ASSOCIATION BETWEENBODY MASS INDEX IN EARLY PREGNANCY AND THE OUTCOMES OF INDUCTION OF LABOUR AT KENYATTA NATIONAL HOSPITAL

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DEDICATION

Dedicated to my familyfor their motivation and belief in me during my training in medicine.

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LIST OF ABBREVIATIONS

ACOG - American College of Obstetricians and Gynecologists

APGAR – Appearance, Pulse, Grimace, Activity, Respiration

BMI - Body Mass Index

IOL - Induction of Labour

KNH - Kenyatta National Hospital

NICE - National Institute of Clinical Excellence

NRFS – Non-Reassuring Foetal Status

RCOG - Royal College of Obstetricians and Gynaecologists

UK - United Kingdom

WHO - World Health Organisation

UoN – University of Nairobi

OPERATIONAL DEFINATIONS

Labour - Regular uterine contractions with progressive cervical dilation and effacement.

Failed Induction of Labour – Failure to achieve labour 24 hours after initiation of induction.

Term gestation – Gestation of 37 weeks or 259 days and above by the first day of the last normal menstrual period or by a first trimester ultrasound estimation.

Elective induction - Induction of labour at term without a medical indication.

ABSTRACT

Introduction: Body mass index (BMI) has many medical implications. High BMI has been shown to increase the risk of certain obstetric complications. Induction of labour (IOL) is a common obstetric intervention and the various outcomes of IOL have been well documented. Failed induction is a possible outcome of IOL and various physiologic and anatomic factors including BMI have been cited as possible risks. Local studies are lacking on how BMI may affect the process of IOL and that was the purpose of this study.

Objective: To determine the association between body mass index in early pregnancy and the outcomes of induction of labour at Kenyatta National Hospital.

Study setting: The study was conducted in the Kenyatta National Hospital labour ward.

Study design: A comparative cross sectional study.

Study population: The study included pregnant women planned for induction of labour with misoprostol. A total of 204 women were included with 103 women having normal BMIand 101 women with BMI of 25or above.

Study methodology: Between the months of June and October 2018, eligible women were recruited consecutively into the study once a decision to induce labour was made. Baseline data was obtained and they were then allowed to continue with IOL as per the Kenyatta National Hospital protocol until delivery of the baby. Outcomes of interest were recorded after the mother had delivered. These outcomes included failed induction of labour, the mode of delivery, the neonatal APGAR score at five minutes, the need for augmentation of labour and any fatal maternal or neonatal outcomes.

Results: Most of the women in the study were in their second decade of life, married, self employed or unemployed. The women with high BMI were more likely to have had a prior delivery and they gave birth to heavier babies. The indications for IOL included postdatism, reduced foetal movements at term, rhesus negative blood type and elective induction at term. The overall rate of failed IOL was 11.8%, Caesarean section rate was 28.4% and 60.2% of all the women who achieved labour required augmentation with oxytocin. The most common indication for Caesarean section was failed induction in the high BMI group and prolonged labour in the normal BMI group. The Caesarean section rate did not significantly differ between the two groups. The rate of failed IOL was higher in the high BMI group (OR 3.5; CI 1.3, 9.2; *p* 0.008) as compared to the normal weight women. A high BMI change during pregnancy was however not associated with higher odds of the outcomes.

Conclusion: High early pregnancy maternal BMI is associated with a higher likelihood of failed IOL. After induction of labour at term with misoprostol, women with above normal BMI are more likely to go for Caesarean section due to failed IOL as compared to normal BMI women.

Recommendations: Women should be counselled about achieving appropriate weight preconceptionally. Those with high BMI and undergoing IOL should also be informed about possible outcomes of induction of labour, including a higher risk of induction failure. Further to this, various ways of achieving labour in overweight and obese women should be explored.

INTRODUCTION

Body mass index (BMI) is a measure of body fat based on height and is calculated as a person's weight in kilograms divided by the square of height in meters. BMI is useful in screening for people who may be at risk of certain health conditions based on the amount of fat in their body.

Based on BMI, people are categorized as underweight, normal weight, overweight and obese. An adult with a body mass index of below 18.5 is considered underweight while that of between 18.5 and 24.9 is considered normal. Individuals with BMI equal to or above 25 are considered overweight. A body mass index of equal to or greater than 30 kg/m^2 is considered obese. Among the obese, three broad categories have been defined as class I with BMI of between 30 but less than 35, class II with a BMI of equal to 35 but less than 40 and class III with BMI equal to or more than 40(1).

According to WHO, by the year 2014, more than 1.9 billion adults, 18 years and older, were overweight. Of these over 600 million were obese. Sedentary life and an increased intake of energy-dense foods rich in fats are important factors in causation of obesity(1,2).Obesity is likely to become a major health issue in Kenya because other than the two stated factors, a desire to have a larger body size has also been observed in low socioeconomic urban areas of Kenya(3). In addition to this, it is estimated that 62% of women aged 15-49 years do not engage in physical activity that is likely to reduce their risk of non-communicable diseases as recommended by WHO(4). Extremes spectra of malnutrition exist in Kenya, such that some rural areas and urban slums suffer under nutrition while other urban areas and some rural areas suffer obesity.

Failed induction of labour is one of the obstetric complications that lead to an increase in the caesarean section rates. Local studies have found an induction of labour failure rate as high as 32%(5). It is good to know all the factors that contribute to induction of labour failure in order to address them and better manage women undergoing this process. Since there is expected population difference on progress of labour after induction due to varying body forms, it would be important to see whether weight influences induction outcomes in a Kenyan population, and this was the purpose of this study.

LITERATURE REVIEW

Maternal BMI and pregnancy outcomes

High maternal body mass index (BMI) in pregnancy is associated with various risks to both the mother and the baby. Obese pregnant women have a higher risk of developing gestational diabetes mellitus, preeclampsia, venous thromboembolism, spontaneous abortion and sleep apnoea. Babies born to obese mothers are also at risk of congenital malformations, macrosomia and still birth (6–14).

In a study of 24,505 singleton pregnancies in Denmark, maternal obesity was associated with more than double the risk of stillbirth and neonatal death(15). A local study, which included 400 women who delivered at the Kenyatta National Hospital (KNH), increased early pregnancy maternal BMI presented similar adverse maternal and foetal outcomes. According to these authors, increased maternal BMI was found to be associated with increased risk of pregnancy induced hypertension, preeclampsia, foetal macrosomia, post term pregnancy, induction of labour(IOL) , caesarean delivery and still births(14). When 186,087 primiparous women in Sweden were included in a population study, high maternal BMI in the first trimester and a greater change in BMI during pregnancy were associated with longer gestation and increased risk of postdates pregnancy(16).

Obesity is also associated with a higher risk of caesarean section. Poobalan and colleagues were able to demonstrate this after a Meta analysis of 11 published cohort studies. According to them, the pooled Caesarean delivery risk increased by 50% in overweight women and was more than double for obese women compared with women with normal BMI(17).

Due to the risks associated with obesity in pregnancy, professional bodies like ACOG and RCOG recommend pre-conception weight loss. When this is not achieved, then in the antenatal period, obese women should be screened for gestational diabetes and their risk of venous thromboembolism assessed(6,13,18).

Low maternal body mass index on the other hand is mostly associated with preterm delivery. In a meta-analysis of 78 studies conducted by Hanz et al, underweight women were found to have a higher risk of preterm delivery and low birth weight babies(19). Near similar conclusion was reached after a study of 437,403 births and the authors recommended a consistent weight gain of 0.23kgs to 0.68kgs per week in order to reduce the associated risks(20).

Weight gain in pregnancy

Pre-conception BMI is considered important in considering the risk a woman has in pregnancy. However, where no such record exists, it is recommended that BMI be calculated in the first trimester as the mean weight and body composition does not change much in early pregnancy (13). In the first trimester, it is considered normal for women to gain between 0.5 to 2 kilograms. Thereafter, normal weight gain is different for the obese and the non-obese. A total gestational weight gain of between 5 to 9 kilograms is normal for obese women, while 7 to 11.5 kilograms is the expected gain for the overweight. For the women with normal BMI, a total gestational weight gain of 11.5 to 16 kilograms is the normal and for the underweight, 12.5 to 18 kilograms(21).

It is estimated that every 3 kilograms of weight gained in pregnancy, the BMI increases by approximately 1 unit(22). The benefit of intentional weight loss in pregnancy as a means to reduce the risks of obesity is unclear and may increase the risk of small for gestational age foetus(23).

Maternal BMI, parturition and Induction of Labour

Molecular studies have been done to try and elucidate how BMI affects pregnancy and parturition. There are suggestions that obesity might cause changes to the placenta, amnion, cervix and myometrium that that may alter foetal development and the onset and synchronization of parturition(24).

Pre-clinical human and animal model studies suggest that a maternal high fat diet may lead to reduced utero-placental blood flow which can compromise the foetus(25) and a reduction in connexin-43(26)and oxytocin receptor expression(27)which are important markers of uterine contractility. In other studies, high leptin levels have been implicated on reduction of uterine contractility(28,29). In vitro studies measuring myometrial contractility and calcium levels have also found lower contractility and calcium levels in the obese women(30).

Such studies as these may provide insight into how best to manage obese women in pregnancy. It is also because of such studies that debate may arise on whether perhaps optimized induction and augmentation regimens may be necessary to enhance the chances of vaginal delivery in obese women(24).

Delivery in women with high BMI also carries additional risks as compared to normal weight counterparts. Vaginal delivery in these women is associated with ineffective uterine contractility and concomitant labour arrest which raises the risk of caesarean section(31,32). The arrest is mostly observed as prolongation of the first stage of labour(33). One can then wonder if women with high BMI should be allowed more adequate time for trial of labour. The flipside to this is the fact that abdominal obesity can also present a challenge in foetal monitoring during labour.

On the same, the risk of non elective caesarean section due to foetal distress has also been found to be higher with raised maternal BMI(31).

The rate of failure of trial of labour in women with prior caesarean deliveries is also higher in obesity. In a study of 14,142 women undergoing trial of labour after previous caesarean delivery, Hibbard et al. found that increasing BMI was associated with a high rate of failure and an increase in uterine rupture rates(34).

Caesarean section delivery in the obese also presents its own technical difficulties. Obesity is considered a risk factor for wound infection, more surgical blood loss and longer operation time(35).The risk of endometritis is also higher in the morbidly obese patient(36). Post operatively, the obese patient also has a high risk of developing thromboembolism.

Induction of labour has been defined by the WHO as the process of artificially stimulating the uterus to start labour(37). It is estimated that up to 25% of all deliveries at term in developed countries are induced(38) while at KNH, the rate is estimated at 12.7%(39). Induction of labour is recommended when the benefits to either the mother or the foetusoutweigh the gains of continuation of the pregnancy. These circumstances can be absolute indications, where induction is the only safe way to ensure the well being of either the mother or the baby, or relative indications where there is no major risk and induction is done for convenience reasons.

Common indications for induction of labour include pregnancy beyond 41 weeks gestation, premature rupture of membranes, chorioamnionitis, hypertensive disorders at term, foetal death in utero among others. Another contentious emerging indication is maternal request for convenience purposes(40).

Conditions where induction of labour is not recommended include women with a caesarean section scar, when the gestation is unknown(38), when there is foetal compromise(40) and in cases where vaginal delivery is contraindicated.

There are various methods for induction of labour. They can be pharmacologic, mechanical or natural. The WHO approves the use of prostaglandins, oxytocin or mechanical dilation with a balloon catheter as methods of induction of labour(38). These are the methods used at Kenyatta National Hospital. The prostaglandins available locally are misoprostol a prostaglandin E1 analogue where at term, a dose of 25ug six hourly orally or vaginally for 24 hours is recommended, and dinoprostone a prostaglandin E2 analogue inserted vaginally in the posterior fornix six hourly and repeated once if labour is not achieved. Prostaglandins used as induction of labour agents have the unique capability to ripen the cervix and at the same time increase the tonicity of the uterus.

Oxytocin is the preferred method of induction with ruptured membranes or when the Bishop score is more than seven. Oxytocin alone without amniotomy as a method of labour induction is less effective(40). In the recent past, oxytocin was generally the most commonly used method in

Africa and Asia and success rates of above 80% have been cited(41). However, with recent availability of misoprostol as an essential obstetric drug, these statistics are bound to change.

There are other methods of induction practiced that may be effective. For example, sweeping the membranes during vaginal examination, despite causing discomfort to the mother, is generally safe and effective where there are no other complications(38,40,42). A combination of both mechanical and pharmacologic methods of induction is also practiced.

There are various complications associated with induction of labour. These include uterine hyper stimulation, uterine rupture, cord prolapse at membrane rupture and failed induction(40). Failed induction is fairly common. It is estimated that as many as 22% of women undergoing IOL in the UK will require emergency caesarean delivery with a further 15% requiring instrumental delivery(40).

The definition of failed induction varies greatly. In some studies, failed induction has been defined as defined as delivery by caesarean after an attempted induction(43). The National Institute of Clinical Excellence however defines failed induction as labour not starting after one cycle of treatment(40). This is an acceptable definition because the initial aim of induction is to achieve labour. With normal labour being defined as uterine contractions that result in progressive dilation and effacement of the cervix, then a cut off of when this is achieved needs to be defined. Perhaps an even more specific definition would be the one adopted by Banos et.al that put failed induction as the inability to achieve the active phase of labour(44).

The rate of failed induction at KNH is 32% and the factors associated with failure include low Bishop score, foetalmacrosomia and primiparity(5). Multiparous women with favourable Bishop Score favour better when induced.

With no other complications, and where delivery of the foetus is not an emergency, failed induction is not an absolute indication for caesarean delivery. There is room for another attempt at induction(38,40)provided the woman has been counselled and is agreeable to this. Consideration of risk factors of failed induction like nulliparity, poor Bishop score(44) among others may further aid in decision making at this point.

High maternal BMI on its own is not an indication for induction of labour(38,40). However, when there is another compelling indication for induction, overweight and obese women are induced in a similar fashion to their normal weight counterparts. The various protocols for induction of labour are standardized for all women; doses are calculated based on the gestational age and not weight as may be the case with other drugs.

However, women with high BMI are much more likely to have failed induction than their normal weight counterparts(43,45). In a population-based cohort study conducted in Ohio where 80,887 women were recruited, this risk was found to increase with the increase in BMI. In this study, induction failure rates ranged from 13% in normal weight women through to 29% for the obese

to as high as 80% in class III obese women without a prior vaginal delivery and with a macrosomic baby (43). In another study comparing IOL outcomes between 144 non-obese and 144 obese women, Maged et al. concluded that there is a higher risk of Caesarean section delivery in obese postdate pregnant women undergoing IOL as compared to their non-obese counterparts(46).It has also been shown that obese women undergoing induction of labour with oxytocin are likely to require a higher dose in order to achieve active labour(47).

Body mass index has also been used as a predictor of the success of induction of labour by some scholars. In a study of 189 singleton pregnant women, Uyar et al. compared the predictive value of Bishop score alone compared to sonographic cervical length combined with BMI and concluded that the latter were better predictors of success with high BMI and longer cervix predicting low success rate(48). Near similar conclusion was reached when 72 women with twin gestation at 36 weeks and scheduled for induction were enrolled in a study. Bishop score, BMI and sonographic cervical length were compared in this study and it was found that BMI independently had better predictive value as compared to cervical length and Bishop score(49). In another study of 509 nulliparous women, the cervical dilation rate was inversely associated with the maternal weight(50).

Such findings stimulate debate on the need for different induction of labour approaches based on maternal BMI. Also, other approaches like early cervical stimulation at term to try achieve spontaneous labour without the need for induction in the overweight and the obese may also be contemplated. Perhaps even, using BMI combined with other parameters, it might be possible to predict a woman’s chance of success at induction more accurately.

JUSTIFICATION

Induction of labour is a common obstetric intervention and had previously been shown to have a failure rate of up to 32% at KNH among other maternal and neonatal risks. Although some of the factors associated with poor outcomes are known, there is still a gap in knowledge. Knowing all the factors that affect IOL can aid in predicting outcomes.

The ability to predict induction of labour outcomes can help clinicians in counselling the patient before on expectations. This is also a basis for future research on different techniques of achieving labour when the prognosis of induction is poor, for example, combined methods, membrane sweeps at term among others.

Prior to this, no local studies had specifically targeted this area and some of the available studies done elsewhere had vague definitions of outcomes and hence may not represent the true picture.

THEORETICAL FRAMEWORK

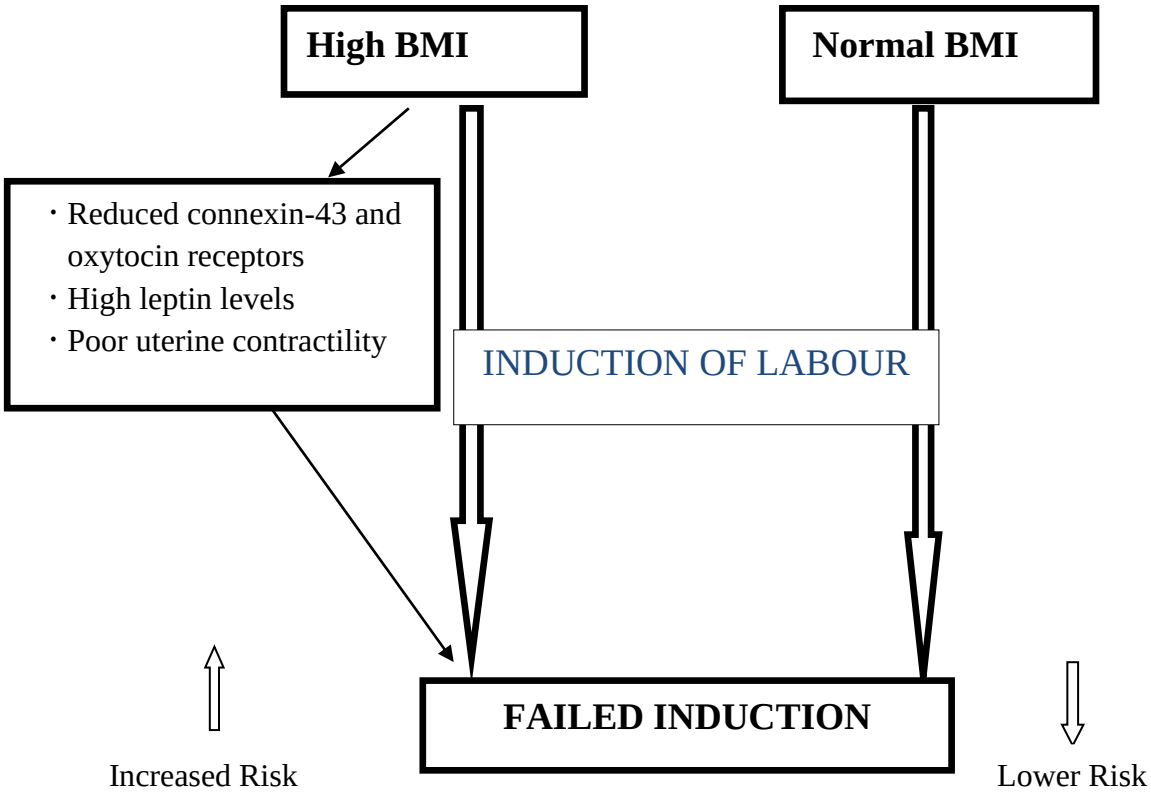
Women were grouped using their weight before twenty weeks of pregnancy into those with a BMI of 25 orabove and those with normal BMI (BMI 18.5 to 24.9). Body mass index had been

shown to influence the outcomes of pregnancy and delivery and was expected to have an impact on the outcomes of induction. High BMI is associated with high leptin levels and reduced oxytocin receptors which are postulated to cause poor uterine contractility. The primary focus of the study was the association between BMI in early pregnancy and the outcomes of induction.

The outcomes of interest in the women undergoing induction of labour included:

1. Rate of failed induction of labour in the different groups.
2. The mode of delivery.
3. Foetal APGAR score at five minutes.
4. Any fatal maternal or foetal outcomes.

CONCEPTUAL FRAMEWORK



RESEARCH QUESTION

What is the association between body mass index in early pregnancy and the outcomes of induction of labour at Kenyatta National Hospital?

OBJECTIVES

Broad objectives

To determine the association between body mass index in early pregnancy and the outcomes of induction of labour at Kenyatta National Hospital.

Specific objectives

To determine:

1. The indications for induction of labour among the study participants.
2. The association between BMI and failed induction of labour.
3. The association between BMI and the mode of delivery after IOL.
4. Theassociation between BMI and neonatal APGAR score at five minutes after IOL.

METHODOLOGY

Study design

The study was conducted as a comparative cross-sectional study where consecutive sampling of eligible women undergoing induction of labour was done until the sample size was achieved.

Study population

Women undergoing induction of labour with prostaglandins at term were recruited into the study. This included women with intact membranes and a Bishop score less than seven hence requiring cervical ripening. The exposed women were those with BMI of 25 or above while the unexposed women were those with normal BMI of between 18.5 and 24.9.

Study area

The study was conducted in the Kenyatta National Hospital labour ward between June and October 2018. The Hospital is a national referral centre and has one public labour ward and three antenatal wards. The hospital admits on average 900 to 2000 maternity cases every month. Approximately 60 to 100 women undergo induction of labour every month.

Sample size

The sample size was calculated with consideration to a population-wide study done by Wolfe KB et al. using the Ohio Department of Health's birth certificate database from January 1, 2006, through to December 31, 2007 and with a sample size of 80,887 women(43). In that study, it was found that increasing BMI was associated with increasing induction failure rates ranging from 13% in normal weight women to 29% in obese women.

The prevalence of failed induction was used as the primary outcome of interest to calculate the sample size. The following sample size formula was used to calculate the desired number (Kelsey et al. 1996);

$$\boldsymbol{n_1 = \frac{\left(Z_{\propto/2} + Z_{1-\beta}\right)^2 p(1-p)(r+1)}{r(p_0 - p_1)^2}}$$

And

$$\boldsymbol{n_2 = rn_1}$$

Where,

n_1= number of exposed

n_2= number of unexposed

$Z_{\propto/2}$= standard normal deviate for two-tailed test corresponding to 95% CI i.e. 0.05

$Z_{1-\beta}$= standard normal deviate corresponding to power level of 80% i.e. 0.842

r = ratio of controls to cases i.e. 1

p_0 = proportion of failed induction of labour of obese women i.e. 0.29

p_1= proportion of failed induction of labour of normal weight women i.e. 0.13

$$\boldsymbol{p = \frac{p_0 + rp_1}{r + 1}}$$

$$\boldsymbol{p = \frac{0.29 + (1\ x\ 0.13)}{1 + 1} = 0.21}$$

$$\boldsymbol{n_1 = \frac{(1.96 + 0.842)^2 0.21(1 - 0.21)(1 + 1)}{1(0.29 - 0.13)^2} = 102}$$

Therefore,

$$\boldsymbol{n_2 = 1\ x\ 102 = 102}$$

The study therefore required**102** with normal BMI and **102**with above normal BMI.

Inclusion criteria

- Women with a normal singleton pregnancy in cephalic presentation at term and unfavourable cervix (Bishop Scorebelow seven).

Exclusion criteria

- Women with no weight record before 20 weeks of pregnancy.
- Women undergoing repeat induction after a prior failure of induction.
- Women with a method of induction other than prostaglandins.
- Women with non-viable foetuses.
- Women with an uncontrolled medical conditions like hypertension, diabetes, cardiac disease or severe anaemia.

Outcomes of interest

Primary outcomes

- Rates of failed induction of labour.

Secondary outcomes

- Vaginal delivery rates.
- Caesarean section rates.
- Indications for the caesarean sections.
- Neonatal APGAR score at five minutes.
- Need for augmentation of labour
- Fatal maternal or foetal outcomes.

Study procedure

Women admitted to the ward at term and not in labour were evaluated for eligibility to participate.Eligible women were recruited into the study once a decision to induce labour with prostaglandins was made.After informed consent was given, a brief interview was conducted to obtain the baseline data of the participants. The pre-twenty weeks BMI was retrieved from the antenatal records.The participants were then weighed and their heights measured to calculate BMI and its change during pregnancy. The patients were then allowed to undergo IOL as per the KNH protocol which at this particular time was vaginal misoprostol 25mcg (vagiprost^{TM}) every six hours up to 24hours.Details about the progress and outcome of the IOL were collected from the inpatient file of the participant after delivery.

Data collection and handling

Data collection for the study was done by the principle investigator with the help of trained research assistants using a pretested questionnaire (appendix 3).The questionnaires were cross-checked for completeness before being filed and then secured in a lockable cabinet by the principle investigator.

Data analysis

A password protected Microsoft Access^{TM} database was designed and used for data entry and validation. The data was then exported to Statistical Package for the Social Sciences^{TM} (SPSS version 22) for analysis.Univariate analysis was done to elucidate the baseline characteristics of the participants. Pearson Chi squared test was applied to evaluate the difference in the outcomes between the two groups. Logistic regression analysis was done to cater for possible confounders.

Data dissemination

The results of the study were compiled in a Thesis book availed to colleagues at the University of Nairobi and the department of Obstetrics and Gynaecology at KNH. The results will also be presented in scientific conferences and submitted to peer-reviewed journals for publication.

ETHICAL CONSIDERATIONS

The study was approved by the KNH/ UoN ethics committee after a proposal had been presented to them. Strict adherence to the study protocol and the guidelines of the KNH/ UoN ethics committee was ensured by the researchers.

1. Informed consent was sought after the researcher had explained the purpose of the study in a language the participants understood. Refusal to participate did not compromise care and the women were informed of this.
2. Confidentiality was maintained and none of the questionnaires had information that could directly identify a participant like the name or hospital number.
3. No coercion was used to force participation.
4. Participants were free to opt out of the study at any point and their care was not compromised by the decision.
5. Women found to have a health problem during the study were referred accordingly.

STUDY LIMITATIONS

The recording of the early pregnancy weight varied from participant to participant. Although the variation in the gestational age when the weight was taken was catered for during analysis, it was hard to cater for the inter-observer variability. Also, lack of early antenatal records excluded some women which may have introduced selection bias.

The exclusion of women with medical conditions meant that a good proportion of women who require induction of labour were left out limiting the generalizability of the study findings.

For some of the outcomes, the researchers relied on information recorded by other clinicians which at times was not comprehensive. For example, a diagnosis of prolonged labour as the indication of Caesarean section was common without further reference as to the cause of the prolongation.

RESULTS

Between June and October 2018, a total of 211 women were screened. Among these women, 103 were overweight or obese and 108 of them had BMI<25kg/m^2. Of thesewomen, five women were excluded as they had a BMI less than 18.5kg/m^2, one woman was excluded due to a medical condition diagnosed after enrolling and for one woman, the decision to induce labour

was changed later due to poor foetal status. After exclusion, 204 women continued with the study with 101 having a BMI of 25 and above and 103 with normal BMI.

Figure 1: Study participants

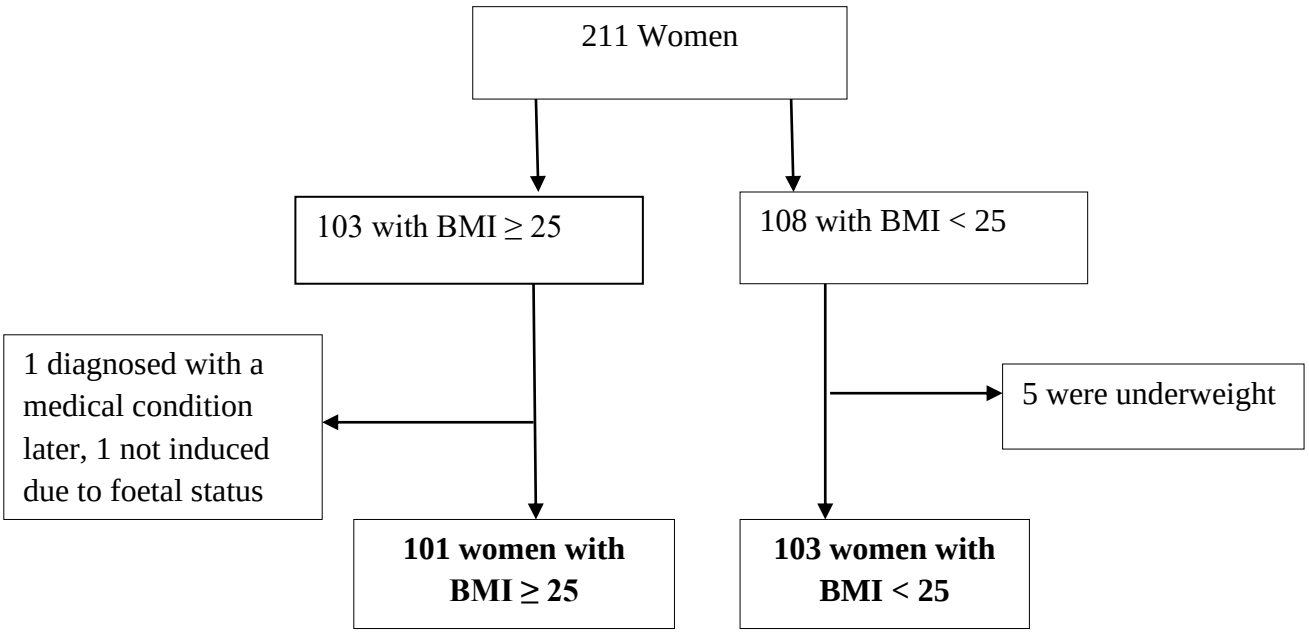
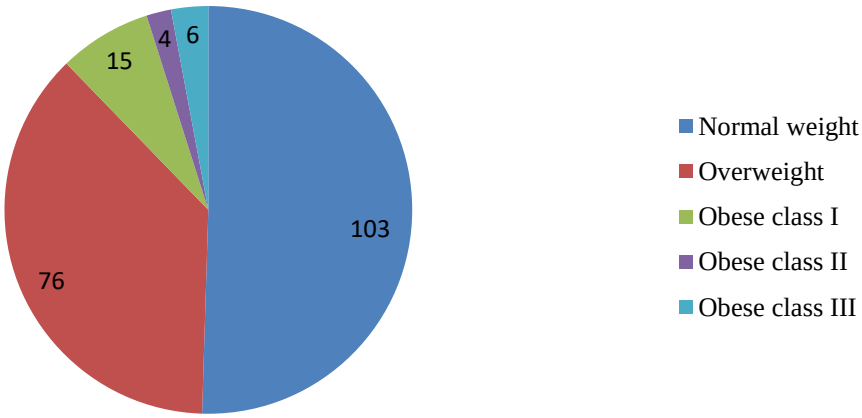


Figure 2: Classification of the participants based on BMI



Most of the women with high BMI were in the overweight category(75.2%) with fewer in the obese category as depicted in figure 2.

Table 1: Demographic characteristics of the participants

Characteristic	Women with BMI ≥ 25.0 (n=101)	Women with BMI<25.0 (n=103)	P value
Age (mean)	27.5 ± 5.3	25.5 ± 4.9	0.005
Marital status			
Married	87 (86.1%)	76 (73.8%)	0.028
Single	14 (13.9%)	27 (26.2%)	
Occupation			
Permanent	16 (15.8%)	10 (9.7%)	0.081
Casual	18 (17.8%)	14 (13.6%)	
Self employed	39 (38.6%)	33 (32.0%)	
Unemployed	28 (27.7%)	46 (44.7%)	

The women with BMI above 25 were on average older (27.5 years ± 5.3) and more likely to be married. Most of the women were either unemployed or self employed. The distribution in occupation between the two groups was not significantly different.

Table 2: Obstetric characteristics of the women

Characteristic	**Women with BMI ≥ 25.0 (n=101)**	**Women with BMI <25.0 (n=103)**	**P value**
Parity			
0	37 (36.6%)	60 (58.3%)	0.002
≥1	64 (63.4%)	43 (41.7%)	
Mean (SD) gestation in weeks at first booking	18.1 ± 3.1	17.2 ± 2.5	0.015
Mean (SD) weight gain in Kgs	6.5 ± 4.8	9.3 ± 4.4	<0.001
	Overweight - 6.2kgs		
	Obese I - 7.4kgs		
	Obese II - 8.6kgs		
	Obese III - 6.2kgs		
Mean (SD)BMI change	2.5 ± 1.9	3.5 ± 1.7	<0.001
Mean gestation in days at induction of labour	286.2 ± 6.2	286.9 ± 5.7	0.389
Bishop score (median, range)	3 (0,7)	3 (0,7)	0.07
Reason for induction			
Elective	18 (17.8)	20 (19.4)	0.172
Postdates	77 (76.2)	77 (74.8)	0.771
Reduced movements			
RH Negative	5 (5.0)	3 (2.9)	0.699

	1 (1.0)	3 (2.9)	0.613
Foetal birth weight	3440 ± 471.6	3218.9 ± 396.4	<0.001

Most of the women had their first antenatal visit after the second trimester. A greater proportion of the women with BMI above 25 had had a prior vaginal delivery as compared to those with normal BMI.The women with high BMI gave birth to heavier babies (3440g ± 471.6) as compared to their normal BMI counterparts (3218.9g ± 396.4). The normal weight women gained more weight in pregnancy as compared to the overweight and obese. The weight gain for the various BMI categories is as shown in table 2. The Bishop score did not significantly vary between the two groups.

Majority of the inductions of labour were done past 40 weeks for both groups and most of the women underwent induction of labour because they had gone past their expected date of delivery by a week or more. For clinical and research purposes, this was coded as post dates. Other women were induced because they were rhesus negative and term while others who came with complains of reduced foetal movements at term, induction of labour was done when the foetal status was confirmed to be good by ultrasound and cardiotocograph. Where no medical indication could be found for induction of labour and the woman was term but had not gone past her expected date of delivery by a week or more, the induction was labelledas elective. The distribution of the indications of labour between the groups was not statistically different.

Table 3: The outcomes of IOLin the various BMI groups

Characteristic	**Total % of all the 204 women**	**Women with BMI ≥ 25.0 (n=101)**	**Women with BMI <25.0 (n=103)**	**Or (95% CI)**	**P value**
Failed IOL	11.8	18 (17.8)	6 (5.8)	3.5 (1.3 – 9.2)	0.008
				****4.3(1.6-11.7)***	***0.004***
NRFS		7 (6.9)	8 (7.8)	1.1 (0.4 – 3.2)	0.819
Prolonged labour		4 (4.0)	13 (12.6)	0.3 (1.1 – 11.1)	0.025
Mode of delivery					
Vaginal		72 (72.0)	74 (71.8)	1.0 (0.5 – 1.9)	0.980
Caesarean	28.4	28 (28.0)	29 (28.2)		

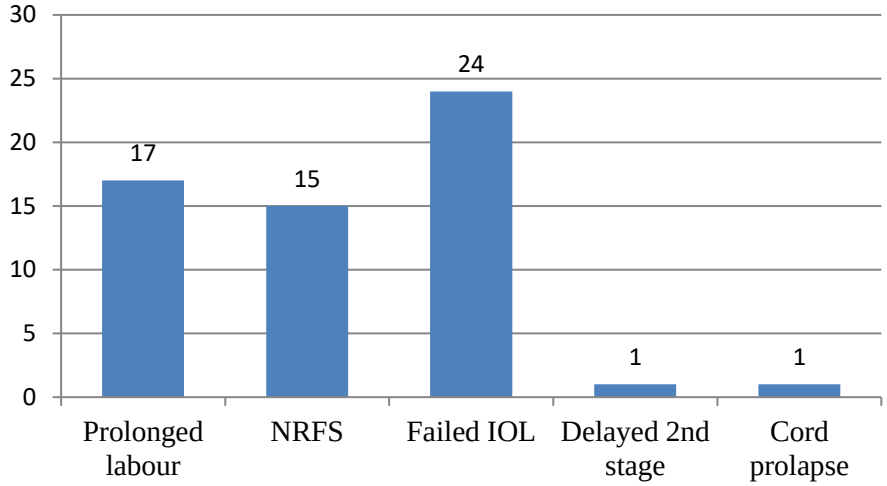
APGAR score					
< 7	1.4	1 (1.0)	2 (1.9)	0.5 (0.0 – 5.7)	1.000
≥ 7		99 (99.0)	101 (98.1)		
Augmentation of labour					
Done	60.2	59 (72.0)	64 (66.0)	1.3 (0.7 – 2.5)	0.391
Not done		23 (28.0)	33 (34.0)		

***Odds ratio after adjusting for parity and baby weight*

Of all the women who underwent induction, 11.8% did not achieve labour as shown in table 3. The overall Caesarean section rate, either due to failed IOL or other indications in labour was 28.4%. For the women who went into labour, 60.2% required oxytocin to augment the labour. Only three babies (1.4%) had an APGAR score lower than seven and this was attributed to meconium aspiration.

Pearson Chi Square test was done to compare the outcomes in the two groups. The results are also as shown in table 3. The exposed women were more likely to have failed induction of labour (OR 3.5 95% CI 1.3, 9.2 *p* value 0.008) and this was the most common indication for Caesarean section in this group. When adjustment for parity and baby weight was done, it was found that a nulliparous woman with high BMI had the highest likelihood of failed IOL (OR 4.3 95% CI 1.6 – 11.7, p 0.004).The normal BMI women were on the other hand more likely to have prolonged labour as the indication for Caesarean section after IOL as compared to the high BMI group. There was however no significant difference in the overall Caesarean section rate between the two groups and though the proportion of women who needed augmentation of labour was slightly more in the normal BMI group, this was not statistically significant.

Figure 3: Indications for Caesarean section delivery after IOL



The Caesarean section rate was one of the outcomes being studied and the indications for Caesarean sections are as presented in figure 3. The three most common indications were failed induction of labour, prolonged labour andnon reassuring foetal status (NRFS) in labour. These were further analyzed as shown in table 3 above.

Table 4: Logistic regression analysis for failed induction

	Wald	Df	P-value	OR (95% CI)
BMI	14.715	1	<0.001	1.2 (1.1 – 1.3)
Baby weight	0.190	1	0.663	1.0 (0.9 – 1.0)
Parity	5.039	1	0.025	0.5 (0.2 – 0.9)
Constant	13.279	1	<0.001	

A binomial logistic regression was performed to ascertain the effects of BMI, baby weight, and parity on the likelihood that participants have failed IOL.Increasing BMI was associated with an increased likelihood of exhibiting failed IOL, but increasing parity was associated with a reduction in the likelihood of exhibiting failed IOL.The baby weight did not significantly alter the likelihood of failed IOL.

Figure 4: Distribution of the outcomes in the various BMI classes

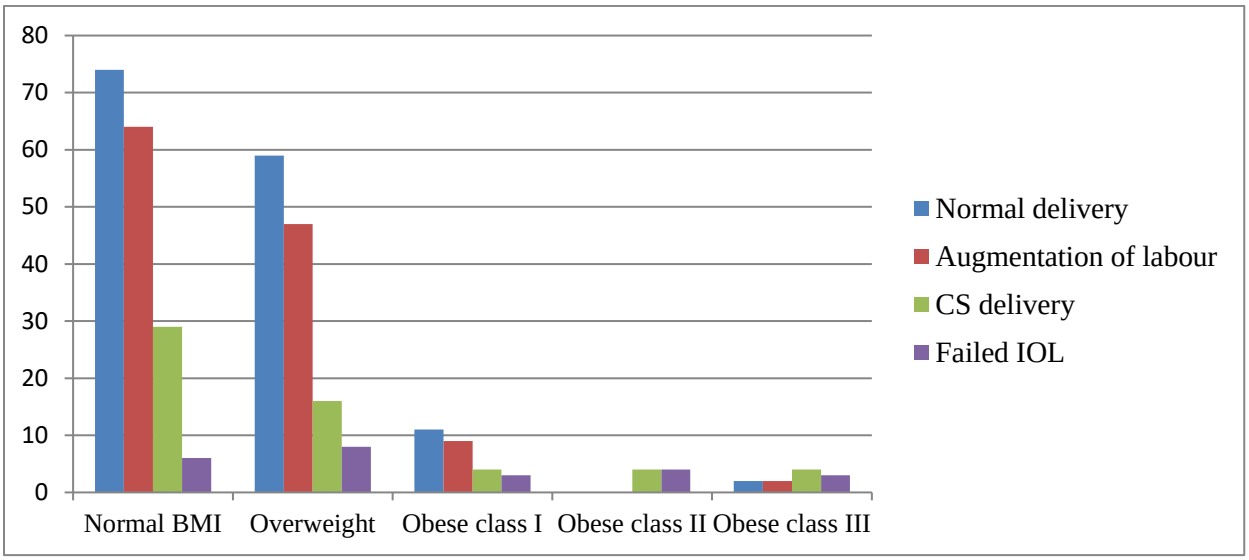


Table 5: Association between the change in BMI during pregnancy and the outcomes

Characteristic	High BMI change (≥3)	Low BMI change(<3)	OR (95% CI)	P value
Mode of delivery				
Vaginal	65 (69.9)	81 (73.6)	1.0	
Caesarean	28 (30.1)	29 (26.4)	1.2 (0.7 – 2.2)	0.554
Women who needed augmentation of labour				
Done	53 (63.1)	70 (73.7)	0.6 (0.3 – 1.2)	0.127
Not done	31 (36.9)	25 (26.3)	1.0	
Failed IOL				
Yes	9 (9.6)	15 (13.6)	0.7 (0.3 – 1.6)	0.369

No	85 (90.4)	95 (86.4)	1.0

Further analysis was done to find out if a greater increase in BMI (change of BMI by 3 or more units) during the course of the pregnancy posed the same likelihood of the outcomes as the exposure as shown in table 5. There was no significant difference in the Caesarean section rate, the need for augmentation of labour or the rate of failed IOL between those women who had a change in BMI of less than 3 units and those who had a BMI change more than 3 units.

DISCUSSION

In this research, we set out to study women undergoing induction of labour at term to investigate the association between their early pregnancy BMI and the outcomes of the induction. We were interested in finding out the indications of induction of labour and the maternal and foetal outcomes before and after delivery.

We found that postdatism was the most common indication for induction of labour among study participants. This resonated with a study done by Esiromo et al. in the same setting that found that postdatism contributed to more than half of all the indications of induction of labour(51). Other indications of induction of labour included reduced foetal movements and rhesus negative blood type. We also found that elective induction of labour, for example for women who present with false labour at term, is an emerging indication. This may be attributed to the wide availability of the necessary pharmacologic agents. The indications for induction did not vary significantly between women with high BMI and those with normal BMI. Our study excluded women with complications hence the absence of other indications of labour like hypertensive disease, premature rupture of membranes or foetal demise in-utero that are common at KNH(51).

In this study, the overall rate of failed induction of labour was 11.8%. This was lower than what has been reported previously. Admani et al. and Esiromo et al. in different studies both done at KNH had found induction failure rates of 32% and 26% respectively(5,51). However, in their studies, any woman who delivered by Caesarean section after induction of labour was deemed to have had failed induction. For our study, failed induction of labour was defined as failure to achieve labour 24 hours after initiation of induction. This definition was adopted from guidelines developed by the National Institute of Clinical Excellence body in the UK(40). Hence, for our study, women who went for Caesarean section in labour after induction were not included in the failed induction group. The rationale for this was that the primary goal of induction of labour is to tip the woman in to labour which is defined as progressive uterine contractions associated with cervical effacement and dilatation(37).

Women with high BMI were found to have higher odds of failure of induction of labour as compared to those with normal BMI. This was even higher if they had not had a prior vaginal delivery (OR 4.3; 95% CI 1.6, 11.7; *P* value 0.004). This is comparable to the findings ofMaged and colleagues in another study who also found that obese women were more than two times likely to have failed induction of labour as compared to non obese women(46). Wolfe and colleagues in a population wide study found rates of failed induction increased with the increasing class of obesity. Nulliparity and foetal macrosomia were also found to increase the likelihood of failed induction in that study(43). In our study, foetalmacrosomia did not increase the likelihood. However, the proportion of macrosomic babies in our study was not large enough to statistically make a conclusion.

In terms of weight gain, the obese women on average gained weight that was within the Institute of Medicine (IOM) recommendations of 5 to 9 kilograms. The overweight and the normal weight women fell slightly short of the expected 7 to 11.5 kilograms and 11.5 to 16 kilograms respectively(21). We compared the outcomes of induction of labour between women who had a higher weight gain in pregnancy(BMI change of three units or more) and those who had lower or no weight gain (BMI change less than three units) and found that the likelihood of failed induction, Caesarean delivery or need for augmentation did not vary significantly between the two groups. Ritho et al. had also concluded that excessive weight gain in pregnancy did not have a significant correlation with pregnancy outcome after studying pregnancy outcomes in obese and normal weight women at KNH(14). It is worth noting however that in both our studies, the initial weight was obtained while the woman was already pregnant rather than her pre-pregnancy weight which may have best demonstrated the total weight gained in the pregnancy.

Concerning the mode of delivery, out of all the women who underwent induction of labour in our study, 71.6% gave birth vaginally. In prior studies at KNH, Admani and colleagues found a rate of 68% while Esiromo and colleagues reported a rate of 74%. This is also comparable to what has been reported from other parts of the world with figures ranging between 72.3% to 79.5%(52).

Despite the higher rate of failed induction in the women with high BMI in our study, the Caesarean section rate in the two groups was not significantly different. This is because the normal weight women had a higher number of Caesarean sections done during labour while the high BMI women had more Caesarean sections done before labour for failed induction. Other authors have found higher Caesarean section rates in women with high BMI as compared to those with normal BMI after induction(46,53). Also in those studies, the indications for Caesarean section did not vary much between the groups. The difference with our study may be due to our exclusion of women with medical conditions and those with methods of induction of labour other than misoprostal which may have varied success rates. One challenge encountered during collecting data on Caesarean section was incomplete diagnosis when prolonged labour was encountered. A good number of clinicians did not further record what caused the prolongation.

For all the women who achieved labour in our study, more than 60% received augmentation of labour with oxytocin. There was not a statistically significant difference on the proportion of women who received augmentation of labour between the normal BMI and the high BMI group. None of the study participants required assisted vaginal delivery.

The number of babies with APGAR score below seven at five minutes in our study was three. The low number is an expected finding because we were dealing with a low risk obstetric group. Also, KNH induction of labour protocol dictated that the women had to undergo electronic foetal monitoring before induction of labour was allowed which meant that mothers with already compromised foetuses were not induced. They were hence not included in the study. No fatal maternal outcomes occurred to any of the participants.

Our study had its limitations and perhaps the reason for some of our findings was our selection criteria. All our women attended antenatal clinic and did so before 20 weeks. This excluded women who had attended antenatal clinic late or had not attended at all, who are usually at more risk of complications(54). Also, most of the women in the exposed group were in the overweight category and fewer in the obese category. This may mean that some of their parameters may have been near similar to those of the normal BMI group. However, this is the expected normal urban Kenya population distribution where most of the women with high BMI are overweight(55).

However, even though our exclusion criteria may have reduced the generalizability of some of our findings to the general population of women undergoing induction of labour, it also allowed us to more accurately measure the association we were interested in by limiting possible confounders. There being few prior studies on the subject matter in the local setting, this was considered necessary.

This study adds to the growing body of knowledge on this subject. High body mass index is associated with many complications in pregnancy including prolonged labour and the need for induction of labour(14,16). We found that high early pregnancy maternal body mass index was associated with a higher rate of failed induction of labour.

CONCLUSSION

Women with high BMI in early pregnancy havea higher likelihood of failed induction of labour as compared to women with normal BMI. Among these women with high BMI,failed induction of labour is the most common indication for Caesarean deliveryafter induction.

RECOMMENDATIONS

Women should be counselled about achieving appropriate weight preconceptionally. Those with high BMI and undergoing IOL should also be informed about possible outcomes of induction of labour, including a higher risk of induction failure. Further to this, various ways of achieving labour in overweight and obese women should be explored.

REFERENCES

1. WHO | Obesity and overweight. WHO [Internet]. World Health Organization; 2016 [cited 2017 Apr 21]; Available from: http://www.who.int/mediacentre/factsheets/fs311/en/
2. Mbochi RW, Kuria E, Kimiywe J, Ochola S, Steyn NP. Predictors of overweight and obesity in adult women in Nairobi Province, Kenya. BMC Public Health [Internet]. 2012 Dec 25 [cited 2017 May 27];12(1):823. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23009185
3. Ettarh R, Van de Vijver S, Oti S, Kyobutungi C. Overweight, obesity, and perception of body image among slum residents in Nairobi, Kenya, 2008-2009. Prev Chronic Dis [Internet]. Centers for Disease Control and Prevention; 2013 Dec 19 [cited 2017 May 27];10:E212. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24355105
4. Health M of. Kenya 2014 Demographic and Health Survey [Internet]. [cited 2017 May 27]. Available from: https://dhsprogram.com/pubs/pdf/fr308/fr308.pdf
5. Admani Rashida, Odawa FX GW. Predictors of successful induction of labour in post-term pregnancies at Kenyatta National Hospital [Internet]. [cited 2017 Sep 18]. Available from: http://obsgyn.uonbi.ac.ke/sites/default/files/chs/medschool/obsgyn/Dr Rashida Admani.pdf
6. RCOG. CMACE/RCOG Joint Guideline Management of Women with Obesity in Pregnancy Centre for Maternal and Child Enquiries. 2010 [cited 2017 Apr 21]; Available from: https://www.rcog.org.uk/globalassets/documents/guidelines/cmacercogjointguidelinemanagementwomenobesitypregnancya.pdf
7. Cedergren MI. Maternal morbid obesity and the risk of adverse pregnancy outcome. Obstet Gynecol [Internet]. 2004 Feb [cited 2017 Apr 21];103(2):219–24. Available from: http://www.ncbi.nlm.nih.gov/pubmed/14754687
8. Weiss JL, Malone FD, Emig D, Ball RH, Nyberg DA, Comstock CH, et al. Obesity, obstetric complications and cesarean delivery rate–a population-based screening study. Am J Obstet Gynecol [Internet]. 2004 Apr [cited 2017 Apr 21];190(4):1091–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15118648
9. Larsen TB, Sørensen HT, Gislum M, Johnsen SP. Maternal smoking, obesity, and risk of venous thromboembolism during pregnancy and the puerperium: A population-based nested case-control study. Thromb Res [Internet]. 2007 Jan [cited 2017 Apr 21];120(4):505–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/17257657
10. Lashen H, Fear K, Sturdee DW. Obesity is associated with increased risk of first trimester

and recurrent miscarriage: matched case-control study. Hum Reprod [Internet]. 2004 Jul 1 [cited 2017 Apr 21];19(7):1644–6. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15142995
11. Dennedy MC, Dunne F. The maternal and fetal impacts of obesity and gestational diabetes on pregnancy outcome. Best Pract Res Clin Endocrinol Metab [Internet]. 2010 Aug [cited 2017 Apr 21];24(4):573–89. Available from: http://www.ncbi.nlm.nih.gov/pubmed/20832737
12. Grossetti E, Beucher G, Régeasse A, Lamendour N, Herlicoviez M, Dreyfus M. [Obstetrical complications of morbid obesity]. J Gynecol Obstet Biol Reprod (Paris) [Internet]. 2004 Dec [cited 2017 Apr 21];33(8):739–44. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15687946
13. Ireland RC of P of. Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland Clinical Practice Guideline on Obesity and Pregnancy. 2011 [cited 2017 Apr 21]; Available from: http://www.hse.ie/eng/about/Who/clinical/natclinprog/obsandgynaeprogramme/guideobesity.pdf
14. Ritho MMK. Effect of body mass index on pregnancy outcome at Kenyatta National Hospital: Cohort Study. University of Nairobi, Kenya; 2012 [cited 2017 May 27]; Available from: http://erepository.uonbi.ac.ke/handle/11295/8334
15. Kristensen J, Vestergaard M, Wisborg K, Kesmodel U, Secher NJ. Pre-pregnancy weight and the risk of stillbirth and neonatal death. BJOG An Int J Obstet Gynaecol [Internet]. 2005 Apr [cited 2017 May 27];112(4):403–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15777435
16. Denison F, Price J, Graham C, Wild S, Liston W. Maternal obesity, length of gestation, risk of postdates pregnancy and spontaneous onset of labour at term. BJOG An Int J Obstet Gynaecol [Internet]. 2008 May [cited 2017 May 27];115(6):720–5. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18410655
17. Poobalan AS, Aucott LS, Gurung T, Smith WCS, Bhattacharya S. Obesity as an independent risk factor for elective and emergency caesarean delivery in nulliparous women - systematic review and meta-analysis of cohort studies. Obes Rev [Internet]. 2009 Jan [cited 2017 Apr 21];10(1):28–35. Available from: http://www.ncbi.nlm.nih.gov/pubmed/19021871
18. Davies G AL, Cynthia Maxwell KO, Lynne McLeod TO, Gagnon R, Melanie Basso MQ, Hayley Bos VB, et al. SOGC Clinical Practice Guidelines on Obesity in Pregnancy. [cited 2017 Apr 21]; Available from: https://sogc.org/wp-content/uploads/2013/01/gui239ECPG1002.pdf
19. Han Z, Mulla S, Beyene J, Liao G, McDonald SD, Knowledge Synthesis Group. Maternal underweight and the risk of preterm birth and low birth weight: a systematic review and meta-analyses. Int J Epidemiol [Internet]. 2011 Feb [cited 2017 Aug 8];40(1):65–101. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21097954
20. Salihu HM, Mbah AK, Alio AP, Clayton HB, Lynch O. Low pre-pregnancy body mass index and risk of medically indicated versus spontaneous preterm singleton birth. Eur J Obstet Gynecol Reprod Biol [Internet]. 2009 Jun [cited 2017 Aug 8];144(2):119–23. Available from: http://www.ncbi.nlm.nih.gov/pubmed/19328619
21. IOM. Weight Gain During Pregnancy - NCBI Bookshelf.
22. Clinical Guidelines Q, Health Q. Maternity and Neonatal Clinical Guideline Obesity in

pregnancy. [cited 2017 May 27]; Available from: https://www.health.qld.gov.au/__data/assets/pdf_file/0019/142309/g-obesity.pdf
23. Oza-Frank R, Keim SA. Should Obese Women Gain Less Weight in Pregnancy Than Recommended? Birth [Internet]. 2013 Jun [cited 2017 May 27];40(2):107–14. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24635465
24. Carlson NS, Hernandez TL, Hurt KJ. Parturition dysfunction in obesity: time to target the pathobiology. Reprod Biol Endocrinol [Internet]. 2015 Dec 18 [cited 2017 Apr 21];13(1):135. Available from: http://www.rbej.com/content/13/1/135
25. Frias AE, Morgan TK, Evans AE, Rasanen J, Oh KY, Thornburg KL, et al. Maternal High-Fat Diet Disturbs Uteroplacental Hemodynamics and Increases the Frequency of Stillbirth in a Nonhuman Primate Model of Excess Nutrition. Endocrinology [Internet]. 2011 Jun [cited 2017 May 27];152(6):2456–64. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21447636
26. Elmes MJ, Tan DS-Y, Cheng Z, Wathes DC, McMullen S. The effects of a high-fat, high-cholesterol diet on markers of uterine contractility during parturition in the rat. Reproduction [Internet]. 2011 Feb 1 [cited 2017 Apr 21];141(2):283–90. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21078880
27. Garabedian M, Hansen W, Mccord L, Manning M, O'Brien J, Curry T. Up-Regulation of Oxytocin Receptor Expression at Term Is Related to Maternal Body Mass Index. Am J Perinatol [Internet]. 2013 Jan 25 [cited 2017 May 27];30(06):491–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23355275
28. Moynihan AT, Hehir MP, Glavey S V, Smith TJ, Morrison JJ. Inhibitory effect of leptin on human uterine contractility in vitro. [cited 2017 May 27]; Available from: http://www.saegre.org.ar/biblioteca/arbol_bibliografico/octubre2006/s000293780-leptin-uter-contract.pdf
29. Lowe NK, Corwin EJ, Harvey J, al. et, Morrison JJ, Levinson G, et al. Proposed biological linkages between obesity, stress, and inefficient uterine contractility during labor in humans. Med Hypotheses [Internet]. Academic, San Diego, CA; 2011 May [cited 2017 May 27];76(5):755–60. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21382668
30. Zhang J, Bricker L, Wray S, Quenby S. Poor uterine contractility in obese women. BJOG An Int J Obstet Gynaecol [Internet]. 2007 Jan 25 [cited 2017 May 27];114(3):343–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/17261121
31. Cedergren MI. Non-elective caesarean delivery due to ineffective uterine contractility or due to obstructed labour in relation to maternal body mass index. Eur J Obstet Gynecol Reprod Biol [Internet]. 2009 Aug [cited 2017 May 27];145(2):163–6. Available from: http://www.ncbi.nlm.nih.gov/pubmed/19525054
32. Sheiner E, Levy A, Menes TS, Silverberg D, Katz M, Mazor M. Maternal obesity as an independent risk factor for caesarean delivery. Paediatr Perinat Epidemiol [Internet]. 2004 May [cited 2017 May 27];18(3):196–201. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15130159
33. Kominiarek MA, Zhang J, VanVeldhuisen P, Troendle J, Beaver J, Hibbard JU. Contemporary labor patterns: the impact of maternal body mass index. Am J Obstet Gynecol [Internet]. 2011 Sep [cited 2017 Apr 21];205(3):244.e1-244.e8. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0002937811007423
34. Hibbard JU, Gilbert S, Landon MB, Hauth JC, Leveno KJ, Spong CY, et al. Trial of Labor

or Repeat Cesarean Delivery in Women With Morbid Obesity and Previous Cesarean Delivery. Obstet Gynecol [Internet]. 2006 Jul [cited 2017 May 27];108(1):125–33. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16816066
35. Tjeertes EKM, Tjeertes EEKM, Hoeks SE, Hoeks SSE, Beks SBJ, Beks SSBJC, et al. Obesity--a risk factor for postoperative complications in general surgery? BMC Anesthesiol [Internet]. BioMed Central; 2015 Jul 31 [cited 2017 May 27];15:112. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26228844
36. Machado LS. Cesarean section in morbidly obese parturients: practical implications and complications. N Am J Med Sci [Internet]. Medknow Publications; 2012 Jan [cited 2017 May 27];4(1):13–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22393542
37. WHO. Managing Complications in Pregnancy and Childbirth: A guide for midwives and doctors Integrated Management Of Pregnancy And Childbirth. [cited 2017 May 27]; Available from: http://apps.who.int/iris/bitstream/10665/43972/1/9241545879_eng.pdf
38. WHO. WHO recommendations for Induction of labour. [cited 2017 May 27]; Available from: www.who.int/reproductivehealth
39. JM N. Indications and pregnancy outcomes of induction at Kenyatta National Hospital. Nairobi University; 2002.
40. (UK) NCC for W and CH, NICE, National Collaborating Centre for Women's and Children's Health (Great Britain), National Institute for Health and Clinical Excellence (Great Britain), Royal College of Obstetricians and Gynaecologists (Great Britain). Induction of labour. Induction of Labour [Internet]. RCOG Press; 2008 [cited 2017 May 27]; Available from: https://www.nice.org.uk/guidance/cg70/evidence/cg70-induction-of-labour-full-guideline2
41. Vogel JP, Souza JP, Gülmezoglu AM, Gaines G, Kabani G. Patterns and Outcomes of Induction of Labour in Africa and Asia: A Secondary Analysis of the WHO Global Survey on Maternal and Neonatal Health. Bhutta ZA, editor. PLoS One [Internet]. Public Library of Science; 2013 Jun 3 [cited 2017 May 27];8(6):e65612. Available from: http://dx.plos.org/10.1371/journal.pone.0065612
42. Boulvain M, Stan CM, Irion O. Membrane sweeping for induction of labour. In: Boulvain M, editor. Cochrane Database of Systematic Reviews [Internet]. Chichester, UK: John Wiley & Sons, Ltd; 2005 [cited 2017 May 27]. Available from: http://doi.wiley.com/10.1002/14651858.CD000451.pub2
43. Wolfe KB, Rossi RA, Warshak CR, al. et, Chazotte C. The effect of maternal obesity on the rate of failed induction of labor. Am J Obstet Gynecol [Internet]. Elsevier; 2011 Aug [cited 2017 Apr 21];205(2):128.e1-128.e7. Available from: http://linkinghub.elsevier.com/retrieve/pii/S000293781100439X
44. Ba  os N, Migliorelli F, Posadas E, Ferreri J, Palacio M. Definition of Failed Induction of Labor and Its Predictive Factors: Two Unsolved Issues of an Everyday Clinical Situation. Fetal Diagn Ther [Internet]. 2015 Jun 26 [cited 2017 May 27];38(3):161–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26138441
45. Arrowsmith S, Wray S, Quenby S. Maternal Obesity and Labor Complications After Induction of Labor in Prolonged Pregnancy. Obstet Anesth Dig [Internet]. 2012 Mar [cited 2017 Apr 21];32(1):39. Available from: http://content.wkhealth.com/linkback/openurl?sid=WKPTLP:landingpage&an=00132582-201203000-00042
46. Maged AM, El-Semary AM, Marie HM, Belal DS, Hany A, Taymour MA, et al. Effect of

maternal obesity on labor induction in postdate pregnancy. Arch Gynecol Obstet [Internet]. Springer Berlin Heidelberg; 2018;298(1):45–50. Available from: https://doi.org/10.1007/s00404-018-4767-8
47. Roloff K, Peng S, Sanchez-Ramos L, Valenzuela GJ. Cumulative oxytocin dose during induction of labor according to maternal body mass index. Int J Gynecol Obstet [Internet]. 2015 [cited 2017 May 27];131(1):54–8. Available from: http://www.sciencedirect.com/science/article/pii/S0020729215003987
48. Uyar Y, Erbay G, Demir BC, Baytur Y. Comparison of the Bishop score, body mass index and transvaginal cervical length in predicting the success of labor induction. Arch Gynecol Obstet [Internet]. 2009 Sep 8 [cited 2017 May 27];280(3):357–62. Available from: http://www.ncbi.nlm.nih.gov/pubmed/19130065
49. Park K-H, Hong J-S, Kang W-S, Shin D-M, Kim S-N. Body mass index, Bishop score, and sonographic measurement of the cervical length as predictors of successful labor induction in twin gestations. J Perinat Med [Internet]. 2009 Jan 1 [cited 2017 May 27];37(5):519–23. Available from: http://www.ncbi.nlm.nih.gov/pubmed/19492921
50. Nuthalapaty F, Rouse D, Owen J. The association of maternal weight with cesarean risk, labor duration, and cervical dilation rate. Am J Obstet Gynecol [Internet]. 2003 Dec [cited 2017 May 27];189(6):S199. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0002937803017290
51. Esiromo Amase. Outcomes of Pharmacological Induction of Labour at or or near term at Kenyatta National Hospital [Internet]. University of Nairobi; 2008 [cited 2017 Jul 30]. Available from: http://obsgyn.uonbi.ac.ke/sites/default/files/chs/medschool/obsgyn/DR. ESIROMO AMASE MARIAN.pdf
52. Fischer R, Machac N, Hunter K, Adriance L. A comparison of induction of labor success rates over three time periods in 20 years at a single academic tertiary care center: are we improving vaginal delivery rates? J Matern Neonatal Med [Internet]. 2018 Apr 3 [cited 2018 Nov 17];31(7):907–13. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28320237
53. Pevzner L, Rayburn WF, Rumney P, Wing DA. Factors Predicting Successful Labor Induction With Dinoprostone and Misoprostol Vaginal Inserts. Obstet Gynecol [Internet]. 2009 Aug [cited 2018 Nov 16];114(2, Part 1):261–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/19622986
54. Raatikainen K, Heiskanen N, Heinonen S. Under-attending free antenatal care is associated with adverse pregnancy outcomes. BMC Public Health [Internet]. BioMed Central; 2007 Dec 27 [cited 2018 Nov 19];7(1):268. Available from: http://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-7-268
55. KDHS. Kenya Demographic Health Survey. 2014;

APPENDICES

Appendix 1

CONSENTFORM (page 1 0f 4)

Title of Study: INFLUENCE OF EARLY PREGNANCY BODY MASS INDEX ON MATERNAL AND FOETAL OUTCOMES FOLLOWING INDUCTION OF LABOUR AT KENYATTA NATIONAL HOSPITAL

Principal Investigator\and institutional affiliation: DR TUNG'ANI MUCHIRI
MMed Obstetrics & Gynaecology student
University of Nairobi

Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol Number; _____

CONSENT FORM (page 2 0f 4)

The researchers listed above are interviewing individuals who are undergoing induction of labour. The purpose of the interview is to find out if body mass index of a pregnant woman affects the progress and outcome of induction of labour. Participants in this research study will be asked questions about their age, number of pregnancies they have had among other personal details. Participants will also have the choice to be weighed, have their height measured and their body mass index calculated.

There will be approximately 250 participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen:

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 15 minutes. The interview will cover

topics such as your socioeconomic status, your obstetric history and some details about your current pregnancy.
After the interview has finished, your current height and weight will be measured and you will be allowed to continue with your planned induction of labour. We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reason why we may need to contact you later is if we find some of your details missing.

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.
Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview. We will do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews.

CONSENT FORM (page 3 0f 4)

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

The information you provide will help us better understand how the weight of a mother can affect her or her baby when she undergoes induction of labour. This information is a contribution to science and will be of future benefit to mothers undergoing induction of labour and their care givers.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

No. All extra expenses will be catered for by the investigators.

WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY?

You are not expected to spend any extra money by being in this study.

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

CONSENT FORM (page 4 of 4)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counsellor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study:	**Yes**	**No**
I agree to have (define specimen) preserved for later study:	**Yes**	**No**
I agree to provide contact information for follow-up:	**Yes**	**No**

Participant printed name:

_____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: _____ **Date**: _____

Signature

_____

Role in the study: _____ *[i.e. study staff who explained informed consent form.]*

For more information contact DR TUNG'ANI MUCHIRI at UNIVERSITY OF NAIROBI from MARCH 2018 to DECEMBER 2018 through phone number 0780477862.

Witness Printed Name

Name _____ Contact information _____

Signature /Thumb stamp: _____ Date; _____

Appendix 2: Consent form in Swahili

Utafiti:INFLUENCE OF EARLY PREGNANCY BODY MASS INDEX ON MATERNAL AND FOETAL OUTCOMES FOLLOWING INDUCTION OF LABOUR AT KENYATTA NATIONAL HOSPITAL *(Utafitikuhusujinsiuzitowa mama akiwamjamzitounavyoadhirimatokeoyajuhudizakuletauchunguwakuzaakwakutumiamadawakatikaHospitalikuuya Kenyatta)*

Mwenyekufanyautafiti: Daktari TUNG'ANI MUCHIRI
Mwanafunziwa Chuo Kikuu cha Nairobi

NingependakukujulishakuhusuUtafitiunaofanywanaDaktariambayeametajwakwamajinahapojuu. Hojayahiibaruanikukusaidiakuamuakamautaitikiakuhusikanahuuutafiti au la. Usiogopekuulizamaswaliyeyotekuhusuhuumswada au

kuhusuhakizako.Ukiridhikakwambamaswaliyakoyoteyamejibiwa, unawezaukaitikiakushiriki au la.Ukiitikiakushiriki, nitakuombakupigasahihiiliuonyesheyakwambaumeelewa.
Hakunayeyoteatakayekulazimishakushirikinaunawezakubadilishamawazoyakokuhusukushirikiwakatiwowotebilahatakulazimishwakupeanasababuzako.
Hakunahudumazozoteutakazonyimwakwasababuyakutoshirikinahuuutafiti.
Utapewanakalayabaruahiiujiwekee.

Nawezakuendelea?NDIO / LA

UtafitihuuumeruhusiwanaKamatiyaMaadiliya Kenyatta National Hospital / UoNnanambariyakeni; _____

DaktariambayeamatajwaanafanyaUtafitikuhusu vile uzitowa mama akiwamjamzitounavyoatharimatokeoyahatuazakuanzishauchunguwakuzaa. Akina mama ambaowataitikiakushirikiwataulizwamaswalikuhusuumriwao, mimbaambazowamekuwanazonamengineo. Kandonahayo, watapimwauzitonaurefuwao.

Wanawakemiambilinaishiriniwatahusishwakwenyehuuutafiti.

NINIITAFANYIKAUKIITIKIAKUSHIRIKI?

Ukiitikiakushiriki, hayayatatendeka:

Utaulizwamaswalikwamudawakamadakikakuminatano.
Maswalihayayatauliziwapahaliambapoutafurahia.Ukishaulizwahayomaswali, uzitonaurefuwakoutapimwakasha utaruhusiwakuendeleanadawayakuanzishauchunguwakuzaa.
Tutakuombanambariyakoyasimuyenyetunawezakukupatanayokamakunahajayakuwasilianawewebaadaye. Hiinambarihaitapewayeyoteasiyeshughulikanahuuutafiti.
Tunawezatukawasilianawewebaadayekamatutapatakunaswalalinalokuhusunahalikujibiwasawasawa.

KUNA HATARIZOZOTEZINAZOTARAJIWA?

Utafitiwowoteukonahatarizake. Lakini, hatuahuchukuliwakupigananahatarihizi.
KatikaUtafitihuu, unawezaukaulizwamanenoambayonisiriyako.
Majibuutakayopeanahayatafunuliwakwamtumwingine.
Maswalimengineunawezakuwahutakikujibunahakunayeyoteatakulazimishakuyajibu. Pia, taarifaitakayotokananahuuUtafitihaitakuhusishakibinafsi.
MwenyeanafanyaUtafitiatahakikishamaelezoyoteyamefichwayasipatikanenawasiohusikanaUtafitinanakalazotezimefungiwavizuri.

.

FAIDAZAKUSHIRIKI NI GANI?

BaadayaUtafitihuu, tutawezakujuakamauzitowa mama akiwamjamzitounaadhirihatuazakuanzishauchunguwakuzaa, mama mwenyewe au mtoto wake. Hiitaarifaitasaidiawamamawenginesikuzausoninawanasayansikwakijumla.

KUNA MALIPOYEYOTE?

Hakunamalipoyeyoteutakayotoailiushiriki.

NA JE, UKITUMIAPESAYAKOUTAREGESHEWA?

HautarajiwikutumiapesazakokwamujibuwaUtafitihuu, lakiniikitokeakwambaulitumiahelazako, mwenyekufanyaUtafitiatakuregeshea.

NA KAMA UKO NA MASWALISIKUZAUSONI?

Ukiwanamaswaliyoyote, wasilianaDaktarialiyetajwaukitumianambariyasimuambayoimepeanwahapachini.

Aidha, unawezakuwasilianaKamatiyamaadiliya Kenyatta National Hospital kwanambariyasimu: 2726300 Ext. 44102 au baruapepe: uonknh_erc@uonbi.ac.ke.

Mwenyeanafanyautafitiatakuregesheapesautakazotumiakupigahiisimu.

HAKIZINGINE

Ukonauhuruwakushiriki au kutoshirikinaunawezakuamuakutoshirikiwakatiwowoteatakamaulikuwaumeitikiahapombeleni.

Taarifayamshiriki

Nimesomahabarihiinanimeielewa. Maswaliyanguyamejibiwanalughaninayoifahamu. Hatarinafaidazautafitihuunimeelezewa.
Naelewakwambasiwezikulazimishwakushirikikatikautafiti.Nimeitikiakushirikikwahiariyangumwenyewe.

Nimepewauhakikayakwambataarifaitakayotokananahuuutafitihaitanihusishakibinafsinamaelezoyanguhayatafunuliwakwamtumwingine..

Kwakupigasahihihapa, sioatihakizangukamamshirikizimeisha.

Nimeitikiakushiriki: **Ndio** **La**

Nimeitikiakupeananambariyasimu: **Ndio** **La**

Majina: _____

Sahihi au kidole_____ **Tarehe**_____

Mwenyekufanyautafiti

Mimi,
nimemwelezamshirikakuhusuutafitiwangunaameitikiakushirikikwahiarizakebaadayakuelezewa.

Majina: _____ **Tarehe**: _____

Sahihi_____

Cheokatikautafiti: _____

Kwamengine, wasilianaDkt TUNG'ANI MUCHIRIwaUNIVERSITY OF NAIROBIkuanziaMweziwatatu 2018 mpakaDisemba 2018ukitumianambariyasimu0780477862.

Shahidi

Jina _____

Sahihi au kidole: _____ **Tarehe**; _____

Appendix 3: Questionnaire

The effect of maternal BMI and the outcomes of induction of labour

STUDY QUESTIONAIRE

Date of recruitment .....
Code No ……..
Data collector's name: ……

A) DEMOGRAPHIC DATA (DIRECT INTERVIEW)

1. **Age in years** ……

2. **Religion** (Tick where appropriate)
a) Christian ☐ b) Muslim ☐ c) Other specify ☐ ……...

3. **Marital status**
a) Married ☐ b) Single ☐ c) Widowed ☐ d) Separated ☐ e) Others specify ☐
……

4. **Education level**
a) None ☐ b) Primary ☐ c) Secondary ☐ d) College ☐ e) Other specify ☐
……..

5. **Employment status**
a) Permanent ☐ b) Casual employment ☐ c) Self-employment ☐ d) ☐
Unemployed

B) BODY MASS INDEX

First weight recorded …… **Gestation age when recorded**…….
Height of the mother …….
First booking BMI …….
Current weight ……. **Gestational weight gain** …….
Current BMI …….. **Gestational change in BMI** …….

C) OBSTETRIC DETAILS

6. **Parity** ……

7. **Date of Last Menstrual Period** …….

8. **Gestational age by date** .....

9. **Gestational age by Ultrasound** …….. (If available)

D) INDUCTION OF LABOUR DETAILS

10. **Indication for Induction** …….

12. **If induction of labour stopped before labour or before all the doses administered, indicate reason:**……..

E) ASSESSMENT OF OUTCOMES

13.

Time 1st dose given	**Number of Doses given**	**Time last dose given**	**Labour achieved?** (Tick as appropriate)		**Duration to labour in hours**
			YES		
			NO		

14.

	At initiation of IOL	24 hours after initial dose
Bishop score		
Cervical dilation		
Uterine Contractions		

15. **Augmentation of labour done? (tick)**

Done	**Not done**

16. **Mode of delivery** (Tick where appropriate)

Vaginal	**Caesarean**

17. **If caesarean, what was the indication** …….

18. **Baby's APGAR score at 5 minutes** …… **Baby's birth weight** …….

19. **Any fatal outcomes?**(Yes or No)**.....**

(Maternal/Foetal mortality, Uterine rupture, Serious morbidity related to labour or IOL, Other)

If yes, elaborate ……