FETOMATERNAL OUTCOMES FOR MOTHERS UNDERGOING LABOR INDUCTION AT TERM AT MOI TEACHING AND REFERAL HOSPITAL, ELDORET, KENYA.

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A Thesis Submitted to the School of Medicine, College of Health Sciences in Partial Fulfillment of the Requirement for an Award of the Degree of Master of Medicine in Reproductive Health of Moi University

DECLARATION

Declaration by Candidate

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This thesis has been submitted for consideration with our approval as university supervisors.

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DEDICATION

This thesis is dedicated to my family; wife Loice, son Christian and daughter Princess

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ABBREVIATIONS

ACOG American College of Obstetrics and Gynecology

ANC Antenatal clinic

APGAR Appearance, pink, Grimace, Activity, Respiration

C/S Caesarean section

FIGO International Federation of Obstetrics and Gynecology

KNH Kenyatta National Hospital

LNMP Last Normal Menstrual Period

MTRH Moi Teaching and Referral Hospital

NRFS Non-reassuring fetal status

PGs Prostaglandins

PGE1 Misoprostol

PGE2 Dinoprostone

RMBH Riley Mother Baby Hospital

W.H.O World Health Organization

OPERATIONAL DEFINITION OF KEY TERMS

APGAR score; a clinical tool to identify those neonates who require resuscitation as well as to assess the effectiveness of any resuscitative measures.

Augmentation of Labor; use of Syntocinon to increase the frequency and intensity of uterine contractions once labor has set in

Cervical ripening is the use of pharmacological or other means to soften, efface, or dilate the cervix to increase the likelihood of a vaginal delivery.

Elective induction is the induction of labour in the absence of acceptable fetal or maternal indications.

Failed Induction; inability to achieve a vaginal birth following an induction of labor.

Induction of labor; refers to techniques for stimulating uterine contractions to accomplish delivery prior to the onset of spontaneous labor.

Induction- Delivery time; refers to time interval from initiation of induction to the birth of the baby irrespective of the eventual mode of delivery.

Montevideo unit; is a graphic portrayal of uterine power that corresponds to the product of the uterine contractions/10 mins multiplied by the intensity of the contractions–the average intrauterine pressure peaks of all contractions in the same 10 min span.

Post-term Pregnancy; for this report, it refers to a pregnancy that has completed 41wks. Synonymous with prolonged pregnancy. The term postdates now rarely used.

Post maturity; a descriptive word for babies born past due date. This is used after a clinical assessment of the newborn for clinical signs suggesting this.

Successful induction is defined as a vaginal delivery within 24 to 48 hours of induction of labour (SOGC 2014, WHO 2010).

Term Pregnancy; A pregnancy that has completed 37 weeks.

ABSTRACT

Background: Failed induction is an important reason for rising caesarian section worldwide. Global rates of induction of labor are rising and vary from 9.5 to 35.6 percent of all pregnancies. Women whose labor is induced have an increased incidence of caesarean delivery, chorioamnionitis, varied duration of labor, and risk of nonreassuring fetal status compared with those in spontaneous labor. There is limited local data on induction of labor and associated fetomaternal outcomes. The Quality health outcomes model was used in the study as a theoretical framework.

Broad Objective: To determine the Fetomaternal outcomes for mothers undergoing labor induction at Moi Teaching and Referral hospital, Eldoret, Kenya.

Methodology: A descriptive cross sectional study was done after IREC approval. Participants were sampled consecutively to achieve the calculated sample size and data collected using a semi-structured questionnaire. Singleton term pregnancies presenting in cephalic were included. Mothers with contraindications to vaginal delivery were excluded. Data was entered into an Excel database and analysis done with SPSS 17.

Results: A total of 384 gravidas who met the inclusion criteria were treated according to protocol between July 2013 and May 2014; 185 (48%) were nulliparas and 199 (52%) were parous, average ANC visits were 3.6, average age was 26 years and the Bishops scores were poor(3). The leading indication for induction was post-term pregnancy at 58.6% (225/384). Sixteen percent of nulliparas and 10% of parous women were delivered by caesarean. The overall caesarean section rate was 12.8 %(49/384). The mean duration of labour induction/cervical ripening to delivery time was 18 hours. The longest induction/cervical ripening-delivery time was 75hrs and the shortest was 5hrs. The mean 5 minute Apgar score was 9. Thirteen neonates (3%) were admitted to new born unit due to Respiratory distress syndrome. Of the thirteen 3 (2.3%) died within 72hrs. Of the neonates admitted to NBU, 76.9% had cervical ripening/induction to delivery time lasting more than 48hrs.

Conclusion: The commonest reason for induction is post-term pregnancy. The mean induction to delivery time is 18 hours. The overall caesarean section rate following induction at MTRH is 12.8 %. The mean 5 minute Apgar score was 9. Fetal outcomes were poor for cervical ripening/induction to delivery time lasting more than 48hrs. Cervical ripening/induction of labour for all indications with poor Bishop Score is good.

Recommendations: MTRH to continue use of existing protocol on induction in view of the current outcomes. The cervical ripening/labor induction to delivery interval should not exceed 48 hours. There is need for a comparative study to compare fetomaternal outcomes for spontaneous and induced labor.

CHAPTER ONE

1.1 Background

Induction of labour is a process of artificially stimulating the uterus to start labour (WHO library 2011). Induction is indicated when the benefits to either the mother or the fetus outweigh those of continuing the pregnancy. Indications include emergent conditions such as ruptured membranes with chorioamnionitis or severe preeclampsia. More common indications include membrane rupture without labor, hypertension, non-reassuring fetal status, and post-term gestation (Williams, 2010). Induction of labour has a large impact on the health of women and their babies and so needs to be clearly clinically justified. Women whose labor is induced have an increased incidence of chorioamnionitis and cesarean delivery compared with those in spontaneous labor. In many cases, it seems that the uterus is simply poorly prepared for labor for instance unfavorable. It is also likely that the increase in cesarean deliveries associated with induction is influenced by the duration of the induction attempt, especially in the circumstance of an unfavorable cervix (Rouse et al, 2000). According to the WHO report on unmet need for induction of labor in Africa: secondary analysis from the 2004 - 2005 WHO Global Maternal and Perinatal Health Survey, it concludes that utilization of induction of labor in health facilities in Africa is very low. Improvements in social and health infrastructure are required to reverse the high unmet need for induction of labor. (Fawole et al, 2012.).

In our setting, Mati et al in 1983 Nairobi Birth Survey reported an overall induction rate of 5.7%. Khisa in 1999 found an induction rate of 14% at Aga Khan Hospital Nairobi [.Onyambu in 2001, in the same hospital found a rate of 8.04%, while Kaguta in 1984

found a rate of 5.6% at Kenyatta National Hospital. In a prospective descriptive cross sectional study done at KNH in 2002, Njagi J, M, found an induction rate of 12.7%. The indications for the above inductions were mainly postdates (approximately 50%), pre-labour rupture of membranes (PROM) and hypertensive disease. The most recent study by Esiromo in 2011 found the commonest indication for induction at KNH to be postdates (50.8%).

1.2 Problem Statement

Globally the annual rate of induction of labour varies from 9.5 to 35.6 percent of all pregnancies. Unpublished data from the WHO Global Survey (2010) on Maternal and Perinatal Health, which included 373 health care facilities in 24 countries and nearly 300000 deliveries, showed that 9.6% of the deliveries involved labour induction. Local data on fetomaternal outcomes following induction of labor is limited.

1.3 Justification

The duration for either labor induction to delivery time or augmentation and successful delivery has received too little attention. More precise data are needed to understand the wide range of individual management. Varying national and institutional guidelines on induction of labour calls for more reviews of existing guidelines and harmonization so that care is standardized for all mothers who will undergo induction of labour. There are limited local studies available on literature search.

Induced labor is associated with an increased cesarean delivery rate, especially in nulliparas (Luthy et al, 2002; Yeast et al, 1999). A number of investigators have reported

that elective induction consistently results in a two- to threefold risk for cesarean delivery (Hoffman and Sciscione, 2003; Maslow and Sweeny, 2000; Smith and et al, 2003). Women whose labor is induced have an increased incidence of chorioamnionitis. WHO recommends a 24hr induction to delivery time; longer intervals are associated with low 5minute APGAR scores and increase in caesarean section rates. The five minute APGAR scores for babies induced for whatever reason coupled with induction to delivery times and presence chorioamnionitis will influence future management guidelines on induction.

The findings of this study will influence patient care on induction of labor in MTRH

1.4 Research Questions

1.4.1 Primary Research Question

1. What are the Fetomaternal outcomes of labour inductions in MTRH?

1.4.2 Secondary Research Questions

i) What is the commonest reason for induction of labour at MTRH?

ii) What is the average duration of time from induction to delivery following induction?

iii) What is the caesarean section rate after induction of labour?

iv) What are the five minute APGAR scores for babies born following induction?

1.5 Objectives

1.5.1 Broad Objective

To determine the Fetomaternal outcomes for indicated labour induction in MTRH.

1.5.2 Specific Objectives

1. To determine the commonest reason for labour induction at MTRH.
2. To determine the average duration of labour induction to delivery time at MTRH.
3. To determine the cesarean delivery rate following term induction of labour at MTRH.
4. To establish the five minute APGAR scores for babies born following term labour induction at MTRH.

CHAPTER TWO: LITERATURE REVIEW

2.1 Scope of the problem

Induction of labour is a common obstetric practice. According to the most current studies, the rate varies from 9.5 to 33.7 percent of all pregnancies annually. Data from the WHO Global Survey (2013) on Maternal and Perinatal Health, which included 373 health care facilities in 24 countries and nearly 300000 deliveries, showed that 9.6% of the deliveries involved labour induction. Overall, the survey found that facilities in African countries tended to have lowest induction rates (lowest; Niger 1.45) compared with Latin American and Asian countries (highest; Sri Lanka 35.5%).

Induction of labour is indicated where the benefits to mother and/or fetus of discontinuing the pregnancy outweigh the risks of awaiting spontaneous onset of labour (Sanchez-Ramos L 2005 and Induction of Labour (2008)). The indication must be convincing, compelling, consented to, and documented. The reason for and method of induction should be discussed between the care provider and the woman in order to obtain clear consent (SOGC 2014).

High Priority reasons for inductions include Preeclampsia ≥ 37 weeks, significant maternal disease not responding to treatment Chorioamnionitis, Suspected fetal compromise and term pre-labour rupture of membranes with maternal GBS colonization. Other Indications include post-term(> 41+0 weeks) pregnancy**,** Uncomplicated twin

pregnancy ≥ 38 weeks **,** Diabetes mellitus (glucose control may dictate urgency), Alloimmune disease at or near term, Intrauterine growth restriction, Oligohydramnios, Gestational hypertension ≥ 38 weeks, Intrauterine fetal death, PROM at or near term, Logistical problems (history of rapid labour, distance to hospital , Intrauterine death in a prior pregnancy (Induction may be performed to alleviate parental anxiety, but there is no known medical or outcome advantage for mother or baby)and significant but stable antepartum hemorrhage (SOGC 2014).

In a 2012 meta-analysis of randomized trials comparing a policy of labor induction to a policy of awaiting spontaneous onset of labor at 39 to 42 weeks: Routine labor induction at >41 weeks of gestation compared with expectant management resulted in lower perinatal mortality (1/2814 versus 9/2785; RR 0.30, 95% CI 0.09-0.99; 10 trials) and a lower rate of meconium aspiration syndrome (RR 0.61, 0.40-0.92; 5 trials, 1395 patients(Gülmezoglu AM, Crowther CA, Middleton P, et al 2012). For induction at $41^{0/7ths}$, the risk of perinatal mortality was also lower than with expectant management, but did not achieve statistical significance (0/501 versus 2/497; RR 0.33, 95% CI 0.03-3.17; 4 trials, 998 patients).

There can be no doubt that elective induction for convenience of the practitioner or the patient is becoming more prevalent. Despite this, the WHO (2011) does not support this practice, except for logistical reasons such as risk of rapid labor, the woman lives a long distance from the hospital, or for psychosocial indications. One reason is that induced labor is associated with an increased cesarean delivery rate, especially in nulliparas (Luthy et al, 2002; Yeast et al, 1999). A number of investigators have reported

that elective induction consistently results in a two- to threefold risk for cesarean delivery (Hoffman and Sciscione, 2003; Maslow and Sweeny, 2000; Smith et al., 2003).

However, induction of labour is not without risk. The World Health Organization (WHO) recommends induction be performed with a clear medical indication and when expected benefits outweigh potential harms (WHO 2011). Induction of post-term pregnancy rather than expectant management with fetal monitoring is supported by several lines of evidence as it lowers perinatal mortality and morbidity.

In the Flanders region of Belgium, 30 percent of women delivering in 1996 and 1997 had induction of labor, and two thirds of these were elective (Cammu et al 2002). The investigators matched 3683 women who had elective inductions with a similar number of women whose labor was spontaneous. Induction resulted in significantly more cesarean deliveries—9.9 versus 6.5 percent—in part due to an increased incidence of dystocia and "fetal distress." This increase appears to be unchanged even when the cervix is more "favorable." Specifically, in a retrospective cohort study, Hamar et al (2001) found that the rate of cesarean delivery following elective induction was significantly increased in low-risk women with a Bishop score of 7 or greater compared with women with spontaneous labor.

Contraindications to labor induction are similar to those that preclude spontaneous labor or delivery. The most common example is a prior uterine disruption such as a classical incision or some type of uterine surgery that involved the myometrium. Most types of placenta previa preclude labor. Labor prohibition due to fetal factors includes appreciable macrosomia, severe hydrocephalus, malpresentation, or nonreassuring fetal

status. The few maternal contraindications are related to small maternal size, distorted pelvic anatomy, and conditions such as active genital herpes infection or cervical cancer (Cammu et al 2002).

Caesarian section following induction is indicated when there is non reassuring foetal status, prolonged labour, antepartum hemorrhage. Meconium staining on its own is not an absolute indication for caesarian section unless associated with a non-reassuring foetal heart. (Hamar et al, 2001)

2.2 Preinduction Evaluation

The condition of the cervix—or "favorability"—is important to the success of labor induction. One quantifiable method predictive of an outcome of labor induction is the Bishop (1964) score. Elements of the Bishop score are presented in table 1 below (Williams 2010). A score of 9 conveys a high likelihood for a successful induction. Women will frequently have an indication for induction but with an unfavorable cervix. As Bishop Score decreases, there is an increasingly unsuccessful induction rate. A favorable preinduction Bishop Score of > 6 is predictive of a successful vaginal delivery. Initial studies were limited to parous women, but the score was later found also to be applicable to nulliparous women (SOGC 2013).

Table 1

The Modified Bishop Score

FACTOR	**SCORE**

Dilatation, CM	0	1-2	3-4
Effacement %	0-30	40-50	60-70
Consistency	Firm	Medium	Soft
Position	posterior	Mid	Anterior
Station	-3	-2	-1 or 0

Assessment of cervical status is fundamental for the clinician to estimate the likelihood of a successful vaginal delivery. Of the Bishop score criteria for predicting successful induction, the most important is cervical dilatation, followed by effacement, station, and position, with the least important being consistency. (Crane 2006, Laughton 2011). Several studies have shown an increased rate of failed induction and CS when women are induced with an unfavorable cervix (Ennen et al 2009).

2.3 Options for Cervical Ripening/Induction: Unfavourable Cervix

To increase the success of a vaginal delivery with an unfavourable cervix, several effective cervical ripening methods can be applied that include mechanical and pharmacologic options. Neither amniotomy nor oxytocin are effective cervical ripening agents and should not be used as such (SOGC 2013).

Pharmacological techniques

Prostaglandin E_2

Prostaglandin E2 acts on the cervix by dissolving the collagen structural network of the cervix. Local application of prostaglandin E_2 (dinoprostone) is commonly used for cervical ripening (American College of Obstetricians and Gynecologists, 1999a, 1999b).

Prostaglandin E_2 gel is available in a 2.5-mL syringe for an intracervical application of 0.5 mg of dinoprostone. Owen et al (1991) did a meta-analysis of 18 studies that included 1811 women. They found that prostaglandin E_2 improved Bishop Scores and induction-to-delivery times when compared with those of untreated controls.

A 10-mg dinoprostone vaginal insert (Cervidil) also is approved for cervical ripening. The insert provides slower release of medication (0.3 mg/hr) than the gel. As with dinoprostone gel, these inserts will shorten the induction-to-delivery interval (Bolnick et al, 2004; Rayburn et al, 1992). An advantage of the insert is that it can be removed should hyperstimulation occur. Prostaglandin preparations should only be administered where uterine activity and fetal heart rate monitoring can be performed (American College of Obstetricians and Gynecologists, 1995b). When contractions occur, they are usually apparent in the first hour and show peak activity in the first 4 hours (Bernstein, 1991; Miller et al, 1991). Perry and Leaphart (2004) compared intracervical with intravaginal administration of the insert and found the latter to result in quicker delivery—11.7 versus 16.2 hours. When more than two sequential doses were used, Chan et al (2004) reported that 59 percent of women required emergency cesarean delivery. Oxytocin induction that follows prostaglandin use for cervical ripening should be delayed for 6 to 12 hours following prostaglandin E_2 administration.

Prostaglandin E_1

Misoprostol (Cytotec) is a synthetic prostaglandin E_1, available as a 100- or 200-mcg tablet for prevention of peptic ulcers. It has been used "off label" for preinduction

cervical ripening and may be administered orally or vaginally. The tablets are stable at room temperature.

Misoprostol tablets placed into the vagina were either superior to or equivalent in efficacy when compared with intracervical prostaglandin E_2 gel (von Gemund et al, 2004; Wing et al, 1995a, 1995b). The Committee on Obstetrics of the American College of Obstetricians and Gynecologists (1999b) reviewed 19 randomized trials in which more than 1900 women were given intravaginal misoprostol in doses ranging from 25 to 200 g. The Committee on Obstetrics recommended the use of a 25mcg intravaginal dose tablet. Misoprostol use may decrease the need for oxytocin, achieve higher rates of vaginal delivery within 24 hours of induction, and reduce induction-to-delivery intervals (Sanchez-Ramos et al, 1997). A 50mcg misoprostol intravaginal dose was associated with significantly increased tachysystole, meconium passage, and meconium aspiration when compared with prostaglandin E_2 gel (Wing et al 1995a). A 25-mcg dose was found comparable to dinoprostone (van Gemund et al, 2004). There is also an increased cesarean delivery rate due to uterine hyperstimulation when compared with that from dinoprostone (Buser et al, 1997). Uterine rupture has been reported with prostaglandin E_1 use in women with a prior cesarean delivery (Wing et al 1998). Prior uterine surgery, including cesarean delivery, precludes the use of misoprostol (American College of Obstetricians and Gynecologists, 2004).

Prostaglandin E_1 tablets are also effective when given orally. Windrim et al (1997) reported oral misoprostol to be of similar efficacy for cervical ripening as intravaginal administration. 50 mcg of oral misoprostol was less effective than 25 mcg administered

vaginally for cervical ripening (Wing et al. 1999). Subsequently, Wing and colleagues (2003) and Hall and associates (2002) reported that a 100-mcg oral dose was as effective as the 25-mcg intravaginal dose. Lo et al. (2003), in a similar group of women at term with prematurely ruptured membranes, found that oral misoprostol predictably induced at least 200 Montevideo units within 30 to 60 minutes, and results were comparable to their standard intravenous oxytocin infusion. Montevideo unit is a graphic portrayal of uterine pressure that corresponds to the product of the uterine contractions/10 mins multiplied by the intensity of the contractions–the average intrauterine pressure peaks of all contractions in the same 10 min span. (Hauth, 1986)

Mechanical Techniques

Mechanical options of cervical ripening include balloon devices (Foley catheter with and without extra-amniotic saline infusion) that apply pressure on the internal o s of the cervix to stretch the lower uterine segment and increase the release of local PG. Simplicity of use, potential for reversibility, reduction in certain side effects such as excessive uterine activity, and low cost are advantages of these methods (SOGC 2013).

Transcervical Catheter

For a single balloon catheter, a no. 18 Foley is introduced under sterile technique into the intracervical canal past the internal os. The bulb is then inflated with 30 to 60 cc of water. The catheter is left in place until either it falls out spontaneously or 24 hours have elapsed. Some practitioners apply a small degree of traction on the catheter by taping it to the inside of the leg.

In a summary of 13 trials with balloon-tipped catheters to effect cervical dilatation, Transcervical Catheter resulted in rapid improvement in Bishop Scores and shorter labors (Sherman et al. 1996). Several comparative trials have been done. Huang et al (2002) randomized 135 women to labor induction with vaginal misoprostol, and intrauterine extra-amnionic Foley catheter with bulb inflation to 30mL, or both therapies. Outcomes were similar in all three groups, and there was no apparent benefit of combining these two techniques. Culver et al (2004) compared oxytocin plus an intracervical Foley catheter to 25 mcg of misoprostol administered vaginally every 4 hours in women with a Bishop score less than 6. The mean induction-to-delivery time was significantly shorter in the catheter-plus-oxytocin.

The addition of extra-amnionic saline infusion (EASI), has been reported to significantly improve the Bishop score and decrease induction-to-delivery times when compared with that by (1) 50-mcg intravaginal misoprostol tablets (Vengalil et al, 1998), (2) 0.5 mg of intracervical prostaglandin E_2 (Goldman and Wigton, 1999; Hemlin and Möller, 1998; Sciscione et al, 1999), or (3) 50-mcg oral misoprostol.

Hygroscopic Cervical Dilators

Cervical dilatation has been achieved with hygroscopic osmotic cervical dilators. These dilators have long been accepted as efficacious when inserted prior to pregnancy termination (Hale and Pion, 1972).

Membrane Stripping

Induction of labor by membrane "stripping" is a common practice. McColgin et al (1990) reported that stripping was safe and decreased the incidence of postterm gestation. They documented significantly increased serum levels of endogenous prostaglandins with stripping (McColgin and et al 1993). Allott and Palmer (1993) randomized 195 women with normal pregnancies beyond 40 weeks to digital cervical examination either with or without membrane stripping. The women were examined as outpatients. Two thirds of those who underwent stripping entered spontaneous labor within 72 hours compared with one third of the other group. The incidence of ruptured membranes, infection, and bleeding was not increased. Importantly, subsequent induction for post-term pregnancy at 42 weeks was significantly decreased with stripping.

Boulvain et al. (1999) reviewed 13 reports that included almost 2000 women who underwent membrane stripping to prevent post-term pregnancy. Stripping was considered beneficial because women in this group were significantly more likely to deliver within 48 hours, within 1 week, and before 41 weeks, thus, fewer women in the stripping group required labor induction.

2.4 Labor Induction and Augmentation with Oxytocin

Synthetic oxytocin is one of the most commonly used medications in obstetrics. It was the first polypeptide hormone synthesized, and the 1955 Nobel Prize in chemistry was awarded for this (DuVigneaud et al, 1953). It has a half-life of 5 to 12 minutes, (Leake RD, Weitzman RE, and Fisher DA. 1980) a time to steady plasma concentration of 40 minutes and a steady-state uterine response of 30 minutes or longer (Seitchik et al. 1983) .Regarding labor, it has two uses; induction and augmentation. Induction implies

stimulation of contractions before the spontaneous onset of labor, with or without ruptured membranes. Augmentation refers to stimulation of spontaneous contractions that are considered inadequate because of failure of progressive cervical dilatation and fetal descent. With oxytocin use, the American College of Obstetricians and Gynecologists (1999) recommends fetal heart rate and contraction monitoring similar to that for any high-risk pregnancy. The physiological dose of oxytocin to produce regular uterine contraction is 8 to 12 mU/min. The ideal dosing regimen of oxytocin is not known and there are both low dose and high-dose protocols. The low-dose regimen begins with 1 to 2 mU/min, increased incrementally by 1 to 2 mU at 30-minute intervals. The high-dose regimen commences with a dose of 4 to 6 mU/min, with dose increments of 4 to 6 mU/min every 15 to 30 minutes. Contractions can be monitored either by palpation or by electronic means of recording uterine activity. Uterine contraction pressures cannot be accurately quantified by palpation (Arrabal and Nagey, 1996).

Oxytocin should be discontinued if the number of contractions persists with a frequency greater than five in a 10-minute period or seven in a 15-minute period or with a persistent nonreassuring fetal heart rate pattern. Discontinuation of oxytocin nearly always rapidly decreases the frequency of contractions. When oxytocin is stopped, its concentration in plasma rapidly falls because the mean half-life is approximately 5 minutes. Response depends on preexisting uterine activity, cervical status, pregnancy duration, and individual biological differences. Caldeyro-Barcia and Poseiro (1960) reported that the uterine response to oxytocin increases from 20 to 30 weeks and increases rapidly at term.

A 2009 Cochrane review included 61 studies (12 819 women) of the methods of cervical ripening and labour induction. (Alfirevic Z. et al. 1990).Oxytocin alone versus vaginal prostaglandins was associated with an increase in unsuccessful vaginal delivery within 24 hours (70% vs. 21%). Oxytocin versus intracervical prostaglandins also had fewer vaginal deliveries (51% vs. 35%) and increase in CS rates (19.1% vs. 13.7%). For all women with an unfavourable cervix regardless of membrane status, the CS rates were increased (19.0% vs. 13.1%, RR 1.42, 95% CI 1.11 to 1.82) when labour was induced, (Alfirevic Z. et al. 1990).

2.5 Amniotomy

Amniotomy refers to rupture of membranes. Amniotomy can be a simple and effective component of labour induction when the membranes are accessible and the cervix is favorable. This intervention creates a commitment to delivery and must be done for convincing and compelling reasons. However, the time interval from amniotomy to established labour may not be acceptable to clinicians or to women, and in a number of cases, after amniotomy alone, labour will not commence. Amniotomy can be used for induction when the cervix is favorable, but the onset of labour is unpredictable and often requires oxytocin. A 2007 Cochrane meta-analysis of 17 trials with 2566 women measured the safety of amniotomy and intravenous oxytocin for induction of labour. Amniotomy alone resulted in fewer vaginal deliveries in 24 hours then amniotomy plus oxytocin (RR 0.03, 95% CI 0.01 to 0.49). Amniotomy and oxytocin resulted in fewer instrumental deliveries than placebo (RR 0.18, 95% CI 0.05 to 0.58). However, there was more postpartum hemorrhage (RR 5.5, 95% CI 1.26 to 24.07) and maternal

dissatisfaction (RR 53, 95% CI 3.32 to 846.51) with amniotomy and oxytocin than with vaginal PG (Howarth GR, Botha DJ. (2001)).

A common indication for amniotomy includes the need for direct monitoring of the fetal heart rate or uterine contractions, or both. To minimize the risk of cord prolapse when membranes are ruptured artificially, care should be taken to avoid dislodging the fetal head. Fundal or suprapubic pressure, or both, may reduce the risk of cord prolapse. Some clinicians prefer to rupture membranes during a contraction. If the vertex is not well applied to the lower uterine segment, a gradual egress of amnionic fluid can be accomplished by several membrane punctures with a 26-gauge needle held with a ring forceps and with direct visualization using a vaginal speculum. The fetal heart rate should be assessed before and immediately after amniotomy.

2.6 Methods Used to Evaluate Newborn Condition

Apgar scoring system

A useful clinical tool to identify those neonates who require resuscitation as well as to assess the effectiveness of any resuscitative measures was first described by Dr. Virginia Apgar. (Apgar, 1953). Each of the five easily identifiable characteristics—heart rate, respiratory effort, muscle tone, reflex irritability, and color—is assessed and assigned a value of 0 to 2. The total score, based on the sum of the five components, is determined 1 and 5 minutes after delivery. The score was first described by Dr. Virginia Apgar, an obstetrician Gynecologist who studied the effects of anesthesia given to a mother during labor on her newborn baby. The Apgar score was the result. It was the first standardized method for evaluating the newborn's transition to life outside the womb. "Five points—

heart rate, respiratory effort, muscle tone, reflex response, and color—are observed and given 0, 1, or 2 points. The points are then totaled to arrive at the baby's score." The score was presented in 1952 at a scientific meeting, and first published in 1953. The rapid, simple method reduced infant mortality and laid the foundations of neonatology, the specialty devoted to newborn care (Apgar, 1953 and Apgar 1962).

Table 2

Apgar Scoring System

Sign	0 points	1 point	2 point
Heart rate	Absent	< 100	➢ 100
Respiratory effort	Absent	Slow, irregular	Good, crying
Muscle tone	Flaccid	Some flexion of extremities	Active motion
Reflex irritability	No response	Grimace	Vigorous cry
Colour	Pale, blue	Body pink, extremities blue	Completely pink

Adapted from Apgar (1953)

The 1-minute Apgar score reflects the need for immediate resuscitation. The 5-minute score, and particularly the change in score between 1 and 5 minutes, is a useful index of the effectiveness of resuscitative efforts. The 5-minute Apgar score also has prognostic

significance for neonatal survival, because survival is related closely to the condition of the infant in the delivery room (Apgar 1958). In an analysis of more than 150,000 infants delivered at Parkland Hospital (Casey et al 2001b) assessed the contemporaneous significance of the 5-minute score for predicting survival during the first 28 days of life. They found that in term infants the risk of neonatal death was approximately 1 in 5000 for those with Apgar scores of 7 to 10, as compared with approximately 1 in 4 for those with scores of 3 or less. Low 5-minute scores were comparably predictive of neonatal death in preterm infants.

2.7 Conceptual Framework

In 1998 the Quality Health Outcomes Model (QHOM) was developed to provide a conceptual framework for quality and outcomes research (Mitchell et al., 1998) using a three-dimensional, nonlinear expansion of Donabedian's structure, process, and outcome formulation (Donabedian, 1985;). The QHOM addresses the integration and interaction of four constructs; systems, intervention, patient/client, and outcome. Interventions include clinical processes, both direct and indirect, and the activities by which they are delivered. Typically, interventions are those things that are altered with the intent of changing other constructs in the model. The context in which the intervention is provided also influences outcomes, along with the patient's characteristics and response to intervention. In utilizing the QHOM for this study, the intervention of interest in the study is labor induction. In measuring the impact of system characteristics on outcomes, Mitchell et al. (1998) proposed the use of such variables as hospital ownership, provider network, and hospital size. In the current model, system variables included hospital and provider characteristics. Provider characteristics will consist of type (medical doctor,

Clinical officer, gender, and years in practice). Hospital variables will include teaching status, ownership and bed capacity. For the purposes of this study, patient characteristics will include race, SES, educational attainment, number of prenatal visits, gestation of the pregnancy and parity. Patient characteristics have a significant and obvious influence on outcomes, where variations in outcomes must be adjusted according to patient health, demographics, and risk factors. The final construct in the QHOM model represents end result of care. Clinical outcomes are still the mainstay of quality healthcare research in which relevant performance outcomes include clinical and organizational factors.

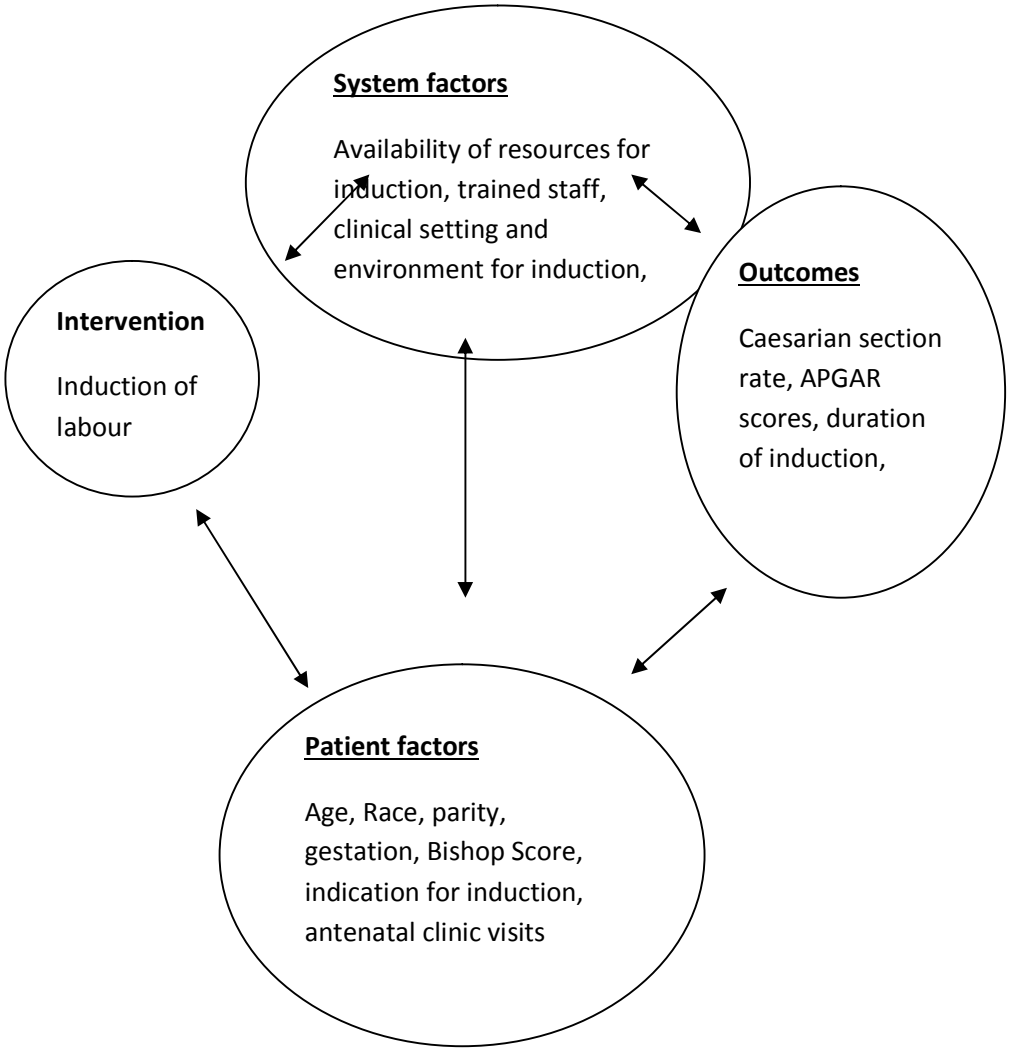

*Figure 1***.** Conceptual framework

CHAPTER THREE: METHODOLOGY

3.1 Study Area

This study was conducted at the Moi Teaching and Referral Hospital (MTRH) – Riley Mother and Baby Hospital (RMBH). RMBH caters for obstetric related cases in the hospital. MTRH is Kenya's second largest national referral hospital with a bed capacity of 550 of which 72 are in reproductive health wards, with a service population of 13 million people. It is located in Western Kenya. MTRH also serves as the teaching hospital for Moi University School of Medicine. The MTRH- AMPATH clinic provides out-patient comprehensive PMTCT care.

The current practice in the department of obstetrics and gynecology is guided by evidence based protocols. Induction of labour protocol (Appendix C) is currently approved in the department and all patients admitted for induction are subjected to it. Both parous and primigravidas were included in the study. Clinical team on duty was responsible for cervical ripening/induction, labour monitoring and delivery for mothers undergoing induction. Fetal monitoring was done for those with meconium staining, prolonged labors or nonreassuring feta heart tones. The RMBH also has operating

theatres for both elective and emergency procedures. Mothers who had indications for caesarian section underwent emergency surgeries. Reasons for caesarian sections were both maternal, fetal or both and included; antepartum hemorrhage, prolonged labour, non-reassuring fetal heart and malposition. Apgar score was done by clinician or nursing officer who received the newborn baby.

3.2 Study Population and Target Population

Study population were women who sought obstetric care in MTRH and were admitted for delivery. The target population were mothers admitted to undergo labour induction in MTRH who met the inclusion criteria.

3.3 Study Design

Descriptive Cross-sectional study.

3.4 Sample Size

The sample size was determined using the fisher et al. (1998) formula;

$$n=\frac{Z^2pq}{d^2}$$

Where:

n = required sample size,

Z = confidence level at 95% (standard value of 1.96),

p = estimated prevalence of caesarean delivery after induction (50%)

q= (1-P)

d = margin of error at 5% (standard value of 0.05).

Therefore:

$$n = \frac{1.96^2 \times 0.5 \times 0.89}{0.05^2}$$

= 384pregnant women

3.5 Sampling Method

MTRH was purposively sampled because it is a referral facility and has a large number of deliveries. Participants who were scheduled for induction were consecutively sampled before induction. The sampled participant was approached by the research assistant and the purpose of the study explained to her before her consent was sought. The induction was done as per the existing MTRH protocol on induction of labour by the clinical team on duty. Those who consented and made the inclusion criteria were recruited until the desired sample size was attained.

3.6 Eligibility Criteria:

Inclusion criteria;

i) Maternal Indications; Chorioamnionitis at term, Diabetes Mellitus, Drainage of liquor

ii) Foetal Indications; chorioamnionitis, post-term gestation, unstable lie after correcting into stable lie, diabetes mellitus at term

iii) Should be a term pregnancy (37 weeks)

iv) Foetus should be in cephalic presentation and singleton.

v) Post-term pregnancies were be included.

Exclusion criteria;

a) Pregnancies with nonreactive Non-stress tests/ nonreassuring foetal status.

b) Previous caesarean section

c) Mothers with Multiple gestation

d) Foetal Malpresentation

e) Contracted pelvis

f) Placenta previa

g) Scarred uterus

h) Transverse lie

3.7 Data Collection

A pilot study was carried out at MTRH hospital to test the feasibility of the study and the questionnaire after obtaining IREC approval and MTRH study permission. The primary source of data was from the patients' charts and files. Mothers sampled and consented had a structured interviewer administered questionnaire (Appendix A) filled by research assistants and the principal investigator. The structured interviewer administered questionnaire captured all the variables of interest for the study. Data collection commenced immediately after study approval and took a period of 9 months.

Mothers selected to participate in the study were treated according to the current MTRH induction of labour protocol. Upon admission, the indication for induction, pre-induction evaluation, pregnancy duration and maternal consent for induction were

verified. No interference with the induction process was done by the principal investigator or the research assistant.

3.8 Data Management and Analysis

Database was created using Excel and exported to SPSS 17 for analysis. It was pass-worded to restrict its access only to principal investigator and research assistants. Data accuracy was maintained by double data entry into the excel database.

Data is presented using percentages, frequencies and graphs. This captures the caesarian section rate, mean APGAR scores and average induction to delivery times. Analysis of data with specific attention to study objective was performed by the statistician in consultation with principal investigator. Content analysis was done manually for qualitative data.

3.9 Ethical Considerations

1. Approval was sought from IREC - Institutional Research and Ethics Committee.

2. The permission to carry out research was granted by MTRH management.

3. Individual consent was sought before carrying out the study from each sampled participant.

4. Privacy and Confidentiality was ensured by consenting participants in private.

5. There was no compensation of study participant.

3.10 Scope and limitation of the study

The study only focused on fetomaternal outcomes of labour inductions.

Factors affecting Fetomaternal outcomes were not be studied. Low birth weight and delayed breastfeeding were not studied as fetal outcomes.

Consecutive sampling was used. This may not allow generalization of results into the general population.

CHAPTER FOUR: RESULTS

4.1 Screening and enrollment into the study

A total of 10382 deliveries were conducted at RMBH during the period of study (July 2013 to May 2014). Of these, 1870 delivered via caesarian section (18% caesarian section rate). During the same period, a total of 479 term induction were done (4.6% of total deliveries were term inductions). 384 met the inclusion criteria. 44 had IUFD, 40 had severe pre-eclampsia before 37weeks, 4 declined to participate in the study, 4 were elective inductions, 1 had twins, and two had uterine scars.

4.2 Target Population Characteristics

A total of 384 women who met the inclusion criteria participated in the study. Their median (IQR) age in years was 26 (22, 29). The median (IQR) gestational age in weeks was 41(39, 41). The mean (SD) number of clinic visits was 3.6(0.8) while the median (IQR) parity was 0(0, 1).

Table 3

Population characteristics

Characteristic	**Result**
Median (IQR) age in years	26 (22, 29)
Mean (SD) number of clinic visits	3.6(0.8)
Median (IQR) parity	0(0, 1)
Education level(average)	Secondary
Median gestational age in weeks	41(39, 40)
Average Bishop score	Poor(4)

It can be seen from the above characteristics that the mean gestational age in weeks was 41, and mothers were mainly primigravidas with an average Bishop Score that was poor.

4.3 Reasons for induction

Among the reasons for labour induction, 225(58.6%) was because of post-term pregnancy, 82(21.4%) PET at term and 70(18.2%) had rupture of membranes at term among others as indicated in figure 3.

The figure below depicts the various indications for induction at term at MTRH.

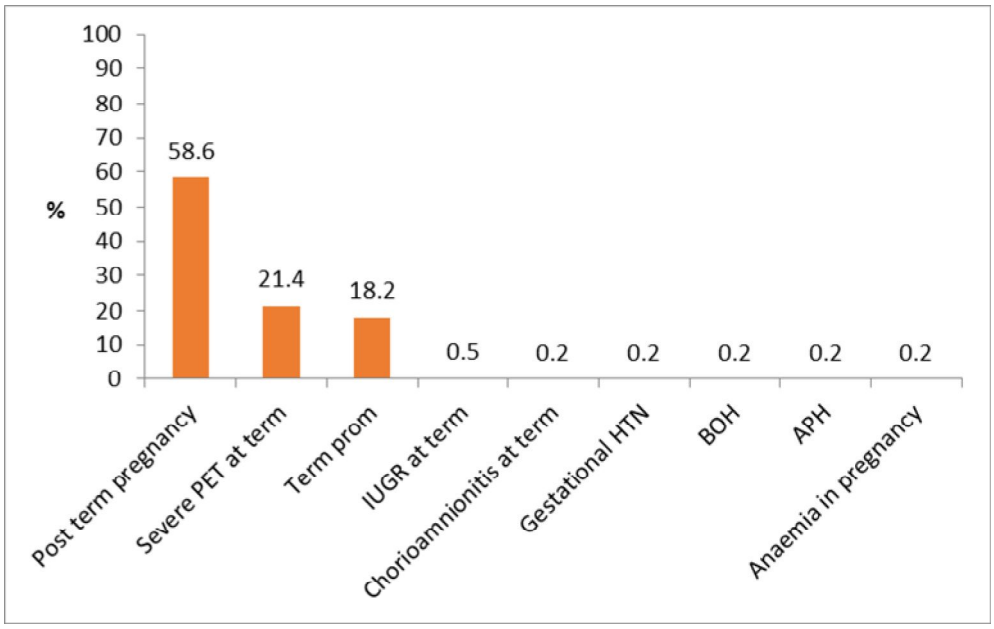

Figure 2. Reasons for labour induction

From the above figure the commonest reason for induction is post-term pregnancy.

4.4 Cervical ripening and induction

Among methods of cervical ripening used, majority 288(75%) used oral misoprostol 50mcg as indicated in table below.

Table 4

Method of cervical ripening used

Method	**Frequency**	**Percent**
Cervical Foley catheter inserted after misoprostol	9	2.4
Cervical Foley catheter with low dose oxytocin	1	0.3
Cervical Foley catheter with traction	7	1.8
Low dose Oxytocin titrated as per protocol	75	19.5
Low dose Oxytocin titrated as per protocol; Oral misoprostol 50mcg	4	1.0
Oral misoprostol 50mcg	288	75.0

The number of clients who were induced with oxytocin was 75 (19.5%). The others (80.5%) needed cervical ripening. Misoprostol was the commonly used cervical ripening agent.

4.5 Duration of labour Induction

The median (IQR) duration of labour induction to delivery time in hours was 18(12, 24.75).

4.6 Mode of delivery following induction at term

The figure below shows the eventual mode of delivery.

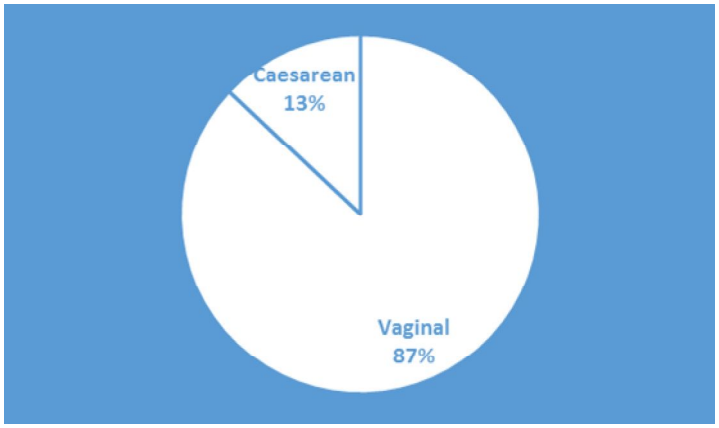

Figure 5. Mode of delivery

The caesarian section rate following induction of labour at term was 13%.

4.7 Neonatal Outcomes

The mean 5 minute Apgar score was 9 as in table 5 below.

Table 5

APGAR scores

APGAR score	**Median (IQR)**	**Mean**
1 minute	9(9, 9)	8
5 minute	9(9, 10)	9
10 minute	10(10, 10)	10

The mean Apgar score was 9 at five minutes.

Thirteen neonates were admitted to the newborn unit due to symptoms of respiratory distress which could among other causes be due to Respiratory Distress Syndrome. Of the

13 newborn admissions, 10 (76.9%) were from mothers who had inductions last more than 48 hours. Of the 13, three died within 72hrs of admission due to neonatal sepsis.

4.8 Summary of results

384 mothers who made the inclusion criteria participated in the study and were treated according to the protocol. The median parity was 0, while the average Bishop Score was poor. Misoprostol was the ripening agent of choice. The main reason for term induction of labour was post-term pregnancy. The average induction to delivery time was 18 hours. The caesarian section rate was 12.8%. The mean five minute Apgar score was 9. Admission to newborn unit was 3.38% (13 neonates out of 384). Poor fetal outcomes recorded for induction/cervical ripening to delivery interval exceeding 48 hours.

CHAPTER FIVE: DISCUSSION

The study evaluated 384 expectant mothers who met the inclusion criteria underwent induction of labour during the study period. The maternal outcomes of interest were induction to delivery time and caesarian section rate. The fetal outcomes of interest were the Apgar scores and need for admission to the newborn unit.

The mean age of patients undergoing induction of labour in this study was 26 years, with the majority (66%) being of age between 22-29 years. This is comparable to the age of patients undergoing induction for all indications at term in a study done at Kenyatta National Hospital (Esiromo M. 2011) where the mean age of patients was 27.6 years, but differs from a similar study done at the Aga Khan Hospital for term inductions where the mean age was 31.2 years (Khisa. 1999, Onyambu B 2001).

Majority of the women undergoing induction were primigravidas (52%).This is comparable to previous studies at KNH (Esiromo M. 2011) and the 40.8% reported worldwide (Joshua P. Vogel, Joa˜o Paulo Souza and A. Metin Gu¨ lmezoglu 2013) where induction was carried out for different indications. The average antenatal clinic visits was 3 in the study. This compares well to the WHO (2012) secondary analysis of data on perinatal and maternal outcomes in selected countries in Africa that reported antenatal clinic visits of 3-4 on average (Joshua P. et al, 2013). The overall Bishop score in this study was poor with a median score of 3. The majority (80%) needed cervical ripening.

The average induction to delivery time from the study was 18 hours with a range of 5hrs to 75hrs. How long the duration of labour should last remains a matter of debate. WHO (2010) recommends a serious review of the induction process if no delivery is achieved within 24hrs. Prior to initiation of the induction process, 80% of mothers had a non-stress test that was reported as reactive. In their study, cunning et al. (2011) while looking at the induction-delivery time at Scotland reported an interval of 22hrs irrespective of the reason for the induction. Guinn et al, 2000) randomized women to intracervical prostaglandin E_2, laminaria plus intravenous oxytocin, or EASI plus oxytocin. Normal saline was infused through the catheter port at 30 mL/hr. Oxytocin infusion was begun immediately after placement of the catheter. The cesarean delivery rate was similar with all three interventions. The induction-to-delivery mean time of 18 hours with catheter infusion was significantly less than that with laminaria plus oxytocin (21.5 hours) or with prostaglandin E_2 gel (24.8 hours). Of the 13 neonates admitted to newborn unit, 10(76.9%) induction to delivery times lasting more than 48 hours. Current

SOGC guidelines (2014) recommend achieving delivery within 24-48 hours upon initiation of induction process.

Induction of labor has been identified as a contributing factor to the rising rate of cesarean deliveries (Cunningham FG et al, 2010). The caesarean section rate following induction in this study was 12.8%. A recent meta-analysis supports this low caesarean section rate compared to the overall institutional rate of 18% during the study period. In the meta-analysis (Ekaterina M. et al 2014) found an overall risk of cesarean delivery was 12% lower with labour induction than with expectant management (pooled relative risk [RR] 0.88, 95% confidence interval [CI] 0.84–0.93; $I2 = 0\%$). The effect was significant in term and post-term gestations but not in preterm gestations. In the same review, Meta-regression analysis showed that initial cervical score, indication for induction and method of induction did not alter the main result. Other studies report higher caesarian section rates. Rashida Admani (2014) looking solely at induction for post-term pregnancy at Kenyatta National Hospital (KNH) found a rate of 32% while Esiromo 2011) found a rate of 26% on inductions for all indications. The rate in this study is low compared to that of 29.65 and 28% described in other settings in Latin America (Guerra et al, 2009) and USA (Pevzner, L., Rayburn, W. F., Rumney, P. and Wing, D. 2009) respectively where induction was also done for all indications.

Though failure to deliver vaginally has been labeled failed induction and forms the basis for a caesarian section, the definition of failed induction remains unclear. Neither Gabbe Obstetrics, Williams' Obstetrics, nor the American College of Obstetricians and Gynecologists (ACOG), has defined failed induction [Gabbe SG et al, 2012 and ACOG bulletin 107)]. Rouse et al, proposed a criteria for failed induction in 2000. In 2011, the

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) and Maternal-Fetal Medicine Units Network (MFMU) reported making failed induction an objective diagnosis, but they too acknowledge that causation could not be established due to labor management that was not standardized [Rouse DJ, et al 2011]. At the time of this writing, no standard definition for failed induction has been adopted.

In this study, the leading cause of induction was post-term pregnancy at 58.6%. This compares well to other works by Esiromo in 2011 found the commonest indication for induction at KNH to be postdates (50.8%) at KNH. Other available studies that have looked at inductions of labour have all been consistent in concluding that postdates is the leading (at least 50%) cause of induction (Mati et al 1983, Khisa 1999, Onyambu 2001, Njagi J. 2002 and Kaguta 1984). Induction of labour at 41 weeks is supported by evidence that show perinatal mortality increases as pregnancy extends beyond 39 to 40 weeks of gestation due to increases in both non-anomalous stillbirths and early neonatal deaths (Cotzias CS. et al 1999, and Rasmussens S. et al 2003). Intrauterine infection, placental insufficiency and cord compression leading to fetal hypoxia, asphyxia, and meconium aspiration are thought to contribute to the excess perinatal deaths (Hannah ME 1993). The perinatal mortality rate at ≥42 weeks of gestation is twice the rate at term, increasing four-fold at 43 weeks, and five- to seven-fold at 44 weeks (Feldman GB, 1992, Naklin J., Backe B., 2006) .Neonates born at ≥41 weeks of gestation experience one-third greater neonatal mortality than term neonates born at 38 to 40 weeks of gestation (Bruckner TA.Cheng YW, Caughey AB, 2008). The WHO (2012) secondary analysis of data on the unmet need of induction in selected countries in Africa reported an induction

of 4.4% with a range of 1.4 – 6.8%. In the same study, Pre-labor rupture of membranes was the commonest indication for induction of labor.

The average 5 minute APGAR scores in our study was 9.The 5-minute Apgar score has prognostic significance for neonatal survival, because survival is related closely to the condition of the infant in the delivery room (Apgar 1958).This is a good result for neonates born post induction of labour in MTRH. 3% of the newborns were admitted to new born unit due to poor APGAR scores and respiratory distress. Guerra et al in their study found an increased risk of Apgar less than 7 at 5 minutes, very low birth weight, NICU admission and delayed breastfeeding associated with labour induction. One large study of elective induction in Scotland also found an increase in NICU admissions following elective induction (Stock S, Ferguson E, Duffy A., Ford I 2012); whether this is only due to hospital policies following induction is unclear.

In this study, the leading institutional factor that affected outcomes with the current protocol on induction was failure to review clients at the right scheduled intervals in 30% of the time. This probably contributed to the prolonged inductions and poor neonatal outcomes seen in the study. According to the works of Joshua, Joao and Metin (2013) when they analyzed the WHO secondary data on maternal and perinatal outcomes on the unmet need of induction of labour in Africa, they identified lack of equipped hospitals including essential drugs and supplies for induction, inadequate staffing and limited skilled personnel as some of the unmet needs that contributed to low rates of inductions in Africa.

5.1 Conclusions

The commonest reason for term induction at MTRH is post-term pregnancy.

The mean induction to delivery time for term inductions is 18 hours.

The overall caesarean section rate following term induction at MTRH is 12.8 %.

The median 5 minute Apgar score following induction at MTRH was 9.

Fetal outcomes were poor for cervical ripening/induction of labour to delivery time lasting more than 18 hours.

Induction of labour at term for all indications with poor Bishop Score is good.

5.2 Recommendations

MTRH to continue use of the current protocol on induction in view of the current outcomes.

Cervical ripening/labour induction to delivery interval should not exceed 48 hours.

There is need for a comparative study to compare fetomaternal outcomes for spontaneous and induced labor.

5.3 Study Limitations.

Long term maternal-fetal outcomes were not considered. Follow up of mothers and their neonates was not done.

There was no comparison group to the study.

Consecutive sampling was used and this may not allow generalization of results into the population.

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APPENDIX A

Questionnaire

A data collection tool for the Masters of Medicine in Reproductive Health project on "The Fetomaternal outcomes of elective induction of Labour at term in MTRH, Eldoret.

Interview date ……..……

Questionnaire number ……..

Good morning/ afternoon/How is your night?

My name is **Dr. Bett Kipchumba (research assistant name)** and I am carrying out a study in this Hospital to find out maternal and foetal outcomes of induced labour at MTRH.

The study outcome will help in future management of induced labour in the hospital. The answers you give will be treated with confidence and your identity will not be revealed to anyone irrespective of his or her status in society.

Thank You.

PRIMARY DATA (Extracted from patient medical files or charts)

Client details

Age…….religion…….district……

Parity……

Last Normal Menstrual Period (LNMP)……...

Gestation by dates…….. Number of clinic visits attended……..

1. What is the reason for induction? (a)Term PROM

   b)post-term pregnancy(c) Severe PET at term (d) Chorioamnionitis at term (e) IUGR at term (e) Diabetes at term (f) Others(specify

   ……..

2. What was the Bishop score before the induction was begun? (Tick where appropriate)

Table A1

Cervix	**0**	**1**	**2**	**3**
Dilatation (cm)	Closed	1-2cm	3-4cm	≥5cm
Cervical Length (cm)	3-4 cm	2cm	1-2cm	<1cm
Consistency	Firm	Medium	Soft	-
Position	Posterior	Midline	Anterior	-
Total Score=10 Favorable=6-10 Unfavorable=0-5				

Total score

a) Less than 6 b) 6 to 9 c) More than 9

3. What method/methods of cervical ripening and induction were chosen?

   a) Oral Misoprostol 50mcg

   b) Vaginal misoprostol 25mcg(Vagiprost)

c) Misoprostol gel (Dinoprostone)

d) Low dose Syntocinon

e) Cervical Foley catheter with traction

f) Cervical Foley catheter with low dose Syntocinon

g) Cervical Foley catheter inserted after Misoprostol

4. What date and time was cervical ripening/ induction started? a) Date ---/---/----

   b) Time ------ hours

5. If catheter was inserted, what was the time interval between catheter insertion and falling?

   a) Less than 12hrs b) 12hrs to 18hrs c) 18hrs to 24hrs d) More than 24hrs

6. What was done when the catheter fell? (a) ARM (b) Syntocinon started (c) No intervention begun

7. How many doses of misoprostol were given orally?

   1 2 3 4 5 6

8. How many doses of misoprostol were given vaginally?

   a) 1 b) 2 c) 3 d) 4 e) 5 f) 6

9. What was the time interval between the given dosages of misoprostol?

   <4hrs = A 4-6hrs =B >6hrs = C

   a) 1st and 2nd dose

   b) 2nd and 3rd dose

   c) 3rd and 4th dose

   d) 4th and 5th dose

   e) 5th and 6th dose

10. Was Syntocinon used after the Misoprostol? a) Yes b) No
11. If yes to question 12, what dose of oxytocin was used?
    a) 2.5 units b) 5 units c) 5 units then 10 units d) 15 units
12. What was the eventual mode of delivery?
    a) Vaginal delivery b) Caesarian Section
13. What was the time interval from induction of labour to delivery in hours? ----------
    -
14. If caesarian section was done, what was the indication? a) foetal distress b) cervical dystocia c) failure of descent d) Specify others
15. What were the APGAR scores of the baby? a) At 1 minute b) At 5 minutes
    a) At 10 minutes
16. Were there any obvious gross malformations/deformations on the baby at birth?
    (a) Yes (b) No
17. If yes to 17 above, specify……

APPENDIX B

Consent Form for the Research

Introduction

My name is Dr. Bett Kipchumba. I am a postgraduate student in Moi University. I am doing a research on Fetomaternal outcomes of labour inductions at Moi Teaching and referral Hospital. Induction of labour is a common obstetric procedure. I am going to give

you information and invite you to be part of this research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask me or any of the staff.

Purpose of the research

Induction of labour is a common obstetric practice. It is dome for many reasons e.g. for pregnancies that have gone past the expected dates. When induction is done we aim at a successful vaginal delivery. We also want to deliver a good baby. This research will help us know how long inductions last in this hospital.

Type of Research Intervention

This research will involve vaginal examinations, insertion of vaginal tablets or cervical catheter insertion. You may also be given a tablet to swallow.

Participant selection

I am inviting all expectant mothers with term pregnancies for induction of labour to participate in the research on the Fetomaternal outcomes of labour inductions.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this hospital will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this hospital for induction of labour. You may change your mind later and stop participating even if you agreed earlier.

Duration of the study

The research takes place over the days you will be on induction until deliery. I will also ask you for your comments for the whole process of induction after you deliver; this will mark the end of the research.

Risks and benefits

This is a minimal risk study. There would be no added physical pain to the participants. However, there would be psychological and social risks appertaining this study. These risks would be reduced by keeping data confidential and not accessible to unauthorized persons. Consenting process would also take place in private consultation room.

Confidentiality

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is

and we will lock that information up with a lock and key. It will not be shared with or given toanyone except ethics and research board and the supervisors.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this hospital in any way. You will still have all the benefits that you would otherwise have at this hospital. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here.

Who to Contact.

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact the following: [Dr Bett Kipchumba, cell phone 0721894658, e-mail kchemalan@yahoo.com)

This proposal has been reviewed and approved IREC, which is a committee whose task it is to make sure that research participants are protected from harm.

Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been

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

Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands what will be done.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

APPENDIX C

MRTH Induction of Labour Protocol Definitions

Labour

Labour is a sequence of uterine contractions that results in progressive effacement and dilatation of the cervix leading to the expulsion of the products of conception per vagina.

Induction of labor (IOL)

Induction of labour is a medical procedure designed to safely initiate labor for specific obstetric indications. The objective of induction of labour is to start active labour and to achieve a vaginal delivery. In order to increase the chances of a successful vaginal delivery cervical ripening may be needed prior to induction.

NOTE: It is important that once an induction has been started that it should not be stopped until delivery has been achieved.

Augmentation of labour

Augmentation is the use of oxytocin to increase the frequency, intensity and duration of uterine contractions in a patient whose labour has commenced spontaneously but is proceeding slower than acceptable as per partograph.

Cervical Ripening

Cervical ripening a process used prior to induction of labour to promote a successful induction of labour. It is the thinning, softening, and opening of the cervix prior to active labour. Whether or not a patient needs cervical ripening should be determined using the Bishops Score.

Bishops Score Table

A successful induction of labour with oxytocin is predicted by the Bishops score. If the Bishops score is less than 5 the patient will need cervical ripening prior to starting the induction with oxytocin.

Table C1

Parameter	**Score**			
Cervix	**0**	**1**	**2**	**3**
Dilatation (cm)	Closed	1-2cm	3-4cm	≥5cm
Cervical Length (cm)	3-4 cm	2cm	1-2cm	< 1cm
Consistency	Firm	Medium	Soft	-
Position	Posterior	Midline	Anterior	-
Total Score=10 Favorable=6-10 Unfavorable=0-5				

***Station** excluded due to its relative lack of influence on the final score among patients of Negroid descent.

***Effacement** may be measured more reproducibly as cervical length in centimeters. Percent effacement is merely a presentation of actual over normal cervical length.

Pre-Induction Assessment

Identify the Indication: See below for a list of the most common indications. The indication must be compelling enough to be an indication for Caesarian Section in case of failure of induction. Exclude any contraindications. Evaluate the patients Bishops score: If Bishops score is < 5, cervical ripening must be administered. If Bishops score is ≥ 5 then start induction with oxytocin. Ideally, cervical ripening efforts should be performed at night initiated about 8 PM while induction procedures should be scheduled to commence before 10AM in the morning.

Indications for Induction

Maternal

- Pre-eclampsia and Eclampsia
- Chronic Hypertension
- Diabetes Mellitus
- Heart Disease
- Chronic renal disease
- IUFD
- Chronic polyhydramnios with maternal respiratory distress
- Abruptio placentae

Fetal

- Postdates gestation
- Rhesus alloimmunization

- Chorioamnionitis
- PROM after 34 weeks
- Placental insufficiency
- Suspected IUGR
- Previous history of IUFD – Timely intervention
- Diabetes Mellitus
- Unstable lie after correcting into longitudinal lie.
- Congenital malformations
- Abruption placentae

Contraindications to Induction

Absolute

- Contracted pelvis
- Placenta previa
- CPD
- Uterine scar due to previous classical cesarean section
- Myomectomy entering the endometrium
- Metroplasty procedure
- Transverse lie.
- Pelvic tumor

Relative

- Breech presentation
- Oligohydramnios

- Previous cesarean section with lower segment transverse scar
- Severe cardiac disease

IV. Approved Cervical Ripening Methods at MTRH

A. Pharmacological

Misoprostol (Vagiprost): 25 mcg PV or PO every 4 hours. May repeat for a total of four doses. May administer buccal misoprostol in case of rupture membranes.

DO NOT USE OTHER FORMULATIONS (ex 100mcg, 200mcg)

Dinoprostone (PGE2): 3mg in 2.5 mL viscous gel of colloidal silicon dioxide in triacetin, every 6 hours intracervically or in posterior fornix or 3mg pessary in posterior fornix every 6rs. May repeat for a total of three doses.

Low dose Oxytocin: 5 units of oxytocin is diluted in 500ml of normal saline and infused starting at 4 drops per minute for 6 - 12 hours. Do not dose escalate for cervical ripening.

B. Mechanical

Foley Catheter: 25- to 50-mL balloon is inserted just above the internal os into the extra-amniotic space to stretch the cervix and promote endogenous release of prostaglandins.

Sweeping of Membranes: A vigorous digital exam of the cervix is performed by hooking the index finger in the extra amniotic space just beyond the internal os to promote endogenous release of prostaglandins. This is repeated every 4 hours.

Nipple Stimulation: Patients stimulate their own nipples to promote endogenous prostaglandin release. Stimulation is performed for 5 minute intervals and repeated every 15 minutes for a total of 4 hours**.** More aggressive protocols for nipple stimulation is associated with uterine hyperstimulation.

V. Approved Methods for Induction of Labor at MTRH

Oxytocin

If the patient has undergone cervical ripening using prostaglandins wait at least 6 hours after the last dose before initiating oxytocin or performing amniotomy At MTRH we use a low dose oxytocin protocol as follows: 5 units of oxytocin is diluted in 500ml of Normal Saline and infused starting at 4 drops per minute and escalated by 4 drops per min every 30 minutes. The dose is escalated until 3 contractions in 10 minutes, each lasting 40 seconds or more, are achieved and maintained at that rate. If there are not 3 contractions in 10minutes at 60 drops per minute, then finish the solution at that rate. Then start a new bottle with 10 units of oxytocin in 500mls and start infusing at 30 drops per min and escalate by 4 drops every 30 minutes as before, to a maximum dose of 40 drops per minute.

If hyperstimulation (>6 contractions per 10 minutes lasting 40 seconds or more) occurs, stop infusion and administer Salbutamol.

Amniotomy

Note: Amniotomy is not mandatory prior to initiation of oxytocin.

Artificial rupture of membranes using Amnihook or Kocher's artery forceps once contractions have started can augment the progress of labour and speed the time to delivery in multiparous patients only. In nulliparous women amniotomy has not been shown to promote a faster time to vaginal delivery. And is associated with increased risk of chorioamnionitis. In cases of polyhydramnios, the release of amniotic fluid must be controlled to prevent abruption placentae due to rapid uterine decompression.

NOTE: Amniotomy should not be performed routinely in patients with HIV or Hepatitis. However in patients with prolonged labor amniotomy can be used to promote a smooth vaginal delivery.

VI. Patient Monitoring during Induction of Labor

NOTE: The labour nurse is responsible for monitoring the patient (as listed below), completing the partograph and advising the Intern, Medical Officer or Consultant of any deviation from expected normal values.

- Partograph should be started once the patient is in active labour or started on oxytocin.
- Blood pressure at least every 4 hours, and every 1 hour in pre-eclamptic/eclamptic patients.
- Pulse every 30 minutes.
- Abdominal palpation to assess contractions for ten minutes every 30 minutes
- Assessment of cervical dilatation at least every 4 hours or more frequently if indicated.

- Assessment of Fetal heart rate every 30 minutes, listening after a contraction for at least one minute.
- Assessment of the color of the liquor, for meconium or blood staining

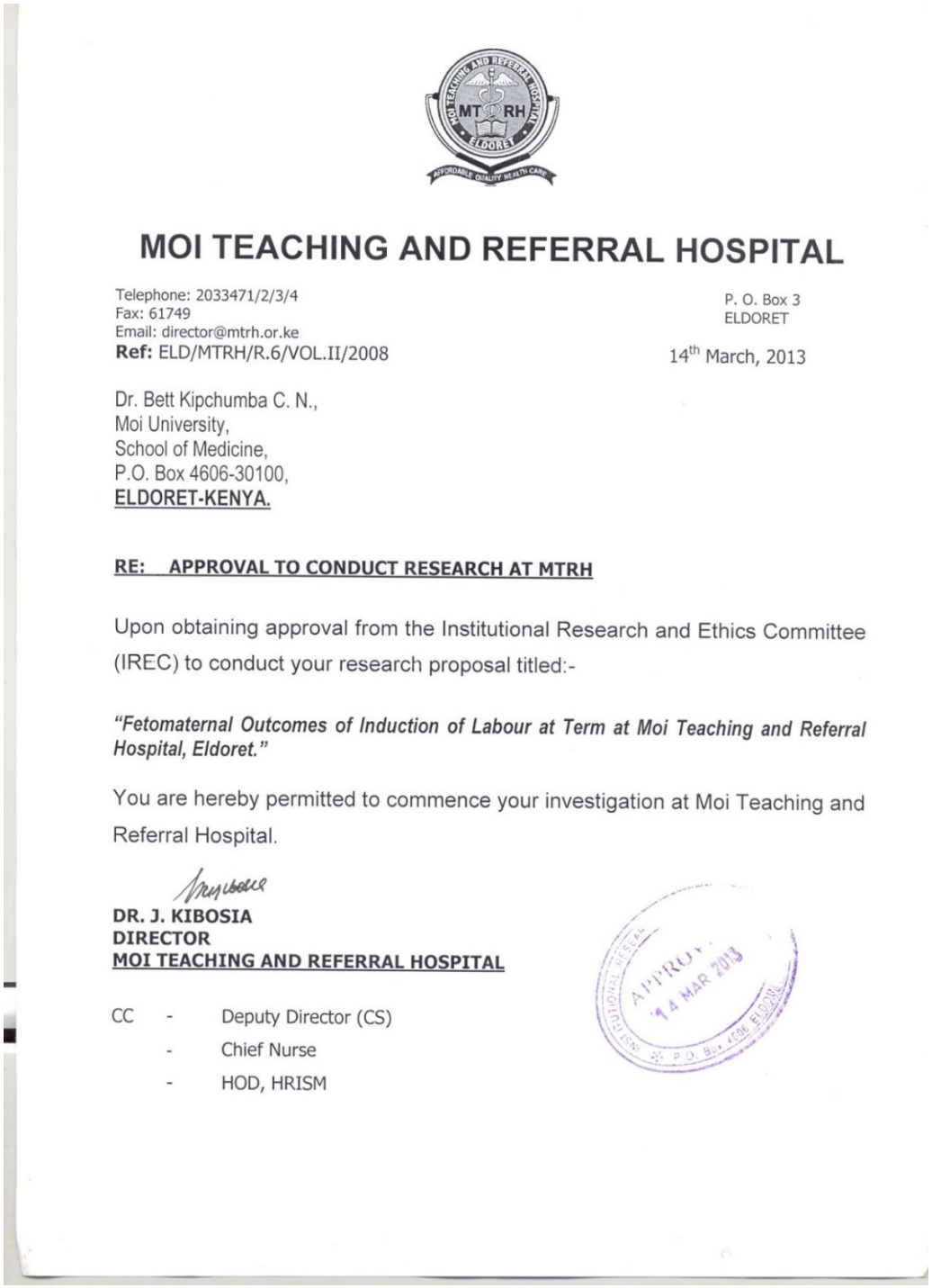
VII. Induction of labour after low transverse cesarean

Vaginal birth after cesarean section is acceptable for spontaneous labour and if the induction with oxytocin and amniotomy alone.

If induction is to be performed with a previous low transverse uterine scar, then the consultant must review the patient and document the decision in the medical record. In these cases the medical officer must manage the induction of labor and must review the patient every two hours.

APPENDIX D

MTRH Approval



MOI TEACHING AND REFERRAL HOSPITAL

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

P. O. Box 3
ELDORET

14th March, 2013

Dr. Bett Kipchumba C. N.,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

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

"Fetomaternal Outcomes of Induction of Labour at Term at Moi Teaching and Referral Hospital, Eldoret."

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

DR. J. KIBOSIA
DIRECTOR
MOI TEACHING AND REFERRAL HOSPITAL

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

APPENDIX E

IREC Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

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

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

Reference: IREC/2012/224
Approval Number: 000952

14th March, 2013

Dr. Bett Kipchumba C N.,
Moi University,
School Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Bett,

RE: FORMAL APPROVAL

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

"Fetomaternal Outcomes of Induction of Labour at Term at Moi Teaching and Referral Hospital, Eldoret."

Your proposal has been granted a Formal Approval Number: **FAN: IREC 000952** on 14th March, 2013. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 13th March, 2014. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

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

Sincerely,

25/03/2013

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

APPROVED
14 MAR 2013

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