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Prevalence and Predictors of Vaginal Delivery following Induction of Labour at Kawempe National Referral Hospital, Kampala, Uganda

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DECLARATION

I declare that this dissertation is original. The work was personally done by the author with guidance from the supervisors and has never been submitted for any academic award to any other university before.

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DEDICATION

I dedicate this dissertation to my family, my dear husband Dr. Solomon Atyam and our lovely sons Ephraim, Ezekiel, and Elisha for their endurance in my absence while i stayed away from home for long hours to try an acquire knowledge and gain skills to practice Obstetrics and Gynaecology.

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ABBREVIATIONS

ACOG	American College of Obstetricians and Gynecologists
ARM	Artificial Rupture of Membrane
BMI	Body mass index
C/S	Cesarean Section
IOL	Induction of Labour
IUFD	Intrauterine Fetal Death
KNRH	Kawempe National Referral Hospital
LGA	Large for gestational age
MNRH	Mulago National Referral Hospital
PROM	Pre-labour (premature) rupture of membranes
RCT	Randomized Controlled Trial
VBAC	Vaginal birth after caesarean section
WHO	World Health Organization
WOA	Weeks of Amenorrhea
ANC	Antenatal Care
A/S	Apgar score

OPERATIONAL DEFINITIONS

Induction of labour: Induction of labour is defined as the process of artificially stimulating the uterus to contract to initiate labour. It may be done by administering oxytocin or prostaglandins to the pregnant woman or mechanically by using Foley catheter or artificially rupturing the amniotic membranes

Failed induction: Is defined as inability to achieve active phase of labor after 24 hours of prostaglandin administration with or without 12 hours of oxytocin infusion with artificial membrane rupture as soon as feasible and safe.

Vaginal delivery: This is the process of giving birth through the vagina canal which may be spontaneous or assisted.

Emancipated minor: Is defined as an individual below the age of majority who is pregnant, married, has a child or cater for their own livelihood.

Predictor: Means something that enables one to know whether or not something is likely to happen in future

ABSTRACT

Background: Induction of labour has been shown to reduce perinatal morbidity and mortality and World Health Organization (2018) recommended induction of labour at 41 completed weeks of Amenorrhea to reduce the risks associated with post-term pregnancy. The prevalence of Induction of labour has continued to rise in the recent past with 25% of mothers in high income countries undergoing induction of labour to shorten their pregnancy duration compared to low- and middle-income countries where fewer mothers are induced to deliver their babies. Induction of labour is indicated when the risk of waiting for spontaneous onset of labour is thought to be higher than those associated with shortening the duration of pregnancy.

Methods: It was a cross- sectional study carried out among mothers who delivered following induction of labour in the labour ward at Kawempe National Referral Hospital. A total of 323 mothers who had induction of labour were selected by consecutive sampling and factors which led to vaginal delivery were identified. Data was collected using interviewer administered questionnaire. Data was entered in epidata version 7 and exported to STATA version 14.0 statistical software for cleaning and analysis. Univariate, bivariate, and multivariate analyses were performed. Any factor with p-value less or equal to 0.05 was considered statistically significant.

Results: The prevalence of vaginal delivery following induction of labour was 76.5% and the predictors of vaginal delivery were rupture of membranes (aPR=1.26, 95%CI =1.116-1.416, *p*=<0.001), use of Intravenous oxytocin for induction of labour (aPR=1.19, 95%CI =1.033-1.362, *p=0.015),* adherence to protocol for induction of labor, (aPR=1.32, 95%CI =1.142-1.551, *p=<0.001)* and birth weight (aPR=0.68, 95%CI= 0.506-0.913, *P= 0.010.*

Conclusion and recommendations: Prevalence of vaginal delivery following induction of labour at Kawempe National Referral Hospital was high. Rupture of membranes, monitoring of labour as per the protocol, use of intravenous oxytocin were positive predictors while birth weight more than 3.5 kg was a negative predictor of vaginal delivery following induction of labour. We recommend that Clinicians should be encouraged to induce women with indication for induction of labour, hospitals should ensure proper monitoring of mothers is done with an induction of labour monitoring tool to improve success of induction and a study should be done to determine whether delivery is spontaneous or assisted following induction of labour

CHAPTER 1: INTRODUCTION

1.1 Background

Induction of labour (IOL) is the process of artificially stimulating the uterus to start labour. It is usually done by administering oxytocin or prostaglandins to the pregnant woman or by manually rupturing the amniotic membranes (WHO 2018) (1). Induction of labour is a common obstetric procedure which has over the years been indicated by various professional societies in circumstances when the risks of waiting for spontaneous onset of labour are greater than the risks associated with shortening the duration of pregnancy (2).

The main indication for IOL is prolonged pregnancy and World Health Organization (WHO) recommended that IOL should be done at 41 completed weeks of amenorrhea (WOA), because studies have shown that IOL may reduce perinatal morbidity and mortality for pregnancies that have continued beyond term (1). Other indications for IOL include pre-labour rupture of amniotic membranes, fetal death, chorioamnionitis, vaginal bleeding mainly following abruption placenta, hypertensive disorders, maternal diabetes and other maternal medical complications.

The success of IOL have been shown by various studies to have a number of predictors such as a high Bishop's score >7 (3), term gestation, ruptured membranes, lower BMI, taller in height, maternal age less than 35 years, multiparity, estimated fetal weight <3500g (4), number of prenatal visits of the women, fetal head circumference, estimated Fetal weight (5) fetal engagement (6), and information on the nature of the procedure (7). From our study however, predictors of success of induction of labour included among others rupture of membranes, birth weight, adherence to protocol and monitoring of labour progress.

Over the recent years, the incidence of IOL to shorten the duration of pregnancy has continued to rise with more pregnant women around the world having undergone induction of Labour to deliver their babies. The incidence is reported to be much higher in high income countries with up to 25% of all deliveries at term occurring following induction of labour. In low and middle income countries however, these rates are generally lower.

Globally, IOL is done in about 20% of the population and about 80% of those induced deliver vaginally (8) which was not very different from our study which showed 76.5% of the women delivered vaginally following induction of labour. Unpublished data by WHO Global Survey on Maternal and Perinatal Health from a multicenter study involving 24 countries shows that 9.6% of deliveries were done following IOL. The Asian and Latin American

countries reported higher proportions of deliveries following IOL when compared to African countries with the lowest being 1.4% (Niger) as compared to 35.5% (Sri Lanka). The reason for the difference in observation above was not documented.

Good uptake of IOL was shown by Abdulkadir and colleagues in their study in Ethiopia where up to 22.4% of women underwent IOL to deliver their babies at Wolliso St. Luke's Hospital and of these women induced, 57.8% delivered vaginally. Predictors for success of IOL were gestational age equal to or less than 42WOA, Bishop Score >5, membrane rapture before induction of labour and multiparity among others (9). In Nigeria, immediate IOL following spontaneous pre-labour rupture of membranes at term was shown to significantly lower the rates of intervention without compromising feto-maternal outcome. More mothers spontaneously delivered their babies vaginally and had a greatly reduced duration of latent labour and hospital stay before delivery while the rates of caesarean section and operative vaginal delivery were lower compared to 12 hours delay of expectant management (10)

The chance of a successful induction depends on both cervical and non-cervical factors.

Cervical status: The status of the Cervical before administration of an induction agent greatly impacts on the duration of induction and the likelihood of vaginal delivery. Despite the limitations of Bishop Score, it still appears to be the best available tool for assessing cervical status. Systematic reviews and a met-analysis have shown that the Bishop's score is more predictive of vaginal delivery compared to the transvaginal sonographically measured cervical length which gave a moderate predictive capacity (3). The cervical status at the start of IOL assessed using the modified Bishop scoring system was also shown to be an important predictor. Bishop score predicted likelihood ratio of successful IOL to be (LR) 2.10, 95%CI=1.67-2.64 (11).

Non cervical factors: Predictors of vaginal delivery following IOL include women with term gestation, ruptured membranes, lower BMI, taller in height, less than 35 years, multiparity, estimated fetal weight <3500g and comorbidities associated with placental insufficiency (eg, preeclampsia (4).

A study in Brazil to assess pre-induction maternal and ultrasonographic factors in the prediction of vaginal delivery showed 56.9% of vaginal delivery irrespective of the induction-to-delivery interval with predictive factors of success being height, BMI, parity,

number of prenatal visits of the women, and high Bishop's score basing on cervical consistency, effacement and dilation. Fetal factors such as head circumference and Estimated Fetal weight (5). A comparative study in Serbia to evaluate clinical and sonographic parameters in prediction of the success of labor induction shows 84.4% success with Bishop's score, cervical length, parity and BMI being predictors of success which were among a few of the many predictive factors that Prado et al found out three years later in their study (12).

According to a recently published data from south Korea, younger maternal age, lower term body mass index and fetal engagement were important predictors for vaginal delivery in an induced labour (6). This study concurred with findings by Marciniak and colleagues in Poland which showed that multiparity, maternal age <30 years, high Bishop's score and birth weight <3.5kg were among the predictors of vaginal delivery following use of foley catheter for cervical ripening and IOL (13).

Kawakita et al found out that 77.4% of mothers delivered vaginally after IOL verses 75.9% reported by Lawani et al. Maternal age, gestational age at delivery, maternal height, pre-pregnancy weight, gestational weight gain, cervical exam on admission (dilation, effacement, and station), chronic hypertension, gestational diabetes, pre-gestational diabetes, and Placental abruption were among the predictors of vaginal delivery (14), (15)

A study in Kenyatta National Hospital, Nairobi, Kenya which is a neighbouring country to Uganda showed a 62% success of IOL and the outcome of induction of labor was influenced by age, type of employment, parity and information on the nature of the procedure (7)

70% of vaginal deliveries were reported within 24 hours following catheter induction although the predictors of success were not documented in an interventional study done at Mulago National Referral Hospital(MNRH), Uganda (16).

1.2 Problem statement

Rates of IOL are generally higher in Asia compared to Africa with an average of 12.1% reported from Asia and 4.4% of the mothers undergoing IOL in Africa (range of 1.4% to 6.8%) yet the success is good in both settings (over 80%) (17). In Uganda an interventional study which did not look at the predictors for success of IOL at Mulago National Referral Hospital (MNRH) showed that catheter induction among mothers admitted at term with indication for induction of labour was safe and effective and resulted in 70% vaginal delivery within 24 hours (16).

Studies have shown that IOL is associated with increased chances of vaginal delivery and a reduced rate of caesarean section (C/S), operative vaginal delivery and duration of hospital stay (10). WHO (2018) recommended IOL to be done for pregnancies that have continued beyond term and for other indications of IOL to reduce perinatal morbidity and mortality (1). In Kawempe National Referral Hospital (KNRH), different pharmacological and mechanical methods are used for IOL. Much as induction of labor is a daily practice at Kawempe National Referral Hospital, there is a limitation in undertaking a study on prevalence, and predictors of vaginal delivery following induction of labour using a variety of methods for Induction of labour. By determining the prevalence and identifying the predictors of success of IOL through this study was important for generation of appropriate recommendations for selection criteria for patients who can benefit from IOL so that more utilization of IOL is done.

1.3 Justification/ Rationale

In contrast to published data on IOL from a study in Italy which showed that 42% of mothers underwent IOL and 78% delivered vaginally (18), Vogel and colleague in their study showed that less than 5% of Mothers in Africa underwent IOL to deliver their babies yet the success was reported to be over 3 out of 4 (17) . The knowledge on prevalence and predictors of IOL would be used to modify the protocol and standardize care provided by health practitioners at KNRH. The findings from this study would also be used as basis for technocrats at ministry of health to provide guidance on the process of IOL as well as standardization of care as well as be utilized by other researchers who may want to carry out more studies on IOL.

1.4 Research questions

1. What is the prevalence of vaginal delivery following induction of labour at Kawempe National Referral Hospital?
2. What are the predictors of vaginal delivery following induction of labour at Kawempe National Referral Hospital?

1.5 Objectives of the study

1.5.1 General Objectives

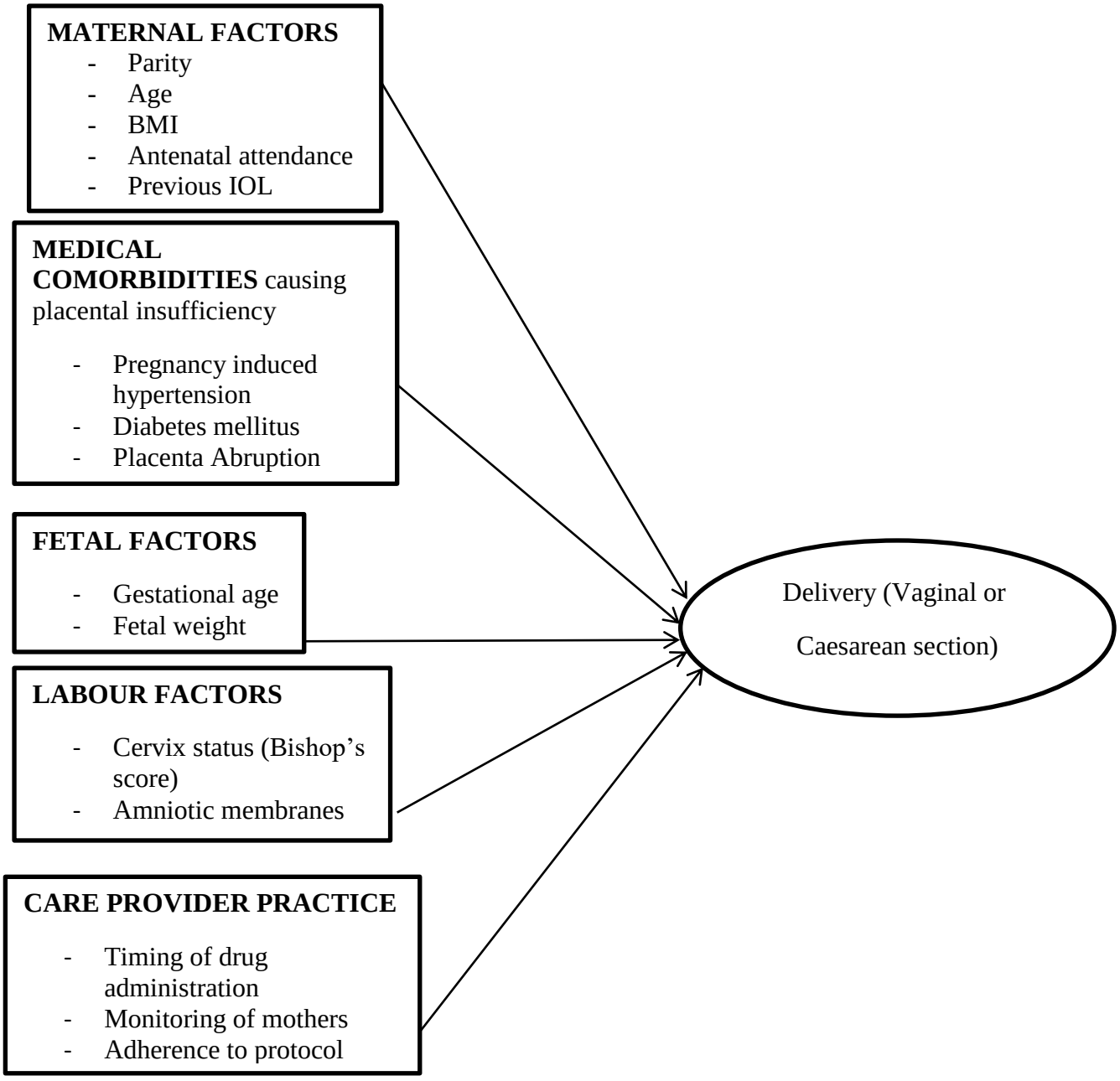
To determine the prevalence and predictors of vaginal delivery following induction of labour at Kawempe National Referral Hospital.

1.5.2 Specific objectives

1. To determine the prevalence of vaginal delivery following induction of labour at Kawempe National Referral Hospital.
2. To determine the predictors of vaginal delivery following induction of labour at Kawempe National Referral Hospital.

1.6 Conceptual frame work

Independent variables **Dependent variable**



Explanation of the conceptual framework

The above conceptual framework postulates that maternal factors, fetal factors, medical comorbidities, labour factors and care provider practice could influence the success of vaginal delivery following IOL.

Adopted from: A study to assess the clinical predictive factors for success and failure of induction of labour (4).

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction and background of induction of labour

Induction of labor refers to technique of artificially stimulating uterine contractions to accomplish delivery prior to the onset of spontaneous labour. It may be performed by administering oxytocin, prostaglandins or any other uterotonic agents to a pregnant woman or by manually rupturing the amniotic membranes, or using Foley catheter for induction that will eventually initiate uterine contractions (1). Over the past several decades, the incidence of induction of labour to shorten the duration of pregnancy has continued to rise. In high income countries, the proportion of infants delivered at term following induction of labour is as high as 25% of births while in low- and middle-income countries, the rates are generally lower (1, 19)

Whereas an RCT in 19 tertiary-care centres in three countries showed that IOL when indicated and done the correct way improved the likelihood of spontaneous vaginal delivery and significantly reduced morbidity associated with expectant management (20), a population based retrospective cohort study from perinatal registry in Austria showed an increased rate of adverse maternal and neonatal outcomes following IOL (21)

2.1.1 Historical background

The history of IOL started way back in Hippocrates' original description of mammary stimulation and mechanical dilation of cervical canal (22). Historically, induction was only done in case of a life-threatening maternal disease but with introduction of safer and improved methods, the incidences of IOL have increased (23). The commonly used method then was Artificial rupture of membranes (amniotomy) popularly known as the 'English Method'(24). Early amniotomy when the cervix is favourable was regarded as a safe and efficacious method in nulliparous labour inductions. In cases of unfavourable cervices, other mechanical methods were used for example use of uterine Bougies, De Ribes' bag, forced rapid dilation of the cervix and oral castor oil which would cause severe diarrhea and hence use was abandoned in the early 20^{th} century (25).

In 1906, Sir Henry Dale gave extracts of the posterior pituitary gland to William Blair Bell, an obstetrician who first used it for IOL and found out that it caused uterine contractions. The initial preparations of the extracts were crude with variable potency and purity and administration of large doses, through intramuscular or subcutaneous routes, were associated with fatal adverse outcomes as it led to uterine hyper-stimulation(26, 27). In 1953, oxytocin,

a synthetic octapeptide responsible for uterine contraction and milk ejection from the posterior pituitary was first produced (28). In the 1970s, prostaglandin (PG) was introduced and their use in clinical practice changed obstetric practices because they induced cervical ripening along with starting uterine activity which mimicked the natural labour process. Several types of Prostaglandins are used for IOL including PGE1, PGE2 and PGF2a. Published data from a Cochrane review at the university of Liverpool (UK) shows that IOL with PGs increase the incidence of uterine hyper-stimulation with fetal heart rate (FHR) changes, but there may be no effect on caesarean section rates, or may reduce them by up to 10% (29).

2.2 Prevalence of success of induction of labour

A multicenter study in Latin America showed that 11.4% of deliveries followed IOL with Peru reporting 5.1% of deliveries while Cuba reported 20.1% and an overall success rate of 70.4% (30). WHO Global Survey on Maternal and Neonatal Health however analyzed Patterns and Outcomes of IOL across continents in 16 countries and reported lower rates of induction being performed in Africa of 4.4% and relatively higher rates of 12.1% of deliveries reported from Asia with even a higher success rate of over 80%. (17) From these two studies we can therefore conclude that African countries are performing fewer IOL compared to the statistics reported from Latin America.

Induction of labor using oxytocin is a routine procedure in obstetrics which is done to hasten the process of vaginal delivery when indicated. A study in Ethiopia in 2015 showed a total number of vaginal deliveries reported to be 78.6% among all the mothers induced. Multiparity and favourable Bishop's score were found to be predictors of successful vaginal delivery hence cervical ripening prior to commencing induction to improve Bishop's Score was recommended for primigravida (17).

An study done at Kenyatta International University a low resource country almost at the same level with Uganda to compare the effectiveness of low dose oral misoprostol and intravenous Oxytocin for IOL in pre-labour rupture of membranes with no contraindication to vagina delivery showed that Oral misoprostol at low doses is as safe and effective as intravenous oxytocin with an average success rate of 82% and a difference of 2% between the two methods. Both methods had similar maternal and neonatal outcomes (31). Two years later, another study in Kenyatta national Hospital, Kenya showed a 62% success of vaginal delivery but the majority of women took more than 24 hours to deliver after IOL (7).

In Uganda, an interventional study in MNRH done on 132 mothers at term with indication for IOL showed a 70% success of vaginal delivery following Catheter induction within 24 hours (16).

2.3 Indications for induction of labour and success rates

Delivery before the onset of labor is indicated when the maternal/fetal risks associated with continuing the pregnancy outweighs the risks associated with delivery (32). The decision to risk continuing the pregnancy over delivery is influenced primarily by the gestational age and severity of the maternal/fetal condition. Two interventions to effect delivery before onset of spontaneous labor are induction of labor and cesarean delivery of which Induction is generally preferred when there are no contraindications to vaginal birth, because of the increased maternal risks associated with cesarean delivery (33). The following are among the other many indications for IOL: Post-term pregnancy, pre-labour rupture of membranes, hypertensive disorders in pregnancy, intrauterine fetal demise or death (IUFD), Gestational diabetes, abruption placenta (33).

Post-term pregnancy: Induction of labour at or beyond term is associated with better perinatal outcomes as compare to expectant pregnancy management as fewer perinatal deaths, caesarean section deliver, NICU admissions were reported following vaginal deliveries among mothers who were induced (34).

Pre-labour (premature) rupture of membranes (PROM): Induction of labour in premature or pre-labour rupture of membranes reduces induction to delivery time with increased rates of vaginal delivery within 24 hours in up to 80% of induced mothers but with a significantly reduced rates of cesarean section (19). Findings by Mbaluka and colleagues in Kenyatta International University showed similarly good outcome with an average of 82% of mothers who had PROM delivering following IOL with either oxytocin or misoprostol (31).

Hypertensive disorders in pregnancy such as Preeclampsia, eclampsia; gestational hypertension; chronic hypertension in pregnancy: Vijgen and associates analyzed the economic impact of expectant management compared to induction of labour in women with gestational hypertension or pre-eclampsia and found out that it is less costly to induce labour than to carry out expectant management because antepartum management of a mother with gestational hypertension or preeclampsia involves utilization of more resources than the cost of care in the post-partum period and yet delivery of a mother following induction of labour could also prevent cesarean section delivery as well as preventing progression of the disease

to severe forms. Basing on clinical and economic consequences of management of mothers with pre-eclampsia, induction of labour is clearly indicated among these patients (35). In addition to the above clinical and economic advantages of urgent delivery of mothers with pre-eclampsia or gestational hypertension which favours induction of labour because of the fewer risks involved as compared to cesarean or operative delivery, recent studies have shown that outcomes of induction of labour in women with hypertensive disorders is as good as that in women without hypertensive disorder using vaginally inserted prostaglandins (36). A study conducted at the university of Cincinnati, showed 71.3% of vaginal delivery following induction of labour among women with Pre-eclampsia irrespective of the Gestational age (37).

IUFD: Best mode of delivery among women with intrauterine fetal demise without any contraindication to vaginal delivery remains vaginal delivery. For women with IUFD who did not achieve spontaneous onset of labour, induction of labour is done to shorten the latency period and a population-based, multicenter case series done by the Stillbirth Collaborative Research Network on 611 women with singleton stillbirths at 20 weeks of gestation or greater resulted in up to 98.5% successful vaginal delivery in women without prior cesarean section delivery (38). In MNRH, Uganda, a study comparing vaginal misoprostol and intravenous oxytocin for induction of labour in women with IUFD found out that 100% of mothers induced with misoprostol delivered within 48 hours and 96.7% of those who used oxytocin also delivered vaginally in 48 hours (39).

Maternal diabetes*:* published data from a single university-affiliated medical center in Israel on all women carrying single tone pregnancies with well-controlled GDM for non-GDM indication for IOL at term demonstrated safety of induction of labour with good maternal and neonatal outcomes(40). Much as vaginal delivery is sometimes contraindicated in Diabetic mothers because of fetal Macrosomia or large-for-date fetuses basing on the increased risk of complications such as shoulder dystocia, birth fractures and other neonatal and maternal morbidity associated with macrosomia, an RCT in 19 tertiary-care centres in France, Switzerland, and Belgium shows that elective induction of labour at 37 to 38 weeks and 6 days of gestation significantly increased the chances of vaginal delivery and it greatly reduced maternal and neonatal morbidity yet it was not associated with increased risk of C/S delivery when compared with expectant management (20).

Abruptio placentae: A 20-year single-center experience at Kyoto university in Japan documented the safety and feasibility of vaginal delivery after placental abruption with intrauterine fetal death, which is not affected by gestational age, parity, cervical maturity, and duration of labor in the presence of intensive medical resources (41).

2.4 Contraindications to induction of labour

Induction of labour is contraindicated when there are maternal and fetal risks associated with labour and vaginal delivery. These contraindications include 2 or more prior cesarean delivery, Prior uterine rupture, Prior myomectomy, Placenta praevia or vasa praevia, Umbilical cord and Transverse fetal lie, active genital herpes infection invasive cervical cancer that call for caesarean delivery (33).

2.5 Methods of induction of labour

There are different methods for IOL which can be done using pharmacological agents such as misoprostol, dinoprostone , oxytocin, or mechanical interventions such as membrane sweeping, amniotomy, balloon catheter or Foley catheter, hygroscopic dilators, saline injection, nipple stimulation, intercourse, acupuncture, castor oil and herbs (42). Either mechanical and/or pharmacological methods are used for induction of labour. A multicenter RCT comparing the effectiveness of cervical ripening using a mechanical method (Foley Catheter) or pharmacological method (Dinoprostone) among women with unfavourable cervices with prolonged pregnancy between 41 weeks 0 days to <42 weeks 0 days showed that both techniques are effective for achieving vaginal delivery (43). Resulted reported from Panelius and colleagues correlated with the above finding since it shows using either misoprostol or Foley catheter for IOL are both effective in Nulliparous women and safe to use as there were no differences in frequency of C/S and in neonatal outcomes in both groups (44).

2.5.1Pharmacological methods

Among the common pharmacological methods used for IOL in our setting include oxytocin and prostaglandins.

Oxytocin: It causes adequate uterine activity that leads to cervical dilatation and hence delivery. Oxytocin does not promote cervical ripening therefore it is not effective in patients with unfavourable cervices. A study to evaluate the effectiveness of Intravenous oxytocin alone for cervical ripening and induction of labour when compared with expectant

management showed that up to 91.6 % of women achieved vaginal delivery within 24 hours as compared to 46.2 % of women on expectant management (45).

Prostaglandins: Used in women with unfavorable cervices, it promotes cervical ripening while stimulating uterine contractility hence initiation of labour as a result of their uterotonic effect.

A systematic review and a met-analysis on use of prostaglandins in Labour induction showed that generally prostaglandins are effective for induction of labour at term when compared to other methods with increased rates of vaginal delivery within 24 hours of induction and fewer cases of caesarean births reported but there was a higher risk of uterine hyperstimulation with changes in the fetal heart rates. In this study however, there were no additional adverse maternal and perinatal outcomes (46) .

Nakintu et al in a study comparing vaginal misoprostol and intravenous oxytocin for induction of labour in women with IUFD in Mulago Hospital in Uganda found out that 100% of mothers induced with misoprostol delivered within 48 hours and 96.7% of those who used oxytocin also delivered vaginally in 48 hours (39).

2.5.2 Mechanical methods

Mechanical method of IOL which includes use of Foley balloon catheter, amniotomy and membrane sweeping is one of the oldest methods used which promotes cervical ripening and hence onset of labour by stretching the cervix. Mechanical stimulation of endocervical canal has been shown to trigger release of prostaglandins which will eventually result into uterine contractions and therefore labour (47).

Foley Balloon Catheter: Originally designed to empty the bladder, a Foley balloon catheter is a cheap method with good outcomes yet it showed lower maternal and fetal complications in women planning a vaginal birth after a prior cesarean section(48). Foley catheter is a safe method of induction for women and babies because it involves no use of medication and has been associated with fewer side effects yet it has shown higher incidence of vaginal delivery (49).Nalubega et al in 2012 demonstrated that a Foley catheter for IOL is safe and effective and led to up to 70% of vaginal delivery within 24 hours of IOL using a foley catheter (16).

Amniotomy or ARM: In women with favourable cervix, amniotomy is an option for inducing labor if the head is well opposed to the cervix. It is a simple, safe and an effective method of IOL which acts through local synthesis and release of prostaglandins leading to

labour. A retrospective descriptive study carried out on 3,586 women who delivered in a National Maternity Hospital induced using Amniotomy shows that 80.5% progressed and had spontaneous vaginal delivery (50).

2.6 Predictors of success of IOL

The chance of a successful induction depends on both cervical and non-cervical factors.

Cervical status: The status of the Cervical before administration of an induction agent greatly impacts on the duration of induction and the likelihood of vaginal delivery. Women with unfavourable cervixes at the time of induction and who may seem to have a high chance of caesarean section at the time of induction may not necessarily have a lower chance of operative delivery if they underwent expectant management. Despite the limitations of Bishop Score, it still appears to be the best available tool for assessing cervical status. Systematic reviews and a met-analysis have shown that the Bishop's score is more predictive of vaginal delivery compared to the transvaginal sonographically measured cervical length which gave a moderate predictive capacity (3).

Non cervical factors: Predictors of vaginal delivery following IOL include women with term gestation, ruptured membranes, lower BMI, taller in height, less than 35 years, multiparity, estimated fetal weight <3500g and comorbidities associated with placental insufficiency (eg, preeclampsia (4).

Critical analysis at Memorial University of Newfoundland, Canada suggested that parous, young women who are taller with lower weight and fetuses with a lower birth weight or increased gestational age are associated with increased induction success. The cervical status at the start of IOL assessed using the modified Bishop scoring system was also shown to be an important predictor. Bishop score predicted likelihood ratio of successful IOL to be (LR) 2.10, 95%CI=1.67-2.64 (11).

A study in Brazil to assess pre-induction maternal and ultrasonographic factors in the prediction of vaginal delivery showed 56.9% of vaginal delivery irrespective of the induction-to-delivery interval with predictive factors of success being height, BMI, parity, number of prenatal visits of the women, and high Bishop's score basing on cervical consistency, effacement and dilation. Fetal factors such as head circumference and Estimated Fetal weight (5). A comparative study in Serbia to evaluate clinical and sonographic parameters in prediction of the success of labor induction shows 84.4% success with

Bishop's score, cervical length, parity and BMI being predictors of success which were among a few of the many predictive factors that Prado et al found out three years later in their study (12).

According to a recently published data from south Korea, younger maternal age, lower term body mass index and fetal engagement were important predictors for vaginal delivery in an induced labour (6). This study concurred with findings by Marciniak and colleagues in Poland which showed that multiparity, maternal age <30 years, high Bishop's score and birth weight <3.5kg were among the predictors of vaginal delivery following use of foley catheter for cervical ripening and IOL (13).

A recent single centre study in nulliparous women at Washington Hospital centre, Columbia showed similar findings with previous study done in Nigeria in2014 by Lawani and associates. Kawakita et al found out that 77.4% of mothers delivered vaginally after IOL verses 75.9% reported by Lawani et al. Maternal age, gestational age at delivery, maternal height, pre-pregnancy weight, gestational weight gain, cervical exam on admission (dilation, effacement, and station), chronic hypertension, gestational diabetes, pre-gestational diabetes, and Placental abruption were among the predictors of vaginal delivery (14), (15)

A study in Kenyatta National Hospital, Nairobi, Kenya which is a neighbouring country to Uganda showed a 62% success of IOL and the outcome of induction of labor was influenced by age, type of employment, parity and information on the nature of the procedure (7)

Cervical status, mainly measured by the Bishop score and parity, has been shown to be the main predictor of successful labor induction. Other predictors such as maternal age, weight, height, body mass index, ethnicity and socioeconomic status have been reported.
Obstetric and medical history such as gestational age at delivery, birth weight and amniotic fluid index have also been described

CHAPTER 3: METHODS

3.1 Study Design

This was a was a cross-sectional study

3.2 Study setting

This was a facility based study in the labour ward and postnatal ward at Kawempe National Referral Hospital (KNRH), a public Health Facility, located in Kawempe division which is about 5km north of the central district of Kampala City. The Hospital provides maternal and child care services to patients from Kampala and neighbouring districts to Kampala as well as referrals from across the country (Hospital registry 2018). The Hospital has several units such as labour ward, maternal fetal unit, post-natal ward, Gynecology emergency ward, General gynecology ward, outpatient clinics, paediatric ward, and special care unit. It offers other services such as radiological, laboratory and theatre (Surgical) services. The hospital also doubles as a teaching hospital for students of Makerere University, College of health sciences and other teaching institutions around Kampala. On average, there were about 50-80 deliveries per day in labour ward and theatre and about 4-8 of these deliveries followed IOL.

If the mother was found to have any indication for IOL, she was admitted to one of the two high risk cubicles in the labour ward where the prescribed induction drug was administered and they were monitored from there by ward midwives. Upon delivery, questionnaires were administered by research assistants or PI to the mothers in the labour ward or post-natal ward. This study was conducted at KNRH because Kawempe is one of the hospitals were the training of Obstetrics and Gynaecology is conducted and being a National Referral, it serves a wide catchment area with the advantage of having a high patient turnover hence generalizability of the study to the population is possible.

3.3 Population

3.3.1 Target population

Pregnant women with a gestation of ≥ 28 completed WOA who delivered in health facilities in Kampala following IOL

3.3.2 Accessible population

Pregnant women with a gestation of ≥ 28 completed WOA who delivered during the study period following IOL who were in the labour ward and postnatal ward at KNRH.

3.3.3 Study population

Pregnant women with a gestational age of ≥ 28 completed WOA who delivered following IOL during the study period who were in the labour ward and postnatal ward at KNRH who met the eligibility criteria.

3.3.4 Study unit

Pregnant women with a gestation of ≥ 28 completed WOA who delivered following IOL at ≥ 28 WOA who met eligibility criteria and had consented.

3.4 Eligibility criteria

3.4.1 Inclusion criteria

- Pregnant women with a gestation of ≥28 weeks with singleton pregnancy in cephalic presentation who delivered following IOL at KNRH
- Mothers who consented to the study.
- Emancipated minors were included in the study and were allowed to consent as adults.

3.4.2 Exclusion criteria

We did not exclude any pregnant women with gestational age of 28 weeks of amenorrhea or more who delivered following induction of labour at Kawempe national referral Hospital during the study period as long as they met the eligibility criteria and consented

3.5 Study variables

Outcome variable: Mode of delivery either vaginal delivery or Caesarean section.

Predictor variables included:

a) Maternal factors such as Parity, Age, BMI, Antenatal attendance and Previous IOL
a) Medical comorbidities causing placental insufficiency namely Pregnancy induced hypertension, Diabetes mellitus, Placenta Abruption
b) Fetal factors like gestational age and fetal weight
c) Labour factors such as cervix status (Bishop's score) and amniotic membranes
d) Care provider practice like timing of drug administration, monitoring of mothers, adherence to protocol

3.6 Sample size estimation

The sample size estimation for the first objective which was to determine the prevalence of vaginal delivery following IOL in the labour ward at KNRH was calculated using the formula by Kish Leslie (1965). $N = \frac{Z^2 p(1-p)}{d^2}$

Where:

N was the required sample size

Z was the Z value corresponding to the 95% confidence interval for a two sided test (1.96)

p was the proportion of successful outcome following catheter induction. And using 70.46% from study in MNRH by Nalubega et al in 2012

d was the tolerable sampling error (0.05).

Using the formula we got a sample size (n) of 323 participants for the study.

For the second objective which was to determine the predictors of vaginal delivery following IOL in the Labour ward at KNRH, the sample size was estimated using Fleiss Formula.

$$N = \frac{[Z_{\alpha/2}\sqrt{p(1-p)(1/q_1 + 1/q_2)} + Z_{\beta}\sqrt{p_1(1-p_1)\,1/q_1 + p_2(1-p_2)\,1/q_2}]^2}{(p_1 - p_2)^2}$$

N = minimum required sample size, participants.

q1 = proportion of pregnant women aged below 24 years who had induced labor, **0.412 (9).**

q2 = proportion of pregnant women aged 24years and above who had induced labor, **0.588 (9).**

p1 = assumed proportion of pregnant women below 24 years who had induced labor and had vaginal delivery, **0.5**.

p2 = assumed proportion of pregnant women 24 years and above who had induced labor and had vaginal delivery, **0.25**.

p = **p1q1+p2q2, 0.312**

Note: (p1-p2) was assumed to be **0.25**, because no literature had reported these proportions in Uganda and in sub-Saharan region.

Therefore, N = 120 participants

Thus the bigger sample size of 323 participants was considered to cater for both objectives.

3.7 Sampling method.

It was consecutive sampling. All mothers who met the eligibility criteria were recruited to the study upon consent until the sample size was achieved.

3.8 Study procedure

All women who delivered following induction of labour at 28 weeks of amenorrhea or more in the Labour ward and post natal ward at Kawempe National Referral Hospital. The research team identified these mothers through inquiry from the midwives and by checking on their files. Each potential participant went through the informed consent process guided by the PI or a research assistant. Upon consent, questionnaires were administered to eligible participants by the PI or any of the research assistants which captured the baseline information and the rest of the data as captured on the questionnaire.

Protocol for labour induction was considered to be adhered to if indication for induction of labour was one of these below as in Mulago NRH guideline: Prelabour rupture of membranes, prolonged pregnancy at greater than 41 weeks gestation, IUFD**,** history of precipitate labour previously or maternal medical indications like pre-eclampsia. Patients who met there pre-requisites for induction of labour at Mulago: Appropriate indication as above, clinical information about gestational age (from history, serial symphisis-fundal height examinations or from ultrasound scan, and Knowledge of fetal presentation were considered adherence to protocol. Use of the following methods of induction of labour: prostaglandins, amniotomy, oxytocin as well as mechanical method like catheter induction as in Mulago NRH guideline also was considered adherence to protocol: If induction was started early in the morning or day but not started at night and also monitoring documented on the file by the doctor or midwife at least 2 times then it was considered adherence to protocol.

3.9 Data collection

This was done by the two trained research assistants together with the PI. For each of the eligible participants, data on socio-demographic characteristics, past obstetric history, preexisting medical condition, any medication that the participant was taking at the time of induction of labour and observation of labour progress until delivery as well as the birth weight was collected using a structured pretested interviewer administered questionnaire.

3.10 Data management

The PI directly supervised the data collection process. Completed questionnaires were cross-checked for completeness and coded on daily basis upon completion and kept safely. The information was entered into Epidata software version 7 and checked for correctness and completeness to eliminate errors. The entered data were cleaned and exported to STATA software version 14.0 for analysis by the principal investigator and the statistician. Access to the data was limited using password and the researcher's computer being accessible by the bio-statistician and the principle investigator only. All the data collection tools were securely kept by the PI.

3.11 Data analysis

The PI entered data in epidata version 7 which was exported to STATA version 14.0, statistical software for cleaning and analysis by the PI assisted by the statistician during the analysis. Presentation of data was done using pie charts and tables. Categorical data were summarized using frequency tables while continuous variables were summarized using mean, and standard deviations. A Chi-square test was used in testing association of categorical variables while continuous data were compared with unpaired student's t-test for those normally distributed and using the Mann Whitney U test for the non-normally distributed data. The prevalence of vaginal delivery following IOL at KNRH was determined by the number of women induced who delivered vaginally following induction of labour divided by the total number of women who had IOL in the study. Predictors of vaginal delivery following induction of labour were determined using modified Poisson regression in bivariate analysis to crudely measure the strength of association between the different predictors of vaginal delivery followed by adjustment in multivariate logistic regression. All independent variables with a p-value less than 0.2 at bivariate analysis were considered for multivariate conditional logistical regression and a p-value less than 0.05 were considered to be statistically significant at multivariate regression. We then assessed for possible interaction and confounding.

3.12 Quality control

Training was conducted by the principal investigator to research assistants and daily sessions were done to remind the team on the study procedure. The PI participated in the study directly as well as supervised the data collection process. The PI would meet with the research assistants daily to address any concerns. The questionnaire was pretested on five mothers who underwent IOL and appropriate adjustments were made on the data collection

tool. All completed questionnaires were checked for completeness and accuracy. Errors and gaps on collected data were corrected immediately and kept safely under lock and key by the PI. Entered data were regularly backed up to avoid loss of data.

3.13 Ethical Considerations.

Clearance by the Department of Obstetrics and Gynecology and Ethical approval was sought from School of Medicine Research and Ethics Committee (SOMREC) [REC REF 2020-028]. Permission to carry out this research at KNRH was obtained from the hospital research and ethics committee of KNRH. Written informed consent was obtained from mothers who delivered following IOL prior to enrollment into the study. The consent form was translated into Luganda, the commonly used native language in the catchment area of study. This was meant to provide all participants involved in the study a clear understanding of what was expected in this study so that they agreed to participate in the study willingly. Participants were encouraged to ask questions to ensure clarity of the study information. At the end of the information session, participants signed the informed consent form as proof of voluntary participation and also to acknowledge their understanding of the study information. For severely ill patients for example eclamptic patients with altered level of consciousness, we obtained proxy consent then a full consent was signed after stabilizing. Emancipated minors were allowed to consent and the ethics committee granted permission to study the minors. Participants had the freedom to voluntarily withdraw from the study at any time and their withdrawal did not jeopardize health care provided to them. We ensured confidentiality of any information collected from the participants by using anonymous codes and privacy was maximally maintained all through the study. This study carried minimal risks to the participants which did not influence routine health care service delivery. All participants were given this information before consenting them for the study.

3.14 Dissemination of data

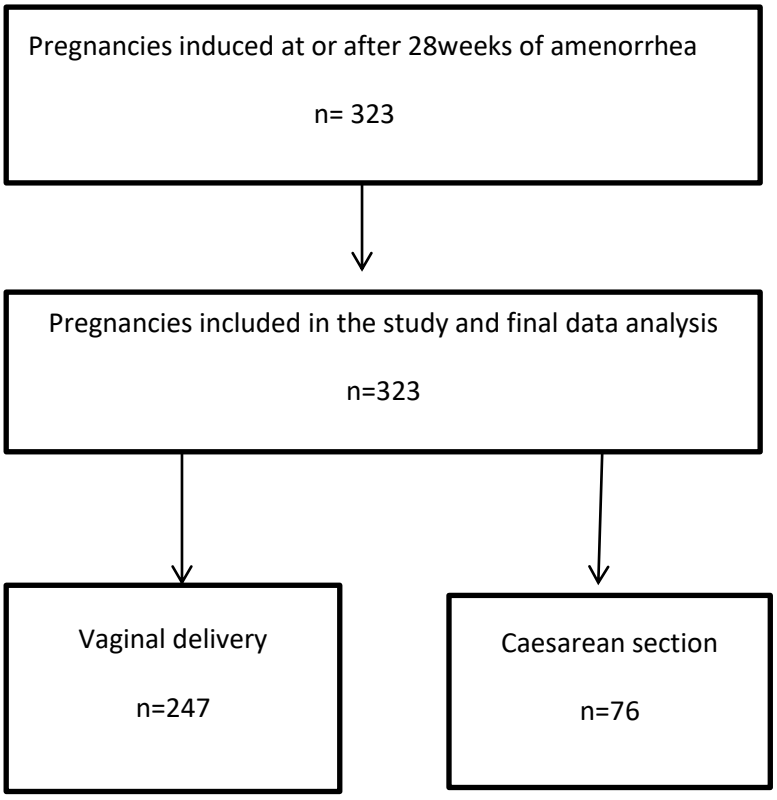
The results obtained from the study will be shared with Kawempe Hospital staff, Directorate of Obstetrics and Gynecology of Makerere University, the directorate of Graduate Studies, Sir Albert Cook library, Ministry of health, Uganda and the findings will be published in any recognized peer review journal.

CHAPTER FOUR: RESULTS

4.1 Social demographic characteristics

The study involved 323 women who met the eligibility criteria and were consecutively recruited into the study. A total of 323 women who had delivered following induction of labour for various indications in the labour ward and postnatal ward as the calculated sample size were enrolled in the study. All the women gave written informed consent and none of them withdrew from the study. Therefore all their data was analyzed. Data was collected from September to December 2020

STUDY PROFILE



The mean age of women in this study was 26 years with a standard deviation of 5.7. One third of the women had normal weight. Of the study participants, 287(88.9%) of the women were either married or cohabiting. Half of the women had attained secondary education although 186(57.6%) were unemployed (Housewife). This information is presented in table 1 below.

Table 1: Socio-demographic characteristics of 323 women who had delivered following induction of labour at Kawempe National Referral Hospital

Variables	frequency	Percentage
Age mean±SD 26±5.7		
BMI categories		
Underweight	10	3.1
Normal weight	97	30.0
Over weight	136	42.1
Obese	80	24.8
Marital status		
Married/ cohabiting	287	88.9
Single	36	11.1
Education status		
Not educated	24	7.4
Primary	85	26.3
Secondary	163	50.5
Tertiary	51	15.8
Occupation		
Unemployed (Housewife)	186	57.6
Self employed	101	31.3
Salaried/wage	36	11.1
Parity		
Prime para	128	39.6
Multi para	195	60.4

SD = Standard deviation

4.2 Prevalence of vaginal delivery following induction of labor

Figure 2 below shows that the prevalence of vaginal delivery following induction of labor was 76.5%.

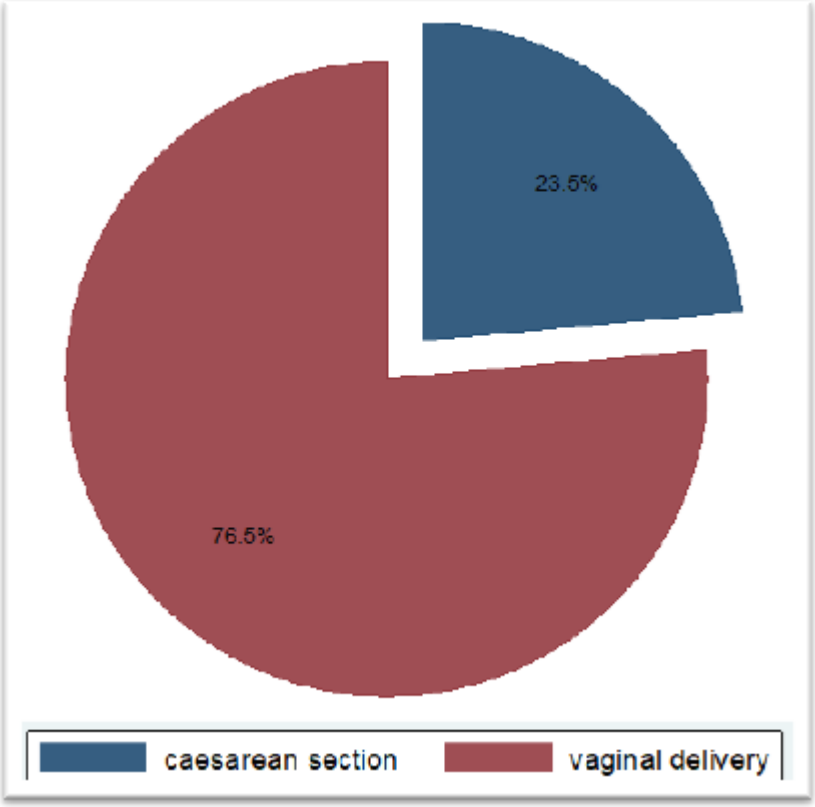


Figure 2: Prevalence of vaginal delivery following induction of labour among women who had induction of labour at Kawempe National referral hospital

4.3 Predictors of vaginal delivery following induction of labor

Predictors of vaginal delivery following induction of labour were determined using modified Poisson regression in bivariate analysis followed by multivariate analysis.

Only factors with p-values ≤ 0.2 at bivariate analysis, those that had biological plausibility and those that were found in literature search to be significantly associated with vaginal delivery following labor induction were taken to multivariate analysis.

4.3.1 Bivariate analysis results

As shown in tables 2 and 3 the factors that were significant (p-value ≤ 0.05) are below

The prevalence of vaginal delivery was 18% statistically significantly more among women who received intravenous oxytocin, for labor induction compared to those who received vaginal dinoprostone cPR - 1.18, 95%CI (1.023-1.364) and *p-0.023.*

The prevalence of vaginal delivery was 32% statistically significantly more among women in whom protocol for labor induction was adhered to compared to those in who it wasn't, cPR – 1.32, 95%CI (1.119-1.554) and *p-0.001*.

Furthermore, the prevalence of vaginal delivery following labor induction was 30% statistically significantly more among women with rupture of membrane as an indication for induction compared to those with pre-eclampsia, cPR – 1.30, 95%CI (1.162-1.456) and *p<0.001*.

Again the prevalence of vaginal delivery was 34% statistically significantly less among neonates with birth weight > 3.5 kg compared to those with birth weight between 2.5 -3.5 kg, aPR – 0.66, 95%CI (0.487-0.899) and *p-0.008*.

Table 2: Bivariate results for maternal predictors of vaginal delivery following induction of labor at Kawempe National Referral Hospital

Variables	Vaginal n(%)	C/section n(%)	cPR	95%CI	p-value
Overall	247(76.5)	76(23.5)			
Age, mean ± SD	26.2±5.5	27.0±6.2	0.99	0.984 -1.006	0.379
Marital status					
Married/ cohabiting	216(87.5)	71(93.4)	1		
Single	31(12.6)	5(6.6)	1.15	0.997-1.330	0.054
BMI categories					
Normal weight	77(31.2)	20(26.3)	1		
Over weight	105(42.5)	31(40.8)	0.97	0.848-1.115	0.690
Obese	57(23.1)	23(30.2)	0.9	0.755-1.067	0.219
Under weight	8(3.2)	2(2.6)	1.010	0.727-1.397	0.963
level of education					
Secondary	130(52.6)	33(43.4)	1		
Uneducated	16(6.5)	8(10.5)	0.81	0.595-1.095	0.169
Primary	66(26.7)	19(25.0)	0.98	0.857-1.127	0.805
Tertiary	35(14.2)	16(21.1)	0.87	0.717-1.064	0.179
Occupation					
Unemployed	142(57.5)	44(57.9)	1		
Self-employed	81(32.8)	20(26.3)	1.06	0.937-1.204	0.344
Salaried/wag	24(9.7)	12(15.8)	0.89	0.7004-1.127	0.328
Parity					
Prime para	91(36.8)	37(48.7)	1		
Multi para	156(63.2)	39(51.3)	1.23	0.987-1.283	0.078
Previous history of induction					
No	207(83.8)	65(85.5)	1		
Yes	40(16.2)	11(14.5)	1.03	0.879-1.208	0.710
number of antenatal visits					
4-9 visits	154(62.4)	54(71.1)	1		
1-3 visits	93(37.7)	22(28.9)	1.09	0.969-1.232	0.150

cPR – crude prevalence ratio

Table 3: Bivariate results for labour factors, labour care practice and fetal factors/ predictors of vaginal delivery following induction of labor at Kawempe National Referral Hospital

Variables	Vaginal n(%)	c/section n(%)	cPR	95%CI	p-value
Indication for induction of labor					
Pre-eclampsia	114(46.2)	41(54.0)	1		
Pupture of membrane	75(30.4)	25(32.9)	1.3	1.162-1.456	**<0.001**
IUFD	44(17.8)	2(2.6)	1.02	0.880-1.182	0.795
Post date	14(5.7)	8(10.5)	0.87	0.622-1.204	0.390
Method used for induction of labour					
Vaginal dinoprostone	88(35.6)	37(48.7)	1		
Intravenous oxytocin	84(34.0)	17(22.4)	1.18	1.023-1.364	**0.023**
Oral misoprostol	53(21.5)	14(18.4)	1.12	0.950-1.329	0.173
Vaginal misoprostol	16(6.5)	5(6.6)	1.08	0.8302-1.411	0.559
Catheter	6(2.4)	3(4.0)	0.95	0.588-1.525	0.823
Duration in labor after drug administration	1320.4±1225.4	1875.4±1442.0	1.00	0.999-1.000	0.618
Timely drug administration					
Yes	182(73.7)	52(68.4)	1		
No	65(26.3)	24(31.6)	0.94	0.813-1.084	0.391
Monitored labor					
Yes	244(98.8)	73(96.0)	1		
No	3(1.2)	3(4.0	0.65	0.291-1.451	0.293
Adherence to protocol					
No	62(25.1)	37(48.7)	1		
Yes	185(74.9)	39(51.3)	1.32	1.119-1.554	**0.001**
Gestation age at delivery	36.1±3.2	36.1±3.2	0.98	0.962-0.996	**0.013**
Birth weight					
2.5-3.5 kg	141(57.1)	37(48.7)	1		
>3.5 kg	21(8.5)	19(25.0)	0.66	0.487-0.899	**0.008**
<2.5 kg	85(34.4)	20(26.3)	1.02	0.907-1.152	0.722

4.3.2 Multivariate results

For multivariate analysis, variables with p-values< 0.2 in bivariate analysis were taken to multivariate logistic regression at 95% confidence interval. A p-value of ≤ 0.05 was considered statistically significant.

The prevalence of vaginal delivery was 19% statistically significantly more among women who received intravenous oxytocin for labor induction compared to those who received vaginal dinoprostone (aPR=1.19, 95%CI=1.033-1.362, *p=0.015).* Furthermore, the prevalence of vaginal delivery following labor induction was 26% statistically significantly more among women with rupture of membranes as indication for induction compared to those with pre-eclampsia, (aPR=1.26, 95% CI=1.116-1.416, *p=0.001).* Again, the prevalence of vaginal delivery was 32% statistically significantly more among women in whom protocol for labor induction was adhered to compared to those in who it wasn't, (aPR=1.32, 95%CI=1.132-1.551, *p=<0.001).* And the prevalence of vaginal delivery was 32% statistically significantly less among neonates with birth weight > 3.5 kg compared to those with birth weight between 2.5 kg -3.5 kg, (aPR=0.68, 95%CI= 0.506-0.913, *p= 0.010*.

No variable was found to interact or confound the relationship between model of delivery (as a dependent) variable and the independent (predictor) variables.

Table 4: Multivariate results for predictors of vaginal delivery following induction of labor at Kawempe National Referral Hospital

	multivariate results		
Variable	**aPR**	**95%CI**	**p-value**
Method used for induction of labor			
Vaginal dinoprostone	1		
intravenous oxytocin	1.19	1.033-1.362	**0.015**
oral misoprostol	1.03	0885-1.210	0.666
vaginal misoprostol	1.00	0.768-1.316	0.971
mechanized	0.95	0.575-1.567	0.839
Indication for induction of labor			
pre-eclampsia	1		
rupture of membrane	1.26	1.116-1.416	**<0.001**
IUFD	1.02	0.885-1.172	0.794
post date	0.91	0.668-1.234	0.537
protocol adherence			
no	1		
yes	1.32	1.132-1.551	**<0.001**
Birth weight			
2.5-3.5 kg	1		
> 3.5 kg	0.68	0.506-0.913	**0.010**
< 2.5 kg	1.00	0.879-0.716	0.945

CHAPTER FIVE: DISCUSSION

5.1 Prevalence of Induction of labour at Kawempe National Referral Hospital

This study aimed to determine the prevalence and predictors of vaginal delivery following induction of labour at Kawempe national referral hospital.

Prevalence Ratios (PR) were used as the measure of association instead of Odds Ratios (OR) because the outcome (Prevalence of Prevalence of vaginal delivery following induction of labour) was greater than 15% (it was 76.5%) hence not a rare occurrence. Using OR (logistic regression) would therefore overestimate (exaggerate) the association.

The prevalence of vaginal delivery following induction of labour at Kawempe National Referral Hospital was high at 76.5% (247/323) which was not very different from study by Nalubega et al 2012 who reported 70.46% successful delivery within 24hrs of catheter induction (16). Indeed a retrospective cohort study done between (2000–2015) on prevalence and risk factors for caesarean delivery following induction of labor reported a similarly high rates, 73.25% of vaginal delivery (51). Much as only 9% of women underwent induction of labour in Hospitals in Mekelle town in Northern Ethiopia, up to 76% of them reportedly had vaginal delivery, either spontaneously or assisted (52). Similarly, Lawani et al reported 75.9% vaginal delivery (53).

The possible explanation for the higher prevalence of vaginal delivery following induction of labour could be that the study setting was a national referral hospital covering a wider catchment area.

5.2 Predictors of vaginal delivery following induction of labour

Participants who had rupture of membranes as indication for induction of labour, induced using intravenous oxytocin, adhered to labour induction protocol and birth weight less than 3.5kg were more likely to deliver vaginally.

Use of intravenous oxytocin: From the study, dinoprostone was the most commonly used method of induction of labour. This is because during the study period, there was a supply of dinoprostone tablets donated by pharmaceutical company which was kept in the cubicle for women with pre-ecampsia with severe features found in labour suite and patients could have access to them free of charge. In this study however, women induced using intravenous oxytocin were 1.2 times more likely to deliver vaginally. Similarly Mbaluka et al in an RCT at Kenyatta Hospital showed oxytocin to be safe and effective in women who had prelabour rupture of membranes just like oral misoprostol (54). This finding was however not in line

with the study by Nakintu in Mulago NRH where intravenous oxytocin was less effective and more expensive though this study was done in patients with intrauterine fetal death (39). The finding in our study could have been because 1 in every 3 women in this study had prelabour rupture of membranes as indication for induction of labour which could have responded well to induction using intravenous oxytocin.

Indication for induction of labour: Forty eight percent of the women induced had pregnancy induced hypertension as indication for induction of labour which is in agreement with a study by Nakimuli et al which showed pre-eclampsia is more prevalent in indigenous African women as well as women of African ancestry (55) compared to other indications for induction of labour with IUFD contributing 13.0%, rupture of membranes (31%), postdates 6.8% and other indication for induction of labour contributed 1.2%. This is similar to findings by Ekele et al in Sokoto where hypertensive diseases of pregnancy and postdates were both reported as the commonest indication for induction of labour (56). Of those induced however, vaginal delivery was more among women with rupture of membranes which showed 1.26 times more likeliness to deliver vaginally compared to women who were induced due to pregnancy induced hypertension. Mbaluka et al in a randomized clinical trial at Kenyatta National Hospital showed overall success rates of induction of labour to be 81% and 83% using oral misoprostol and intravenous oxytocin respectively in women who had induction of labour due to pre-labour rupture of membranes at term (57). Furthermore 100% vaginal delivery was achieved within 24 hours with artificial rupture of membranes plus oxytocin infusion in nulliparous women with favorable cervix at term compared to 68% vaginal delivery among women who used sublingual misoprostol for induction of labour though misoprostol was well accepted by women (58). Rupture of membranes as a method of induction of labour has been shown to trigger local synthesis and release of prostaglandins leading to labor within 6 hours in nearly 90% of term patients. Turnbull and Anderson found amniotomy without additional drug therapy to successfully induce labor in about 75% of cases within 24 hours (59). This could explain why induction of labour with pharmacological agents in women who had spontaneous rupture of membranes resulted into 26% more likeliness of vaginal delivery.

Adherence to protocol: From the study, those who adhered to protocol were 1.32 times more likely to deliver vaginally compared to those who did not adhere to the protocol. This is in agreement with findings by Rhinehart-Ventura and colleagues in retrospective chart

review which showed that adherence to protocol was associated with increased rates of vaginal delivery (nulliparous women, 90.2.8%; $P = .043$; multiparous women, 94%; $P < .0004$) (60). In addition, induction of labour showed a 2-hour decrease in time to delivery among all women on induction of labour and a 4-hour decrease in time to vaginal delivery among women undergoing elective induction of labour (61). Furthermore, inadequate adherence to recommendations of induction of labour led to increased rates of cesarean section performed in 37% of the women subjected to induction (62) . This is because protocol is evidence based and is therefore able to standardize care.

Birth weight: The study found the rates of vaginal delivery following induction of labour to be 32% less among neonates that weighed 3.5 kg and above which is not any different from a study by Tarimo et al in Northern Tanzania where birth weight ≥3.5 kg was associated with 24% increased risk of Caesarean section compared to normal birth weight (2.5–3.5 Kg) following induction of labour (51)

5.3 Limitations

- Study involved retrospective use of existing data so most patients did not have Bishop's score documented yet it is an important predictor variable
- Monitoring of patients in active phase of labour was not done on the partograph
- Much as majority (76.5%) of the mothers delivered vaginally, the study did not look at women who could have had assisted vaginal delivery among those who delivered vaginally
- Vaginal delivery included both spontaneous and assisted vaginal deliveries as some women could have had assisted vaginal deliveries but this data was not captured on the questionnaire

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS:

6.1 Conclusion

1. There was a high prevalence of vaginal delivery following induction of labour in Kawempe National Referral Hospital
2. The positive predictors of vaginal delivery following induction of labour were monitoring of labour as per protocol, use of intravenous oxytocin for induction of labour, and rupture of membranes while birth weight of the neonates more than 3.5 kg was a negative predictor

6.2 Recommendation

1. Clinicians should be encouraged to induce women with indication for induction of labour
2. Hospitals should ensure proper monitoring of mothers is done with an induction of labour monitoring tool to improve success of induction
3. A study should be done to determine whether delivery is spontaneous or assisted following induction of labour

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APPENDICES

APPENDIX I: HOW TO DETERMINE THE STATUS OF THE CERVIX USING BISHOP'S SCORE

The Bishop scoring system is based on a digital examination of the cervical of a patient with a minimum score of zero point and a maximum of 13 points. The parameters used in the scoring include cervical dilation, position, effacement, consistency of the cervix, and fetal station.

Bishop scoring system:

Score	Dilation (cm)	Position of cervix	Effacement (%)	Station (-3 to +3)	Cervical Consistency
0	Closed	Posterior	0-30	-3	Firm
1	1-2	Mid position	40-50	-2	Medium
2	3-4	Anterior	60-70	-1, 0	Soft
3	5-6	--	80	+1, +2	--

In our study the Bishops score was obtained from the chart as assessed by the doctors following a digital cervical exam finding which scored from 0 to a maximum of 13 points using cervical dilation, position, effacement, cervical consistency, and fetal station as the parameters assessed. Cervical dilation, effacement, and station are scored 0 to 3 points, while cervical position and consistency are scored 0 to 2 points. A Bishop score of 8 or greater is considered to be favorable for IOL and the chance of a vaginal delivery with induction is similar to spontaneous labor. A score <7 is considered unfavorable and if an induction is indicated there is need for cervical ripening.

APPENDIX II: CONSENT FORM

Research participation and consent form:

Research title: Prevalence and predictors of vaginal delivery following induction of labour in Kawempe National Referral Hospital, Kampala, Uganda

Principal Investigator

Name: Dr. Ajok Jennifer

Address: Makerere University College of Health Sciences, Department of Obstetrics and Gynaecology, Masters in Obstetrics and Gynaecology year two (2)

Cell phone number: +256-782 182862

Introduction/Background of the study

What you should know about this study:

You are being asked to join a research study.

The research is about the prevalence and predictors of vaginal delivery following induction of labour at Kawempe National Referral Hospital.

This consent form explains the research study and your part in the study.

Please read it carefully and take as much time as you need.

You are a volunteer. You can choose not to take part and if you join, you may leave at any time. There will be no penalty if you decide to opt out of the study.

Induction of labour

This is the process of stimulating the uterus to contract and hence to start labour. WHO recommends induction of Labour for any mother who has reached 41 weeks of Amenorrhea to prevent the several maternal and neonatal complications associated with post-term deliveries. There are a number of other conditions that occur in pregnancy such as pre-eclampsia with severe features, pre-labour rupture of membranes, Gestational diabetes and many others that may necessitate induction of labour to be performed before spontaneous onset of labour. IOL can be done by using several methods such as inserting tablets in the

vagina, taking the tablets by mouth, giving injections through the veins (Blood vessel), breaking the waters or insertion of a rubber tube into the cervix through the vagina.

Funder of the study:

Principal investigator who is a masters' student in Obstetrics and Gynaecology of Makerere University.

The purpose of the study:

You have been chosen to participate in this study because you are one of the mothers with an indication for induction of labour who can be managed by any of the methods used for IOL. This study is experimental and will intend to find out how many mothers of those who undergo induction of labour will progress and have vaginal delivery and what factors led to them to achieve vaginal delivery.

Duration of time the participant will take in the study:

The study will start when labour is induced and end when the mother has delivered.

Study procedures:

After accepting to be a participant in this study, you will be required to sign the form. You will be asked a couple of relevant questions by one member of the study team related to your particulars, medical history, past and present pregnancy details. Prescribed drugs or other methods will be administered by the doctor or midwife on ward and then you will be monitored until delivery as per the standard guideline on management of labour and all the findings will be recorded in your file.

Participants in the study:

A total of 323 (three hundred and twenty three) mothers on induction of labour will be involved in the study.

Risks / discomfort to the patient:

There will be labour pains because of uterine contractions. The questionnaire will take a short time about 15 to 30 minutes. You will have inconvenience of periodic checks by the team on ward after every 30 minutes to listen to the heartbeat of the baby and your heart beat, every two hours to check your blood pressure and the decent of the baby and every 4 hourly, the

vaginal examination will be done to find out how the cervix is opening. All these parameters checked will help to guide the team taking care of you on how your labour is progressing and then all the findings shall be documented in your file.

Benefits to the patient:

The study may help to reduce on the duration of time you will spend in the hospital awaiting delivery. The information that we will obtain from the study will help to improve on the process of initiation of labour when medically indicated and will also help in patient selection for induction of labour.

Protecting privacy during data collection.

The interview will be conducted in a separate enclosed space free from interference. Your name will not be indicated in the questionnaire

Protecting data/ confidentiality.

The information collected about you shall be kept confidential in a controlled place. The filled questionnaire will be kept in a lockable cabinet accessible to only members of the study team and no information about you shall be disclosed to outsiders. The Research Ethics committee however may have access to private information that will identify the participants by names.

Incentives/rewards for participation.

Your participation is on voluntary basis, there will be no monetary rewards. You will receive a bar of washing soap as appreciation for participating in the study.

In case of injuries during the study, like perineal tears sustained during vaginal delivery, the principal investigator will take care of repairing the perineum.

Reimbursement:

Participants will be enrolled when they have come to hospital with indication of induction of labour. Their transport costs and meals will not be catered for. The study does not involve follow up so upon delivery the study will end.

Questions about the study:

For any questions about the study, please call the principal investigator

Dr Ajok Jennifer

Phone number: +256-782 182 862.

Participants with questions about their rights:

Call the Chairman of Makerere University, College of Health Sciences, School of Medicine Research and Ethics Committee (SOMREC), on +256 772 421 190

Right to refuse/withdraw.

This is completely a voluntary study where you have to right to leave or withdraw from the study at any time without any penalty. If you leave the study, you will be given all the health care services that are routinely given to mothers in your category. There will be no penalty if you decide to leave the study at any one time.

Dissemination of results:

You will be given a feedback on findings from the study and you will be informed of any incidental findings concerning your health discovered during the study. This will be done through a phone call incase patient has already left the facility.

Consent/ Assent

……. has described to me about this study purposes, procedures, possible benefits and risks involved including my rights regarding the study. I have understood that my decision to participate will not alter my usual medical care. My identity will be concealed. I am aware that I may withdraw at any time. I understand that by signing this form, I do not waive off any of my rights but merely indicate i have been informed about the study which i am voluntarily agreeing to participate. A copy of this form will be provided to me.

_____	_____	_____
Name of participant	Signature or thumbprint	Date

_____ _____ _____

Name of parent/guardian for minors signature/ thumb print Date

_____ _____ _____

Name of witness Signature Date

Research assistant: I have explained the purpose, procedure, risk and benefits of this study to the participant and i have answered all her questions.

_____ _____ _____

Name of person obtaining consent Signature Date

EKIWANDIIKO EKYOKUKKIRIZA

Okwetaba mu kunoonyereza n'ekiwandiiko eky'okukkiriza:

Omutwe gw'okunoonyereza: Bubonero obuleeta okuzaala obulungi oluvanyuma lw'okuwalirizibwa okufuna ebisa mu ddwaliro lye ggwanga ekkulu e Kawempe Omunoonyereza omukulu

Erinnya: Omusawo Ajok Jennifer

Wasaangibwa: Etendekero eryawaggulu kolegi ya Sayansi w'ebye obulamu ekitongole ekya ndwadde z'abakyaala n'eby'okuzaala (akuguka ali mu mwaka gwa kubiri 2)

Enamba y'essimu +256-782182862

Ennyanjula

Kiki ky'olina okumanya ekikwaata ku musomo guno:

Osabibwa okwegatta ku musomo gw'okunoonyereza.

Omusomo gukwata ku Bubonero obuleeta okuzaala obulungi oluvanyuma lw'okuwalirizibwa okufuna ebisa mu ddwaliro lye ggwanga ekkulu e Kawempe

Ekiwandiiko ekyokukkiriza kinyonyola omugaso gwo ku musomo gunno.

Mwattu kisome n'obwegendereza era twaala obudde bwona bwewetaaga.

Oli nakyeewa. Osobola okusalawo obutetaba era singa wetaba osobola okuvaamu obudde bwonna. Tewajja kubaawo kubonerezebwa singa osalawo okuva mu musomo.

Okuwaliliza okufuna ebisa

Eno ye mbeera eyo kuwaliliza nabaana okugaziwa okusobola okutandiika okufuna ebisa Ekitongole ky'ebyobulamu eky,ensi yonna kisemba okuwaliliza okuzaala ku mukyaala yenna awezezza sabiiti 41 nga ali lubuto, okuzziyiza obuzibu ku mukyaala azaala oba omwana eyakazaalibwa nga buva ku nakku z'okuzaala okuyitako

Waliwo embeera endala nyingi ezibaawo nga omukyaala ali lubuto okugeza nga amakilo, ensundwe okwabika nga omukyaala tanatuusa kuzaala, endwadde ya sukaali nga omukyaala ali lubuto, n'endala nyingi eziyinza okwetaagisa okumuwaliliza okulumwa nga tanaba kutandiika kulumwa okwa bulijjo. Okuwaliliza okulumwa omwana kusobola okukolebwa mu nkola eziwerako okugeza nga okuteeka amakerenda mu bukyaala ,okumira amakerenda

n’omumwa, okukubwa empiso mu misiwa egitambuza omusaayi okuyiwa amazzi oba okuteeka akaseke mu nabaana nga kayita mu bukyaala.

Asasulira omusomo.

Omunoonyereza omukulu. Muyizi akuguka mu dwadde z’ekyaala n’okuzaala mu Ssetendekero e Makerere

Ekigendererwa ky’omusomo:

Olondeddwa okwetaba mu musomo gunno kubanga oli omu ku bakyaala abalabika nga bakuwalilizibwa okufuna ebisa era nga ojja kulabirirwa nga tukozesa emu ku ngeri ezo eyo kuwaliliza okufuna ebisa. Gunno omusomo gwakugezesa era gugenderela okuzuula bakyaala bameka kwaabo abawalilizibwa okufuna ebisa abanagenda mu maaso n’ebazaala okuyita mu bukyaala era mbeera ki ebaleetedde okuzaala nga bayita mu bukyaala.

Ekiseera omwetabi kyanamala mu musomo.

Omusomo gujja kutandiika nga owaliliziddwa okulumwa ebisa era gukome nga omukyaala azzadde.

Enkola y’omusomo

Oluvanyuma lw’okukkiriza okwetaba mu musomo gunno, kijja kukwetaagisa okuteeka omukono ku kiwandiiko , ojja kubuuzibwa omu ku bali ku musomo gunno ebibuuzo ebyetaagisa ebikukwaatako eby’obulamu bwo, eby’embuto ezayiita n’eluno. Eddagala erilagiddwa n’enkola endala bijja kukolebwaako omusawo oba omuzaalisa ali ku kasenge wooli ake ddwaliro era ojja kugobererwa paka nga ozadde nga enkola bweeri eyo kulabirira abakyaala abalumwa, era ebinazuulibwa byona bijja kuwandiikibwa mu fayiro yo.

Abetabi mu musomo

Omugatte gwa 323 (ba maama ebikumi bisatu mu abiri mu basato) abawaliliziddwa okulumwa ebisa bebajja okubeera mu musomo.

Obulabe n’okutataganyizibwa kw’omulwadde.

Wajja kubaawo okulumwa ebisa olwokuziimba kwa nabaana, ebibuuzo bijja kutwaala akaseera katono, eddakiika 15 -30, ojja kufuna okutataganyizibwa nga okeberwaako buli luvanyuma lwa akaseera ka dakiika assatu okuwuliliza enkuba y’omutima gw’omwana n’ogugwo, okukebera entambula y’omusaayi gwo buli luvanyuma lwa saawa bbiri n’engeri omwana gyakamu era buli luvanyuma lwa esaawa nya (4) tujja kukeberako mu bukyaala okuzuula engeri nabaana gyeyeggula. Bino byonna bikeberwa okuyamba abakukolako

okulaba nga bw'ogenda mu maaso mu kulumwa omwana era ebinazuulwa byona bijja kuwandiikibwa mu failo yo.

Okuganyulwa kw'omulwadde:

Omusomo guyinza kukendeeza ekiseera ky'onamala mu ddwaliro nga olinda okuzaala. Bwiino anajibwa mu musomo gunno ajja kuyamba mu kutereeza kutandika okulumwa ebisa bwekiba nga kilagiddwa mu nkola ey'ekisawo. Era kijja kuyamba mu kulondawo balwadde ki abetaaga okuwalilizibwa okulumwa ebisa.

Okukuuma ebyaama mu kiseera eky'okukunganya bwiino.

Ebibuuzo bijja kubuuzibwa mu kaseenge akenjawulo awatali kutataganyizibwa erinya lyo terijja kuwandiikibwa ku lupapula olw'ebibuuzo.

Okukuuma bwiino n'ebyaama

Bwiino akuŋŋanyizibbwa nga akukwaatako ajja kukuumibwa mu kifo ekilabirirwa . Ebibuuzo ebididdwamu bijja kukuumibwa mu kabada esibibwa era nga etukibwaako abo bokka abakola ku musomo, era tewali bikukwatako bijja kubulirwa abebweeru, mpozi akakiiko akakwasisa empisa mu kunoonyereza kayinza okuba n'olukusa olutuuka ku bwiino akukwatako nga omuntu na amanya.

Okusiimibwa/obulabo ku lw'okwetaba

Okwetaba kwo kwa bwanakyeewa tewajja kubaawo kusasulwa kwa sente ojja kufunayo omuti gwa sabbuni nga okusiimibwa okweetaba mu musomo.

Singa wabaawo obuvune mu kiseera ky'omusomo okugeza nga okuyulika wansi mu kiseera eky'okuzaala omunoonyereza omukulu ajja kukolako mu kukudabiriza.

Okuliyilirwa:

Abetabi bajja kuytingizibwa mu musomo bwebanaaba bazze mu ddwaliro nga bakuwalilizibwa okulumwa ebisa, ebisale by'entambula n'eby'okulya tebijja kubaweebwa. Omusomo teguliimu kugobererwa singa aba amaze okuzaala.

Ebibuuzo ebikwaata ku musomo.

Bwewabaawo ebibuuzo ebikwata ku musomo, mwattu kubira omunoonyereza omukulu

Omusawo: Ajok Jennifer

Namba ya ssimu +256-782 182 862

Abetabi abalina ebibuuzo ku ddembe lyaabwe:

Eddembe ly'okugaana oba okuvaamu

Gunno omusomo gwa bwanakyeewa ddala olina eddembe lyo okuvaa mu musomo obudde bwonna nga tobonerezeddwa. Bwoovamu Ojja kufuna obujjanjabi bwona bwolina okufuna

nga abakyaala abalala abali mu mbeera yo, tewajja kubaawo kubonerezebwa bwosalawo okuva mu musomo obudde bwonna.

Okumanyisa ebivuddemu:

Ojja kuteegezebwa ebinaaba bizuuliddwa okuva mu musomo ojja kubulirwa ebilala ebinaaba bizuuliddwa nga bikwaata ku bulamu bwo mu kiseera ky'omusomo kino kijja kukolebwa nga tukukubira essimu singa omulwadde anaaba amaze okufuluma eddwaliro.

Okukkiriza/Nzikkirizaganya:

……Anyinyonyodde ebikwata ku musomo guno, enkola,emiganyulo egisoboka,obulabe obulimu wamu n'eddembe lyange ku musomo. Nkiteggedde nti okusalawo kwange okwetaba tekujja kutataganya ndabilira yange mu byeddaggala. Ebinkwatako bijja kukweekebwa. Nkimanyi nti nsobola okuvaamu obudde bwonna, nkitegeera nti okusa omukono ku kiwandiiko kino sejjaako ddembe lyange, naye ndaga nti nyinyonyoddwa ebikwaata ku musomo gwe nzikkiriza okwetabamu nga nakyeewa. Ekiwaandiiko nga kino kijaa kuba kimpeebwa.

Okkirizza nga nakyeewa okwetaba mu musomo gunno.

…… ……..

..……/……/..…..

Erinnya ly'omwetabi Omukono /Ekinkumu Ennaku z'omwezi

…… …….

……/……/……

Erinnya ly'omuzzadde/omukuumi Omukono /Ekinkumu Ennaku z'omwezi

ku lwaabo abatanesalirawo

…… …… ……./……../……

Erinnya ly'omujulizi Omukono Ennaku z'omwezi

Omuyambi mu kunonyereza: Nyinyonyodde omugaso,enkola ,obulabe n'emiganyulo egy'omusomo gunno eri omwetabi, era nzizeemu ebibuuzo bye byonna.

…… ……..

……../……/…….

Erinnya ly'omuntu afunye okukkiriza Omukono Ennaku z'omwezi

APPENDX III: QUESTIONNAIRE

APPENDX III: QUESTIONNAIRE

A study on prevalence and predictors of vaginal delivery following induction of labour at Kawempe National Referral Hospital:

1. Participant's number ..... Date .....
2. Participant initials .....

A. **Participant's Socio-Demographic characteristics**:

3. Date of Birth .....
4. Age (years) .....
5. Weight (Kgs) .....
6. Height (cm) .....
7. Marital status: 1 Married 2 Cohabiting 3 single 4 widowed
8. Educational status: 1 uneducated 2 primary 3 secondary 4 Tertiary
9. Occupation: 1 student 2 Housewife 3 self-employed 4 salaried/ wage

B. Obstetric History

10. Gravidity.....Parity .....
11. Previous history of induction of Labour.....
12. If yes why were you induced? 1 post-term 2 other conditions in pregnancy (specify).....
13. How many Antenatal visits did you attend with current pregnancy? .....

C. Process of induction

14. Diagnosis.....
15. Indication for induction of labour .....
16. Cervical status:

i.	Cervical dilatation (cm)	a	Closed	b	1-2	c	3-4	d 5-6
ii.	Cervical effacement (%)	a	0-30	b	40-50	c	60-70	d 80%
iii.	Cervical consistency	a	Firm	b	Medium	c	Soft	
iv.	Cervical position	a	posterior	b	central	c	Anterior	
v.	Presenting part station	a	-3	b	-2	c	-1,0	d +1, +2
vi.	Score	a	0	b	1	c	2	d 3
vii.	Total Bishop's Score.....							

17. What was the gestational age at (Weeks) at IOL? .....

35

18. Which method was used: 1 Vaginal misoprostol 2 Oral misoprostol 3 Vaginal dinoprostone 4 intravenous Oxytocin 5 Foley Catheterization 6 Membrane sweep 6 Amniotomy

19. Date of drug prescription.....

20. Time of drug prescription .....

21. Date of drug administration.....

22. Time of drug administration.....

23. Was prescribed drug administered timely? 1 Yes 2 No

24. Was labour monitoring done? 1 Yes 2 No

25. Was the protocol adhered to? 1 Yes 2 No

26. How long did labour take.....

27. Mode of delivery 1 Vaginal Delivery 2 Caesarean Section

28. Time of delivery.....

29. Date of delivery .....

30. Birth weight of the baby (Kg) .....

Interviewer's name ..... Date.....

APPENDIX IV: BUDGET AND BUDGET JUSTIFICATION

ITEMS	ITEM QUANTITY	UNIT COST	TOTAL COST
Fees for SOMREC approval	1	100,000/=	100,000/=
Box files	2	5000/=	10,000/=
Pens	10	500/=	5,000/=
Printing of research proposal	20 copies	5000/=	100,000/=
Translating consent forms from English to Luganda	1	100,000/=	100,000/=
Printing of consent forms	5 pages x323 x2	100/=	323,000/=
Printing of data collection tools	2 pages x 323	100/=	64,600/=
Pre-testing of Data collection tool			100,000/=
Allowance of research assistants	323 copies	50,000/=	1,615,000/=
Compensation for participants	323 clients	4,000/=	1,292,000/=
Data analysis	1statistician	1,000,000/=	1,000,000/=
Photocopying dissertation	100 pages x 6 copies	100/=	60,000/=
Binding dissertation	6 copies	10,000/=	60,000/=
Air time		100,000/=	100,000/=
Miscellaneous	1	200,000/=	200,000/=
Grand total			**5,129,600/=**

APPENDIX V: BUDGET JUSTIFICATION

Printing and photocopying: Edited copies of the proposal, consent forms and data collection tool will be printed and photocopied.

Data collection Tool: Before carrying out the study, the data collection tool will be pretested and the research assistants will be exposed to the research tool which will also help them to familiarize themselves with the tool and will also allow us to make any necessary adjustments to the questionnaires. The research assistants will have to be compensated for their time

Data analysis: Data analysis will be done with the help of the biostatical and a report will then be written. Six copies of the report will have to be printed and the information will be disseminated.

APPENDIX VI: TIME FRAME FOR KEY ACTIVITIES

ACTIVITY	OCT-DEC 2019	JAN 2020-MAY	SEPTEMBER-DEC 2020	JAN JUNE 2021	JUNE-AUGUST 2021	SEPTEMBER-OCTOBER 2021	NOVEMBER-DECEMBER 2021
Proposal development							
Proposal presentation / Ethical Clearance							
Data collection							
Data entry and analysis							
Report writing							
Report submission Presentation							
Report dissemination							

APPENDIX VII: IOL GUIDELINE

Mulago National Referral and Teaching Hospital, Kampala, Uganda

Induction of Labour Guideline (Full Guideline)

Introduction

Induction of labour is the artificial method of stimulating labour and childbirth. The need for induction arises when it is believed that pregnancy outcome will be improved by artificially interrupting the pregnancy, rather than allowing it to continue to its natural conclusion.

Augmentation of labour is an artificial process employed to speed the progress of labour, by increasing the strength, frequency and duration of contractions.

Indications for Induction of Labour at Mulago

- **Prelabour rupture of membranes at term**, (this may be performed immediately or after 24 hours of expectant management in the absence of infection)[i]
- **Preterm prelabour rupture of membranes** at greater than 34 weeks gestation (this may be performed immediately or after 24 hours of expectant management in the absence of infection)[ii]
- **Preterm prelabour rupture of membranes** at less than 34 weeks in the presence of infection WITHOUT fetal compromise
- **Prolonged pregnancy at greater than 41 weeks gestation[iii]**
- **IUFD (considered as a separate regimen) [iv],[v]**
- **Stabilising induction in the presence of an unstable lie**
- **History of precipitate labour in a previous pregnancy** however it should be noted that there is no evidence that offering induction prevents precipitate labour as it has not been the subject of clinical research[vi]. Due to the risks associated with precipitate labour occurring in Mulago on balance, we feel this is an appropriate indication for elective induction only
- **Maternal medical indications**

The following scenarios are NOT indications for induction of labour at Mulago

- **Suspected fetal macrosomia[vii],[viii]**
- **Small for gestational age infants/fetal growth restriction WITHOUT compromise[ix], [x], [xi]**

- **Maternal request** [3,xii]

Absolute contraindications to induction of labour at Mulago

- **Previous caesarean section/uterine scar, even in the presence of previous successful VBAC –** due to lack of resources enabling electronic fetal monitoring and rapid access to theatre
- **Malpresentation –** except in situation of stabilising induction with successful ECV
- **Multiple pregnancy**
- **Fetal growth restriction with suspected fetal compromise** (i.e. suspected IUGR with oligohydramnios in the absence of a history of ruptured membranes). Note that there is a paucity of evidence for the routine use of biophysical profile in the assessment of fetal wellbeing in high risk pregnancies, however without the facility for Doppler assessment or CTG monitoring, it may be appropriate to perform BPP. Note that there is some evidence that BPP may increase the rate of caesarean section without improving outcome[xiii].
- **HIV positive women with intact membranes or SROM/PROM of less than 6 hours duration**

Indications for augmentation of labour at Mulago

- **Failure to progress in labour -** in the absence of suspected CPD or clinical suspicion of uterine rupture. Exercise caution and consider consulting where malposition is suspected.

Essential pre-requisites for induction of labour at Mulago

- **Appropriate indication**
- **Accurate clinical information about gestational age (from history, serial examinations and USS (first trimester is desirable))**
- **Knowledge of state of woman's cervix**
- **Knowledge of fetal presentation (and position if augmentation of labour)**
- **Biophysical profile in women being induced for medical reasons with small for gestational age infants or suspected IUGR**

Evidence for different IOL methods

Amniotomy alone for induction of labour

A Cochrane systematic review[xiv] of 2 trials involving a total of 310 women there were no trials of amniotomy vs intracervical prostaglandins, no conclusions could be drawn about amniotomy alone vs no intervention or amniotomy vs oxytocin alone. One trial of amniotomy alone vs a single dose of vaginal prostaglandins showed that women who had amniotomy alone had a significantly increased need for oxytocin augmentation. There is therefore not enough evidence available to recommend the use of amniotomy alone for induction of labour.

IV oxytocin alone for induction of labour

A Cochrane systematic review[xv] of 61 trials involving a total of 12819 women showed that oxytocin was better than expectant management in achieving delivery within 24 hours. Use of oxytocin alone was associated with a higher unsuccessful vaginal delivery rate at 24 hours when compared with vaginal and intracervical prostaglandins.

Amniotomy and IV oxytocin for induction of labour

A Cochrane systematic review[xvi] of 17 trials involving a total of 2566 women showed that amniotomy with intravenous oxytocin resulted in fewer women remaining undelivered vaginally at 24 hours when compared with amniotomy alone. Amniotomy and IV oxytocin resulted in fewer instrumental vaginal deliveries when compared with placebo. It was noted that there was significantly more postpartum haemorrhage in women undergoing induction with amniotomy and oxytocin compared to vaginal prostaglandins, and reduced maternal satisfaction with the induction process. There were no differences in caesarean section rate, failure to deliver or uterine hyperstimulation in women with amniotomy and oxytocin compared to vaginal prostaglandins.

Sublingual misoprostol for induction of labour

A Cochrane systematic review[xvii] of 3 trials involving a total of 502 women showed that sublingual misoprostol appears to be at least as effective as oral misoprostol at the same dose. However there was a lack of data available to comment on relative complications and side effects. The review recommended that sublingual misoprostol should not enter clinical use until safety and optimal dosage have been established through larger clinical trials.

Oral misoprostol for induction of labour

A Cochrane systematic review[xviii] of 56 trials involving a total of 11590 women showed that when oral misoprostol 20-25mcg 1-2 hourly was compared with placebo, women receiving oral misoprostol were more likely to deliver vaginally with a lower caesarean section rate than with placebo. There was also a reduction in caesarean section rate when compared with dinoprostone, but there was some evidence that labour was slower. When oral misoprostol was compared with oxytocin, there was a higher incidence of meconium stained liquor in the misoprostol group. When oral and vaginal misoprostol were compared there were no differences in delivery outcome. The evidence suggested that the risk of hyperstimulation may have been reduced with oral misoprostol, however this difference was difficult to interpret due to heterogeneity.

Membrane sweeping for induction of labour

A Cochrane systematic review[xix] of 22 trials involving a total of 2797 women showed that when membrane sweep is performed at term, it reduces the duration of pregnancy and the frequency of pregnancy continuing beyond 41 weeks, compared to no intervention. The number needed to treat was 8, to avoid 1 induction of labour. There was no evidence of increased infection rate however women reported discomfort, bleeding and irregular contractions more frequently than those with no intervention.

Mechanical methods of induction of labour

A Cochrane systematic review from 2001[xx] of 45 trials mainly involving small populations showed insufficient evidence in terms of successful vaginal delivery at 24 hours compared with placebo or prostaglandins. There was some suggestion that there was a lower incidence of hyperstimulation with mechanical methods compared with prostaglandins (intracervical, vaginal or misoprostol), and when compared with oxytocin, mechanical methods reduce the risk of caesarean section. Mechanical methods included balloon catheters, laminaria tents and amniotic infusions). An updated review in 2010 commissioned for WHO demonstrated balloon catheters to be at least as effective as dinoprostone but with virtually no hyperstimulation. Furthermore, the speed of induction appeared similar to dinoprostone. As a result the draft WHO guidelines in 2010 recommend the use of the Foley balloon as first line (along with oral misoprostol solution and vaginal dinoprostone).

Recommended methods of induction of labour at Mulago

The most commonly employed method of induction of labour involves the use of prostaglandins followed by amniotomy and oxytocin.[xxixxii] There are many different prostaglandin regimens in use worldwide, but Misoprostol is the prostaglandin of choice at Mulago due to its availability, cost and stability.

In our setting, a Bishop score of 6 or more is considered favourable for induction with amniotomy and oxytocin. Amniotomy should always be attempted prior to commencing oxytocin, however, in the event that it is impossible to perform amniotomy, oxytocin infusion can be commenced, and after 2 hours of regular contractions, amniotomy should be attempted again.

In women with a Bishops score of less than 6, the recommended regime is oral misoprostol, followed by ARM and oxytocin once the cervix is favourable.

Contraindications to specific induction methods

- **Misoprostol**
    - Trained staff and tocolytics e.g. nifedipine should be readily available – absence of these contraindicates use
    - Emergency access to theatre should be available – absence contraindicates use
    - Known misoprostol allergy
    - Hypertonic uterus
- **Foley catheter**
    - Ruptured membranes if suspicion of infection
    - Bleeding PV
    - Low lying placenta
- **Oxytocin**
    - Hypertonic uterus

Induction Process

- Ensure pre-requisites for induction are met
- Explain to patient indications for induction and induction process. Obtain verbal informed consent and document that this has been obtained.

- Where misoprostol is contraindicated, or there are concerns about hyperstimulation in the context of an unfavourable cervix, consider the use of a Foley catheter for priming the cervix.
- Offer alternative management options where appropriate
- Detailed obstetric examination of the patient should be performed, paying attention to lie, presentation, symphysis fundus height – and correlation with patient's expected delivery date – and fetal heart rate. If there is any abnormality detected, evaluate further using ultrasound, or discuss with a senior.
- Perform a digital vaginal examination – unless there are contraindications – and calculate the Bishop score.

Modified Bishop Score

If Bishop Score is less than 6

- The preferred misoprostol regime[xxiii] is either
    - Oral solution – 200mcg diluted in 200ml water, ingest 20-25mcg every 2 hours. If no response in NULLIPAROUS women after 2 doses, dose can be doubled (50mcg 2 hourly)

- If the oral route is not available
    - Vaginal Misoprostol – 25 mcg vaginally every 4 hours, maximum of 6 doses

- Sublingual misoprostol is not recommended for clinical use outside the context of a clinical trial due to safety concerns

The fetal heart should be auscultated every 15 minutes for 30 minutes after the administration of misoprostol.

The fetal heart should be auscultated and Bishop score should be calculated every 4 hours prior to each dose of misoprostol (note with oral solution this will be prior to every second dose of misoprostol).

Once regular painful contractions have established, intermittent auscultation should be performed every 30 minutes throughout the first stage of labour.

Where a woman is experiencing 3 contractions every 10 minutes, if she is due to receive a dose of misoprostol it should be withheld.

In situations of hyperstimulation – 6 or more contractions every 10 minutes with fetal heart rate abnormalities – tocolysis should be given. Alternatives are:

- SC terbutaline 250 mcg
- Oral nifedipine sublingual 20mg
- Oral salbutamol 5mg

If when a woman is examined prior to being given misoprostol the Bishop score is 6 or more, amniotomy should be performed and oxytocin commenced.

If the Bishop score is more than 6

Perform amniotomy

- Obtain informed consent
- Auscultate the fetal heart rate
- Place mother in dorsal position with her knees apart
- Assess the Bishop Score, if favourable, the head is fixed and no cord is palpated, proceed with amniotomy
- Using 2nd hand, insert amnihook or Kocher's forceps into the vagina, guiding along fingers towards membranes
- Place 2 fingers against membranes and rupture them gently
- Drain fluid slowly noting colour – particularly look for thick meconium staining and bleeding
- Auscultate fetal heart – if less than 110 or greater than 160 bpm, especially in the presence of thick meconium, suspect fetal distress

If regular painful contractions commence within an hour of amniotomy, oxytocin infusion may not be necessary.

Oxytocin can be commenced immediately if there are medical indications to do so.

If it is impossible to perform amniotomy, for example if the head is high or it is not physically possible to rupture the membranes, consider using misoprostol to prime the cervix.

Oxytocin should be used with caution, due to the risks of hyperstimulation.

Monitoring

The fetal heart should be monitored every 30 minutes in women undergoing oxytocin induction/augmentation. Note that it is imperative that the fetal heart is auscultated IMMEDIATELY AFTER A CONTRACTION FOR 1 MINUTE and that the rate and rhythm are recorded. If the fetal heart rate is less than 110 or more than 160 beats per minute, the infusion should be stopped immediately.

Contractions should be assessed every 30 minutes, aiming for 3 contractions lasting more than 40 seconds, every 10 minutes. Once this pattern is achieved, there is no need to increase the oxytocin, and the patient should be maintained at the current infusion rate.

Partographs should be used in all women undergoing induction of labour

Oxytocin preparation and infusion

Oxytocin should not be commenced within 4 hours of misoprostol being given

Oxytocin should be prepared as a solution with 500ml of 0.9% saline or 5% dextrose, whichever is available.

For most giving sets 1ml = 20 drops, however this may vary and should be checked on the giving set packet.

The starting dose of oxytocin is determined by parity. At Mulago the following oxytocin regimes are used

Oxytocin is titrated to the patient's contractions, aiming for 3 contractions every 10 minutes, lasting 40 seconds or more. Once the contractions reach 3 in 10, then maintain the infusion at that rate and do not increase it any more (unless the contractions decrease in frequency again).

APPENDIX VIII: SCHOOL OF MEDICINE RESEARCH AND ETHICS COMMITTEE (SOMREC) CLEARANCE

MAKERERE UNIVERSITY
P.O. Box 7072 Kampala, Uganda
E-mail: rresearch9@gmail.com
Phone: 256 414 533541
Fax: 256 414 541036/0414 532204

COLLEGE OF HEALTH SCIENCES
SCHOOL OF MEDICINE

RESEARCH ETHICS COMMITTEE

May 26, 2020

Dr. Jennifer Ajok
Department of Obstetrics and Gynaecology

Category of Review
[X] Initial review
[X] Full board review
[ ] Expedited review
[ ] Continuing review
[ ] Amendment
[ ] Termination of study
[ ] SAEs

Dear Dr. Ajok,

Re: Approval of proposal #REC REF 2020-028

"Prevalence and predictors of vaginal delivery following induction of labour at Kawempe National Referral Hospital, Kampala- Uganda"

Thank you for submitting an application for approval of the above – referenced **proposal**. The committee reviewed it and granted approval for one-year, effective May 26th, 2020. Approval will expire on May 25th, 2021.

Continuing Review
In order to continue work on this study (including data analysis) beyond the expiration date, the School of Medicine Research and Ethics Committee must reapprove the protocol after conducting a substantive, meaningful, continuing review. This means that you must submit a continuing report form as a request for continuing review. To best avoid a lapse, you should submit the request six (6) weeks before the lapse date. Please use the forms supplied by our office.

Amendments
During the approval period, if you propose any change to the protocol such as its funding source, recruiting materials, or consent documents, you must seek School of Medicine Research and Ethics Committee approval before implementing it.

Please summarize the proposed change and the rationale for it in a letter to the School of Medicine Research and Ethics Committee. In addition, submit three (3) copies of an updated version of your original protocol application- one showing all proposed changes in bold or 'track changes,' and the other without bold or track changes.

Reporting
Other events which must be reported promptly in writing to the School of Medicine Research and Ethics Committee include:
Suspension or termination of the protocol by you or the grantor
Unexpected problems involving risk to participants or others

Adverse events, including unanticipated or anticipated but severe physical harm to participants.

Do not hesitate to contact us if you have any questions. Thank you for your cooperation and commitment to the protection of human subjects in research.

Documents approved for use along with the protocol

- English and translated informed consent form
- Data collection tool

Please Note:

1. Final approval is to be granted by Uganda National Council for Science and Technology.
2. All the study documents including the revised proposal, Informed Consent Forms, Data Collection Tools and any other study documents should be stamped by the REC.
3. Approval from National Drug Authority should be sought where applicable.
4. Approval for use of research devices should be sought from the Ministry of Health/Uganda National Council for Science and Technology where applicable.
5. Administrative clearance should be sought from the various study sites.
6. This study will be monitored by the School of Medicine Research Ethics Committee to assess for compliance to both national and international research guidelines for protecting the rights and welfare of research participants.
7. The REC should be involved in the dissemination of study findings to the different stakeholders. (This applies to staff research, collaborative research and PhD students).
8. The REC should be informed in writing of the process of study closure.

MAKERERE UNIVERSITY
SCHOOL OF MEDICINE
APPROVED
VALID UNTIL
★ 25 MAY 2021 ★
RESEARCH & ETHICS COMMITTEE
P.O.BOX 7072, KAMPALA

Yours sincerely,

Assoc. Prof. Ponsiano Ocama
Chairperson School of Medicine Research and Ethics Committee

APPENDIX IX: ADMINISTRATIVE CLEARANCE FROM KNRH

IH Charge Ward
Received 21/9/20

Office of the Executive Director

Kawempe National Referral Hospital

Plot 1035 / 3883, Kawempe, Bombo Road

P. O .Box 3253, Kampala, Uganda

23rd/06/2020

The Executive Secretary

Uganda National Council of Science and Technology

P. O Box 6884, Kampala

Dear Sir/ Madam

RE: RECOMMENDATION FOR FINAL APPROVAL TO CONDUCT RESEARCH AT KAWEMPE NATIONAL REFERRAL HOSPITAL

This is to introduce to you DR. JENNIFER AJOK, a second year post graduate student in the Department of Obstetrics and Gynaecology at Makerere University, College of Health Sciences.

The student has sought administrative clearance to conduct a research titled **PREVALENCE AND PREDICTORS OF VAGINAL DELIVERY FOLLOWING INDUCTION OF LABOUR AT KAWEMPE NATIONAL REFERRAL HOSPITAL, KAMPALA, UGANDA.**

Clearance by the Hospital has been granted and she is therefore recommended to your office for consideration for final approval to commence the study.

Any assistance accorded to her will be highly appreciated.

Yours sincerely

Dr. Nekemiah Katusiime Arwanire

Ag. Executive Director.

KAWEMPE NATIONAL REFERRAL HOSPITAL
23 JUN 2020
DIRECTOR