kulingana na kanuni za hosipitali. Punde unapojifungua, mwanao atachunguzwa kutathmini iwapo ameathirika na mbinu hii kwa njia moja au nyingine. Mwanao atafuatiliwa kwa muda wa siku moja.

Baadhi ya habari itakayohitajika kutoka kwako ni kama ifuatayo:

Umri wako, mimba amazo umewahi kuwa nazo, Umri wa mimba yako

Muda utakaochukua kati ya wakati wa uamuzi wa kutumia kifyonza na kuzaliwa kwa mwanao.

Mbinu ya kujifungua kujifungua kutumia kifyonza na nani aliyekuzalisha

Athari zozote kwa mama zinazotokana na mbinu hii kama kuraruka katika njia ya uzazi na kuvuja damu.

Uzito wa mwanao na hali yake atakapozaliwa

Iwapo mwanao atalazwa kwa wodi ya watoto waliozaliwa..

Athari zozote kwa mtoto zinazotokana na mbinu hii kama vidonda kichwani, damu kuganda chini ya ngozi ya kichwa , kushindwa kupumua vizuri na wakati mwingine kifo.

Madhara gani nitakayotarajia kutokana na utafiti huu?

Baada ya kulazwa hospitalini, utahudumiwa kama kawaida kulingana na kanuni za hosipitali, kama akina mama wengine wanaotumia mbinu hii ya kifyonza kujifungua. Kwa hivyo, athari utazopata zinaweza kutokana na mbinu hii kama kuraruka katikaa njia ya uzazi, ama kuvja damu. Unaweza pia kujifungua kwa njia ya upasuaji iwapo mbinu hii haitafaulu.Vile vile, mbinu hii inaweza kuathiri mwanao. Anawezapata shida ya kupumua, huenda azaliwa kama amechoka, huenda anaweza kupata vidonda kichwani, damu kukusanyika chini ya ngozi ya kichwa chake, kulazwa kwa wodi ya watoto na hata kifo.

Je, utafiti huu una manufaa gani?

Manufaa ni kwamba utafuatiliwa kwa karibu na mtafiti msaidizi. Iwapo utapata athari zozote kutokana na njia hii ya kujifungua, basi utachunguzwa na kuhudumiwa mapema. Utafiti huu una manufaa kwa jamii kwa sababu matokeo yake itawawezesha wahudumu wa afya kujua mengi yanayotokana na mbinu hii ya kujifungua. Hii itawawezesha wahudumu wa afya kutoa huduma bora zaidi za afya kwa akina mama watakaojifungua na mbinu hii siku za usoni.

Malipo

Washiriki wa utafiti huu hawatapokea malipo yoyote.

Je, nitawasiliana na nani nikiwa na maswali yanayohusu utafiti huu?

Unaweza kuwasiliana na mtafiti mkuu kwa njia z ifuatazo:

Simu ya mkononi: 0713876556

Anwani ya barua pepe *harnab2014@gmail.com*

Kwa maswali kuhusu haki zako kama mshiriki wa utafiti, unaweza kuwasiliana na Kamati ya Maadili na Utafiti (IREC) 053 33471 Ext.3008. IREC. Ni kamati inayotathmini tafiti mbalibali ili kulinda haki na usalama wa washiriki wa utafiti.

Je, taarifa nitakayotoa itawekwa fiche?

Hatua zitachukuliwa ili kuweka fiche taarifa zote kukuhusu. Taarifa fiche ni taarifa iliyokusanywa ama inakusanywa ama kuwekwa na inayoweza ikafuatiliwa hadi kwa asili yake ambayo ni wewe. Matumizi au kubainishwa kwa taarifa hii haina budi kufuata miongozo za kitaifa zinazohusiana na taarifa aina hii. Kwa kutia sahihi cheti ya hiari ya utafiti huu, unatoa ruhusa kwa matumizi na ubainifu wa taarifa yako ya kibinafsi. Uamuzi wa kushiriki wamaanisha unakubali kutumiwa na kubainishwa kwa taarifa hii na watafiti kulingana na maelezo yafuatayo.

Kwa utafiti huu, Dkt. Harriet Nabalayo Sitti na kundi lake watashiriki habari inayohusu athari utakazopata wewe na mwanao, zinazohusiana na kujifungua kutumia kifyonza. Kushiriki huku kunaweza kuhusiana ama kutohusiana na utafiti wenyewe. Pia, wanaweza kushiriki ujumbe wa rekodi zako za kiafya na mashirika yafuatayo:

Kamati ya Kitaifa ya Maadili ya Viumbe hai (yaani National Bioethics Committee)

Kamiti ya Maadili ya Utafiti (yaani IREC)

Sheria za Kitaifa za kuhifadhi siri pengine hazitazingatiwa na mashirika haya. Hata hivyo, mashirika haya yana sera na mipangilio yao yenyewe kuhakikisha kila liwezekanavyo linatekelezwa kuweka fiche taarifa yako ya binafsi.

Matokeo ya utafiti yatawekwa kwa rekodi yako ya kitafiti kwa muda usiopungua miaka sita. Kisha, taarifa yoyote itakayokosa kwa rekodi zako za kiafya itachomwa moto. Taarifa itakayowekwa kwa rekodi yako ya kiafya itawekwa milele.

Kibali utakachotoa cha kushirikishwa kwa taarifa zako za kibinafsi miongoni mwa watafiti hakina muda wa kwisha, ila tu utakapoelezewa vingine. Kama utaamua

kubadili msimamo wako na kuondoa kibali cha kushirikishwa taarifa yako ya binafsi, tafadhali wasiliana na Dkt. Harriet Nabalayo Sitti kwa maandishi ukimjulisha kujiondoa kwako. Anwani utakayotumia ni SLP 4606 – 30100, Eldoret. Mara tu utakapofanya hivyo, tutakoma kuchukua taarifa zozote kwako. Hata hivyo, taarifa yako ya kiafya yaweza kuhifadhiwa kwa minajili ya kuripoti na kutathmini ubora wa utafiti.

Una haki ya kuonyeshwa na kunakili taarifa yako ya kibinafsi bora tu daktari wako ama mtafiti awe na taarifa hiyo. Hata hivyo, hutaweza kuonyeshwa baina ya taarifa yako hadi kukamilika kwa utafiti ili kuhakikisha ubora wa utafiti unalindwa.

Hakutokuwa na madhara yoyote kwa matibabu, ada au kujiandikisha kwako kwa bima, wala kuhitimu kwako kwa manufaa yoyote endapo utakataa kushiriki.

Sehemu ya II: Ridhaa kwa Hiari ya Mshiriki:

Nimesoma ama kusomewa maelezo yote ya utafiti huu. Mtafiti au mwakilishi wake amenielezea utafiti huu kwa kina na kuyajibu maswali yangu yote kuuhusu. Nimeelezwa madhara yanayoweza kutokea, usumbufu na manufaa yoyote (ikiwepo). Ninajitolea kushiriki kwa utafiti huu kwa hiari yangu.

_____ _____ _____

Jina la mshiriki Sahihi ya mshiriki/chapa ya kidole ghumba Tarehe na saa

(Mshahidi kuweka chapa ikiwa mshiriki hawezi kuandika) namba ya simu ya mshiriki ----------

_____ _____

Jina la Mwakilishi/ Mshahidi Mahusiano yake na Mshiriki

_____ _____ _____

Jina la mtu anayepokea ridhaa ya hiari Sahihi ya mtu anayepokea ridhaa ya hiari Tarehe Tarehe

_____ _____ _____

Chapa ya jina la mtafiti Sahihi ya mtafiti Tarehe

APPENDIX 2: QUESTIONNAIRE

FETAL AND MATERNAL OUTCOMES IN VACUUM ASSISTED DELIVERIES AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

To be used in labor ward.

Date of admission_____

In-Patient Number_____

Year of Birth_____highest level of education---------- marital status

Age_____

Parity _____

LMP_____EDD_____GBD_____

Labor characteristics

Did the client go into spontaneous labor [ ] or was induced [ ]?

Was there augmentation of labor with oxytocin Yes [ ] No [ ]

Was there use of epidural anesthesia? Yes[ ] No[ ]

What was the fetal position?

What was the fetal station?

Was caput succadeneum present? Yes [ ] No[ ]

Was moulding present? Yes [ ] No[ ] grade ?

What was the duration of 2^{nd} stage of labor (hours)?

What was the indication for vacuum assisted delivery?

Is there any other diagnosis for the mother?

Was an episiotomy given? Yes [ ] No [ ]

Was analgesia given? local anesthesia yes [ ] no [ ] epidural anesthesia yes [ ]

Parenteral or oral analgesia yes [ ] no [ ] (specify which one)

Was there shoulder dystocia? Yes [ ] No [ ]

Procedural Factors

Who was the operator of the vacuum extractor? Midwife [ ] Registrar [ ] Consultant []

Was kind of vacuum extractor was used? Soft cup [ ] Rigid cup[ ]

What was the number of pulls needed for delivery? 1 [ ] 2 [ ] 3 [ ]

What was the number of pop-offs?

What was the mean time between the decision to delivery of the infant? ---- minutes

Was the vacuum delivery

Successful Vacuum Extraction

	Alive	FSB
Sex		
Birthweight (g)		
Apgar score at 5 minutes		

Failed vacuum Extraction (CS done)

	Alive	FSB
Diagnosis during CS		
Sex		
Birth weight		
Apgar score at 5 minutes		

Was neonatal resuscitation done? By whom? (Specify)

Neonatal complications

Were there scalp injuries?

Chignon/ scalp edema? Yes [ ] no [ ]

Scalp lacerations? Yes [ ] no [ ]

Cephalohematoma? Yes [ ] no [ ]

Any other scalp injury?

Any other injury.

Was the baby admitted to the newborn unit (NBU)? Yes [ ] No [ ]. If yes, what was the diagnosis on admission?

What was the condition of the neonate 24 hours after the delivery?

- Good and ready for discharge
- Sick, specify diagnosis.
- Dead(specify diagnosis at time of death)

Maternal complications

Were Genital tract injuries sustained?

Cervical tear

1st degree perineal tear

2nd degree perineal tear

3rd degree perineal tear

4th degree perineal tear

Was there postpartum hemorrhage? Yes [ ] no [ ]. What was the cause of PPH? Atony [ ] trauma [ ] tissue [ ] coagulopathy [ ] If yes, was blood transfusion done? Yes[ ] no [ ]

What was the condition of the mother after 24 hours?

- Discharged home?
- To stay in hospital, why?
- Dead? (specify diagnosis at time of death)

Print Name of person filling the questionnaire _____

Signature of person filling the questionnaire _____

Date _____ Day/month/year

APPENDIX 3: MTRH PROTOCOL ON ASSISTED/ OPERATIVE VAGINAL DELIVERY

Assisted/Operative Vaginal Delivery

Introduction

Operative vaginal delivery refers to the use of a vacuum or forceps in vaginal deliveries. Both methods are safe and reliable for assisting childbirth, if appropriate attention is paid to the indications and contraindications for the procedures. The benefits and risks to both the woman and her fetus of using either instrument or the risks associated with proceeding to the alternative of cesarean section delivery must be considered in every case. The choice of instrument should suit both the clinical circumstances, the skill of the health care provider and the acceptance of the woman. The health care provider should have training, experience and judgmental ability with the instrument chosen. Informed consent is an essential step in preparing for an operative vaginal delivery.

Operative vaginal delivery should be avoided in women who are HIV positive to reduce mother-to-child transmission.

Assessing the Descent of the Baby

Prior to performing an operative delivery, it is essential to determine that the vertex is fully engaged. Descent of the baby may be assessed abdominally or vaginally. When there is a significant degree of caput (swelling) or moulding (overlapping of the fetal skull bones), assessment by abdominal palpation using ―fifths of head palpable, is more useful than assessment by vaginal examination.

Currently in MTRH there will only be access to vacuum assisted delivery, therefore the following protocol will concentrate on that.

Vacuum Assisted Delivery

The vacuum should not be regarded as an easier alternative to forceps. Use of vacuum equipment requires different but not less skill. The vacuum is designed to produce traction upon the fetal scalp in order to assist maternal expulsive efforts. It cannot be used to apply rotational forces.

Trying to complete a rotation can cause a skull fracture or a haemorrhage resulting in serious harm to the baby.

The vacuum will less likely to succeed in the absence of maternal expulsive effort.

The vacuum may be used judiciously to correct attitude (deflexion), if it is properly applied and appropriate traction used.

Indications

Fetal

Evidence of fetal compromise that requires immediate delivery

Maternal

Failure to deliver spontaneously following the appropriate management of the second stage of labour

Conditions which require a shortened second stage or in which pushing is contraindicated (e.g. some maternal medical conditions)

Maternal exhaustion

Contraindications

Contraindications can be divided into absolute and relative contraindications. As with any relative contraindication to a procedure, the applicability of the criteria will depend on the clinical circumstances and the skill of the health care provider.

Contraindications – Absolute

Non-vertex presentation

Face or brow presentation

Unengaged vertex

Incompletely dilated cervix

Clinical evidence of cephalopelvic disproportion (CPD)

Obstructed labour

Contraindications – Relative

Preterm less than 34 weeks

Mid-pelvic station

Unfavourable attitude of the fetal head

Prerequisites

Informed consent

Vertex presentation

Engaged vertex

Term fetus

Fully dilated cervix

Ruptured membranes

Adequate maternal pelvis by clinical assessment

Empty maternal bladder

Appropriate local analgesia, if available

Adequate facilities and backup available (theatre for CS and neonatal resuscitation)

Health care provider knowledgeable about the instrument, its use and the complications that may arise from its use

Ongoing fetal and maternal assessment

Technique

A useful mnemonic has been adapted for vacuum extraction. (Appendix 1)

This mnemonic is the first 10 letters of the English alphabet. The vacuum should be applied with rigorous adherence to the mnemonic provided. It is important that the indication is clear and well understood by the parents. Consent of the woman must be obtained and properly documented.

Provide emotional support and encouragement.

Analgesia is not essential but may be desirable, if available.

The bladder should be empty. If the woman is not able to void, consider catheterization.

Final confirmation of full dilatation and fetal position should be made.

The proper function of the vacuum equipment should be determined before the cup is applied.

The cup is applied by compressing it in an anteroposterior diameter and then introducing it into the posterior fourchette while protecting the maternal tissues and making space with the opposite hand.

It is important to apply the vacuum cup to the flexion point for the best result. Once in the vagina, the cup is moved approximately 3 cm from the anterior fontanelle toward the posterior fontanelle over the sagittal suture.

When the vacuum extractor cup is centred over the flexion point, flexion and asynclitism are promoted. Placing the cup off to the side of the sagittal suture or closer to the anterior fontanelle promotes asynclitism, deflexion and cup disengagement.

Take care to ensure that no maternal tissue is between the fetal head and the vacuum cup. This should be reconfirmed before each pull on the vacuum and following any re-application or suggestion of loss of contact during traction.

No rotational force is applied; the fetal head may rotate on its own with descent.

Traction should always be in the direction of the pelvic curve—initially downward and finally upward. A common error is to attempt to extend the head prematurely, thereby increasing the diameter that must pass over the perineum and increasing the likelihood of perineal trauma.

Apply traction with contractions and with maternal expulsive efforts.

After every vacuum delivery, the newborn should be observed to ensure that the expected swelling on the head does not enlarge significantly and that there is no evidence of developing hypovolemia, which might occur with a subgaleal haemorrhage.

Vacuum failure

Before undertaking any attempt at operative vaginal delivery, consider the risk of failure for vaginal delivery and the potential for other complications, such as shoulder dystocia and postpartum haemorrhage. Ensure adequate assistance is present if such complications should occur. Consider the fetal status before making your attempt to deliver the baby and the time necessary to initiate a caesarean section if the procedure fails. Under circumstances in which fetal well-being is suspect and/or the potential for success of an operative vaginal delivery is in doubt, proceed directly to caesarean section, if available. If times permits, consider transfer to the next level of care. Whenever operative delivery is considered, a health care provider skilled in newborn resuscitation should be present at the birth. This person’s sole responsibility must be

the care of the newborn. The vacuum procedure has failed when descent or delivery has not been accomplished. The procedure should be abandoned at this point, and an alternate method of delivery should be selected.

When to halt—beware

3 pulls over 3 contractions, no progress →abandon procedure

3 pop-offs: after 1, reassess carefully before reapplying

After 20 minutes of application with no progress→ reassess

The above recommendations should be considered the maximal limits. The incidence of scalp trauma is increased when the cup application is greater than 10 minutes compared to less than 10 minutes. It is imperative that some descent is observed with each pull. If these limits are approached, progress does not occur or there is evidence of scalp trauma, the procedure should be abandoned.

Potential complications

Complications usually result from not observing the conditions of application or from continuing efforts beyond the guidelines described above.

Fetal complications

Localized scalp oedema (artificial caput or chignon) under the vacuum cup is harmless and usually disappears within a few hours.

Cephalohematoma requires observation. It will usually resolve in 3–4 weeks.

Scalp abrasions (common and harmless) and lacerations may occur. Clean and examine lacerations to determine if sutures are necessary. Necrosis is extremely rare.

Intracranial bleeding is extremely rare. It requires immediate intensive neonatal care.

Maternal complications

Tears of the genital tract may occur. Examine the woman carefully and repair any tears to the cervix or vagina , or repair the episiotomy.

Care after Assisted vaginal delivery

Active third stage management

Prepare for newborn resuscitation

Umbilical arterial blood gas analysis, where laboratory facilities exist

Examination for maternal trauma

Examination for neonatal trauma

Scalp trauma

Signs of cerebral irritation (poor sucking, listless)

Signs of scalp swelling, cephalohematoma or subaponeurotic bleeds

The newborn should be examined carefully at the time of the initial newborn exam. Careful monitoring should be continued in the immediate neonatal period and, at minimum, a second full examination of the newborn should be completed prior to discharge. Any abnormal findings will require further investigation.

Documentation of the indication, definition and method of operative technique

Review birth with the family

Documentation

The indication, definition and method of operative technique employed must be clearly and completely documented in all operative deliveries. The position and station of the fetal head at the commencement of the intervention must be stated. A written note should be prepared for both the woman's and the baby's charts. The need for the intervention must be:

Convincing

Compelling

Documented

Suggested format for a chart (Appendix2):

Date and time of birth

Name of physician or other primary health care provider

Indication for operative delivery

Record of informed discussion with the woman of the risks, benefits, and options

Position and station of the fetal head and method of assessment (i.e. vaginally and/or abdominally)

Amount of moulding and caput present

Assessment of maternal pelvis

Assessment of fetal heart rate and contractions

Type of analgesia or anesthesia used, if any

Use of episiotomy, description and timing, and details of repair

Ease of application of vacuum or forceps

Number of attempts and duration of traction for forceps and duration of application for vacuum (start and stop time noted), and force used

Apgar score

Results of cord blood analysis, if done

Neonatal resuscitation activities, if needed

Description of maternal and neonatal injuries, if any

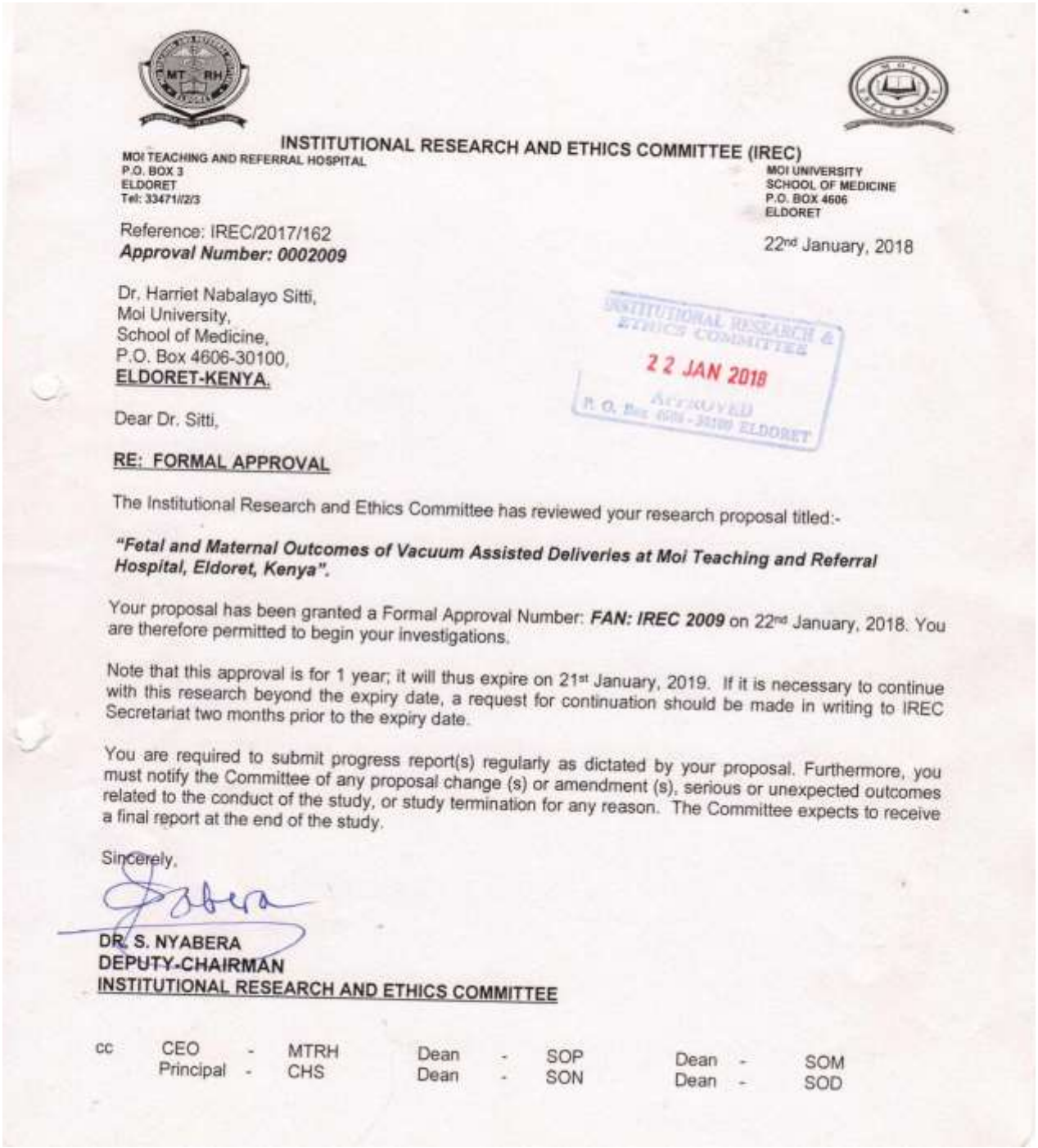
APPENDIX 4: VACUUM MNEMONIC

A	Analgesia, may not be necessary Neonatal assistance
B	Bladder should be empty
C	Confirmation: Full dilatation/membranes ruptured
D	Determine position fetal head Think: shoulderdystocia
E	Equipment (ambubag available?)
F	Fontanelle, position cup Sweep around, clear maternal tissue
G	Gentle traction, pull with contractions only
H	Halt: No progress after 3 contractions 3 pop offs No progress after 20 minutes
I	Incision, consider episiotomy
J	Jaw, remove cup when jaw is reachable

APPENDIX 5: DOCUMENTATION CHECKLIST

Indication for operative delivery
Date and time of birth
Name of physician/ primary health care provider
Record of informed discussion with the woman of the risks, benefits, and options
Position and station of the fetal head and method of assessment (i.e. vaginally and/or abdominally)
Amount of moulding and caput present
Assessment of maternal pelvis
Use of episiotomy, description and timing, and details of repair
Assessment of fetal heart rate and contractions
Type of analgesia or anesthesia used, if any
Ease of application of vacuum
Number of attempts and duration of application for vacuum (start and stop time noted)
Neonatal resuscitation activities, if needed
Apgar score
Description of maternal and neonatal injuries, if any

APPENDIX 6: IREC APPROVAL



INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

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

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

Reference: IREC/2017/162
Approval Number: 0002009

22nd January, 2018

Dr. Harriet Nabalayo Sitti,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
22 JAN 2018
APPROVED
P.O. Box 4606 - 30100 ELDORET

Dear Dr. Sitti,

RE: FORMAL APPROVAL

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

"Fetal and Maternal Outcomes of Vacuum Assisted Deliveries at Moi Teaching and Referral Hospital, Eldoret, Kenya".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 2009*** on 22nd January, 2018. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 21st January, 2019. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

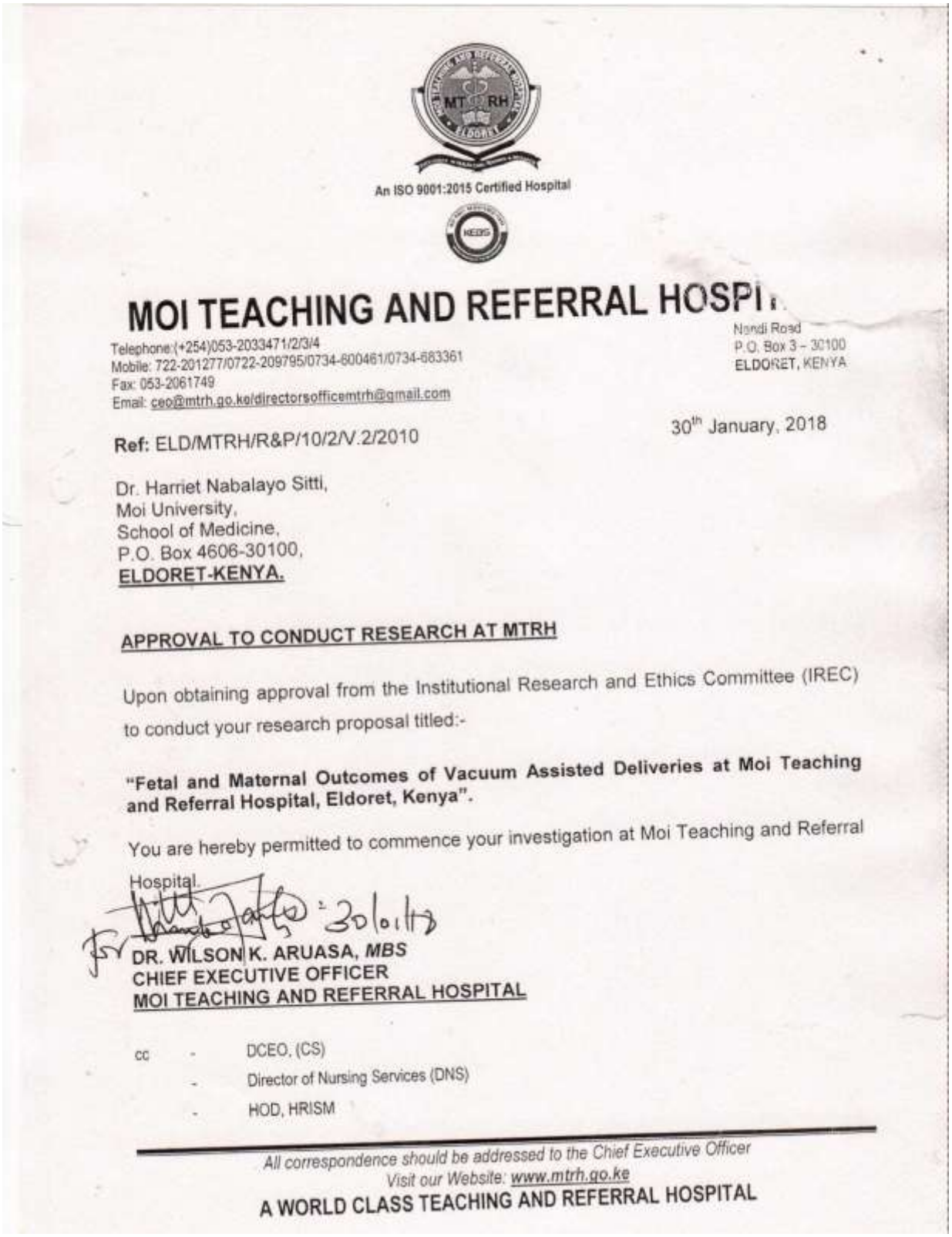
You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects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

Sincerely,

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

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

APPENDIX 7: AUTHORIZATION FROM MTRH



An ISO 9001:2015 Certified Hospital

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ELDORET, KENYA

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

30th January, 2018

Dr. Harriet Nabalayo Sitti,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

APPROVAL TO CONDUCT RESEARCH AT MTRH

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

"Fetal and Maternal Outcomes of Vacuum Assisted Deliveries at Moi Teaching and Referral Hospital, Eldoret, Kenya".

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

30/01/18

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

cc - DCEO, (CS)
- Director of Nursing Services (DNS)
- HOD, HRISM