COMPARISON OF PREGNANCY OUTCOMES BETWEEN EARLY/FULL TERM AND LATE/POST TERM GESTATIONS AT KENYATTA NATIONAL HOSPITAL BETWEEN 2017 AND 2019: A COMPARATIVE CROSS-SECTIONAL STUDY

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A research dissertation submitted in partial fulfilment of the degree of Master of Medicine in Obstetrics and Gynaecology, Faculty of Health Sciences, University of Nairobi.

2023

DECLARATION

I declare that this dissertation is my original work and it has not been presented for an academic award in any other university. References made to others' work have been clearly indicated.

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CERTIFICATE OF AUTHENTICITY

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ACKNOWLEDGEMENTS

I wish to thank the Almighty God for this far I have come, for granting me the wisdom, strength, courage and good health that enabled me to undertake this research and finish it successfully.

I am especially grateful to my supervisors; Prof. P. M. Ndavi and Dr. P. Owende for their immense support, continuous guidance and patience through this process.

Special thanks to my research assistants who aided in data collection, to the patients whose files I used to collect the data and to Mr. Andrew Aballa for the data analysis.

Last but not least, my sincere appreciation to my family for being very supportive through the whole process.

May God bless you all.

DEDICATION

This dissertation is dedicated to my husband Dr. Seymour Sinari, my son Liam, my mother Lady Justice Lilian Mutende and my sister Eng. Jean Otsyula; you have all given me immense support, inspiration and encouragement all through my postgraduate training. May God reward each of you greatly.

LIST OF ABBREVIATIONS

ACOG- American College of Obstetricians and Gynaecologists

ANC- Antenatal Clinic

EDD – Estimated date of delivery

FHR- Fetal Heart Rate

IOL- Induction of labour

IUFD- Intrauterine Fetal Demise

KNH- Kenyatta National Hospital

LNMP - Last Normal Menstrual Period

NBU- New Born Unit

NICE- National Institute for Health and Care Excellence

PPH- Postpartum Haemorrhage

RCOG- Royal College of Obstetricians and Gynaecologists

SMFM- Society for Maternal Fetal Medicine

SVD- Spontaneous Vertex/delivery

UoN- University of Nairobi

WHO- World Health Organization

OPERATIONAL DEFINITIONS

Gestational age: Time measurement from the first day of the last normal menstrual period to the current date.

Preterm gestation: Gestation less than 37 completed weeks.

Early term gestation: Gestation of 37 0/7 weeks through 38 6/7 weeks.

Full term gestation: Gestation of 39 0/7 weeks through 40 6/7 weeks.

Late term gestation: Gestation of 41 0/7 weeks through 41 6/7 weeks.

Post term gestation: Gestation of 42 weeks and beyond.

Low-risk term pregnancy: Pregnancy with no active complications at 37 0/7 weeks gestation and beyond and with no maternal or fetal factors that place the pregnancy at increased risk for complications.

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ABSTRACT

Background: As pregnancy continues past the expected due date, there is increased risk of both maternal and perinatal complications during pregnancy, labour or following birth and this is especially so for late and post term pregnancies. Currently, there is limited published data on pregnancy outcomes at early, full, late and post term gestation in our set up. Many women would want to know their management options once at term. Evidence based information on the outcomes of pregnancy at the various gestations at and beyond term in our setting especially in relation to morbidity and mortality involved is important and will aid when counseling them on the various management options available with risks versus benefits of each with the aim being achievement of a positive pregnancy outcome.

Objective: To compare the pregnancy outcomes in women who delivered between 37 0/7 and 40 6/7 weeks gestation to those who delivered at 41 0/7 weeks and beyond at Kenyatta National Hospital between 2017 and 2019.

Methodology: A comparative cross sectional study was conducted at Kenyatta National Hospital for women who delivered at the maternity unit at a gestation of 37 0/7 weeks and beyond between January 2017 and December 2019. The files of 278 women, 137 who delivered at a gestation of 37 0/7 - 40 6/7 weeks and 141 who delivered at 41 0/7 weeks gestation and beyond were retrieved and data was extracted from their files. Data analysis was done using Statistical Package for Social Sciences (SPSS) version 25. Socio-demographic characteristics, perinatal outcomes, and maternal outcomes that were categorical were summarised and presented as frequencies and proportions, while those that were continuous were presented as means with standard deviations. Comparisons of the socio-demographic and obstetric characteristics, perinatal outcomes as well as maternal outcomes between the two groups were analysed using Chi-square test and logistic regression at 95% confidence interval. A p-value < 0.05 was considered significant.

Results: 278 women, 137 who delivered at a gestation of 37 0/7 - 40 6/7 and 141 who delivered from 41 0/7 weeks gestation, were evaluated using their case records and their outcomes compared. Socio demographic and obstetric characteristics were comparable between the two groups. After adjusting for socio demographic characteristics, participants who delivered at 41 0/7 weeks of gestation and beyond compared to those who delivered at 37 0/7 - 40 6/7 weeks gestation were 3.17-fold (95% CI=1.86-5.41) more likely to undergo induction of labour (P<0.01) and 2.89-fold (95% CI=1.54-5.42) more likely to deliver via a caesarean section (P<0.01). Birth weight was significantly higher when patients delivered at 41 0/7 weeks and beyond compared to 37 0/7 - 40 6/7 weeks gestation. The odds of giving birth to a baby with macrosomia compared to one with normal birth weight was 6.03-fold higher (95% CI=1.71-21.28) when delivery was at 41 0/7 weeks and beyond compared to 37 0/7- 40 6/7 weeks (P=0.005). Poor Apgar score at 5 minutes was more likely among children born at 41 0/7 weeks and beyond compared to 37 0/7- 40 6/7 [OR=6.00 (0.67-53.43)] but the difference was not statistically significant. Status of liquor, duration of labour, need for augmentation, mean blood loss irrespective of mode of delivery, intrapartum FHR, need for NBU admission and early perinatal mortality were comparable in both study groups.

Conclusion and Recommendations: This study showed increased fetomaternal risks in late and post term gestations in comparison to early and full term gestations, Late and post term pregnancies were associated with increased rates of induction of labour, caesarean deliveries and macrosomia. Management of pregnancies that progress past due date should include

counselling regarding risks associated with increasing gestational age. Induction of labour should continue to be offered at confirmed gestation of 41 0/7 weeks and beyond in accordance with national guidelines. Women who opt for expectant management should be monitored closely in the antepartum and intrapartum period as gestation advances.

INTRODUCTION AND LITERATURE REVIEW

Background

ACOG classifies deliveries occurring at or beyond 37 0/7 weeks of gestation into early term(37 0/7 weeks through 38 6/7 weeks), full term(39 0/7 weeks through 40 6/7 weeks), late term(41 0/7 weeks through 41 6/7 weeks and post term(42 0/7 weeks and beyond) following recommendations by a work group that was convened to determine whether term pregnancy should be redefined(1). This was done as it was noted that there were varied perinatal outcomes depending on time of delivery during this period(2).

Worldwide, prevalence of late and post term pregnancy varies widely and this may be due to regional differences in how gestational age is estimated based on history, physical examination and early pregnancy ultrasound and also due to variations in management once women are beyond their EDD (3–5). Studies have shown that routine use of early pregnancy ultrasonography decreases the incidence of post term pregnancy (6,7). In Europe, Zeitlin et al found a post term pregnancy prevalence range of 0.4 to over 7 %(4). Mya et al found a late and post term pregnancy prevalence of 7.5 to 7.9% in a survey done in Low and Middle Income Countries(5).

Estimation of gestational age

It is important to estimate gestational age accurately so as to avoid unnecessary interventions and morbidities and mortalities, associated with preterm births, and also to facilitate clinicians to provide timely interventions in the cases of prolonged pregnancies so as to avoid morbidities and mortalities associated with these (7–9).

Gestation is estimated in various ways from clinical history, physical examination or early ultrasound findings. Most commonly, Naegele's rule (subtracting 3 months, adding 7 days and 1 year to the first day of the LNMP) is used. LNMP itself though may not be a very accurate

way of estimating gestation (7,8). This is because the woman may recall a wrong date, she may have had irregular menses, she may confuse an early pregnancy bleed with LNMP, and she may be on hormonal contraception or have been breastfeeding which would alter ovulation timing.

Other parameters that have been used to estimate gestation include an early ultrasound, date of quickening, fundal height measurements, and the timing of a positive pregnancy test. Most of these parameters are quite subjective so a combination would be a better predictor of a best obstetric estimate. An early obstetric scan is best for estimation of gestational age(7,9). When ultrasound is done before 14 0/7 weeks, the gestational age determination is through measuring the crown–rump length and this is accurate by ±5–7 days. Gestational age determination by ultrasound in the 2nd trimester (between 14 0/7 weeks and 21 6/7 weeks of gestation) is done using a composite of fetal biometric measurements that include the biparietal diameter, head circumference, femur length and the abdominal circumference. This is accurate by ± 7–10 days(9). ACOG recommends data from the LNMP and an ultrasound exam done before 22 weeks of gestation that affirms or corrects the EDD as a best measure for estimating gestational age(9).

According to WHO, a good obstetric estimate of the gestational age is achieved by relying on either LNMP in a patient with regular menstrual cycles or an early obstetric scan if her cycle is irregular. WHO recommends one ultrasound scan before 24 weeks of gestation (early ultrasound) for pregnant women to estimate gestational age, improve detection of fetal anomalies and multiple pregnancies, reduce induction of labour for post-term pregnancy, and improve a woman's pregnancy experience(10).

According to ACOG, if ultrasound estimation prior to 16 weeks contradicts LNMP estimation with over seven days, revise EDD to scan date. If done from 16 0/7 to 21 6/7 weeks and it

contradicts LNMP estimation with over ten days, or from 22 0/7 to 27 6/7 weeks and it contradicts with over 14 days, revise it to scan date. (9).

In a study done by Dribsa at Pumwani Maternity Hospital in Nairobi in 1998, estimated gestational age was calculated using LNMP and onset of fetal quickening (11). Endere, in a study done at St. Mary's Mission Hospital in Nairobi in 2003, estimated gestational age by a best obstetric estimate arrived at by using at least 3 out of the following parameters: LNMP, onset of quickening, gestation at which fetal heart rate was first heard with none electric fetal stethoscope, fundal height consistent with dates, positive PDT done 6 weeks after LNMP and early pregnancy ultrasound before 24 weeks(12). Nyakinyua, in a study done at KNH in 2017, estimated gestational age by using LNMP and a scan which gave a gestation that was comparable with the gestation given by dates and did not have a discrepancy of greater than 10 days or an early obstetric scan done before 23 weeks (13). Hovi et al, in a study done in Finland in 2006, estimated gestational age using LNMP, but if a discrepancy of over 7 days in 1st trimester scan estimation (or over 14 days in 2nd) was noted, scan date was used (14). In this study, recorded gestation of LNMP and a corresponding obstetric scan done before 24 weeks was used to estimate gestation. Gestation by dates was accepted unless the LNMP was unknown or there was a discordance of more than 10 days on scan upon which the gestation by scan was used.

Factors associated with gestational length and onset of labour

The average length of human gestation is 280 days or 40 weeks from the first day of the woman's LNMP, however very few women actually deliver on this date(15,16). Variations on gestation length have been noted amongst different population groups and ethnicities with White women having longer gestational lengths than Blacks and Asians (15,16).

Onset of labor varies from case to case. Calculations based on Naegele's formula only give a rough guide of the EDD. The process is comprised of a combination of maternal, fetal and

placental factors(17). This include: uterine distension, activation of fetal hypothalamus-pituitary- adrenal axis resulting in increased fetal cortisol, increased estrogen, oxytocin and prostaglandin levels with falling levels of progesterone. Alteration in any of the above may result in failure or delay of onset of labor. Studies have demonstrated the association of several factors with variation in gestational length and this include parity, socio demographic factors, progesterone levels, smoking, previous gestational length in other pregnancies, maternal age and maternal weight (16).

The aetiology of post term pregnancy is largely unknown, given the complex mechanisms involved in initiation of labor, but there are various factors that have been hypothesized. Wrong dates due to inaccurate LNMP is one of the causes of its increased prevalence(6). Genetic factors: Post term pregnancy is more common where there has been a prior case of post term pregnancy and where there have been other post term deliveries in the family (11,13,16,17). Late and post term pregnancies are also more common among primigravid women and in women who deliver at a younger age (11,13,14,18). Studies have demonstrated fetal factors such as congenital anomalies and male fetus as being a risk for developing late and post term pregnancies(13). Placental sulphatase deficiency which results in low estrogen levels which is important in initiation of labour can also cause prolongation of pregnancy(18).

Outcomes of late and post term pregnancies

As pregnancy continues past the expected due date, there's increased risk of both maternal and perinatal complications during pregnancy, labour or following birth (19–22). There is risk of placental insufficiency due to placental aging as the pregnancy continues, increased risk of oligohydramnios, meconium passage and abnormal intrapartum fetal heart rate (14,19,23). There's increased risk of macrosomia (14,19,24), prolonged labor, maternal anxiety and obstetrical trauma(25). Increased rates of induction of labour, instrumental and caesarean

delivery also occur(19,25). Increased perinatal morbidity and mortality are also noted with increasing gestation(4,19,24).

Caughey et al in various studies demonstrated higher maternal and perinatal risk when the pregnancy progresses past forty weeks of gestation (19–22). They found an increase in assisted vaginal delivery as well as chorioamnionitis and endomyometritis past forty weeks, increase in PPH as well as an increase in IUFD and caesarean delivery past 41 weeks.

Singh et al, in India found higher rates of caesarean delivery, presence of meconium stained liquor and NICU admission in postdated pregnancies (beyond 40 weeks) when compared to term pregnancies (37-40 weeks)(23)

Marahatta et al, in India found similar rates of SVD and instrumental delivery but significantly higher rates of caesarean delivery and perinatal mortality in post term pregnancies when compared to term pregnancies(24).

Dribsa, in a study at Pumwani Hospital, found a trend of reduction in Apgar score with increasing gestation, admission to NBU also increased with gestational age (11).

Hovi et al, in Finland, found that perinatal mortality did not increase past the due date and that rate of admission to NBU were similar but macrosomia, intrapartum asphyxia, meconium stained liquor, PPH, prolonged labour, IOL and caesarean delivery occurred more significantly in post-term in comparison to those at term (14).

It is important to minimize or avoid these risks by proper timing and planning of management of pregnancies at term and beyond. Management options include induction of labour and expectant management with fetal antenatal monitoring(26). Individualized care of the woman should be undertaken and this should involve advice on the various options available as well as risks and benefits of the various approaches(22,26). Currently, WHO advocates for induction of labour if one is sure the woman has completed forty one weeks. It doesn't recommend it for low-risk pregnancies that are below forty one weeks(27).Our national guidelines are in

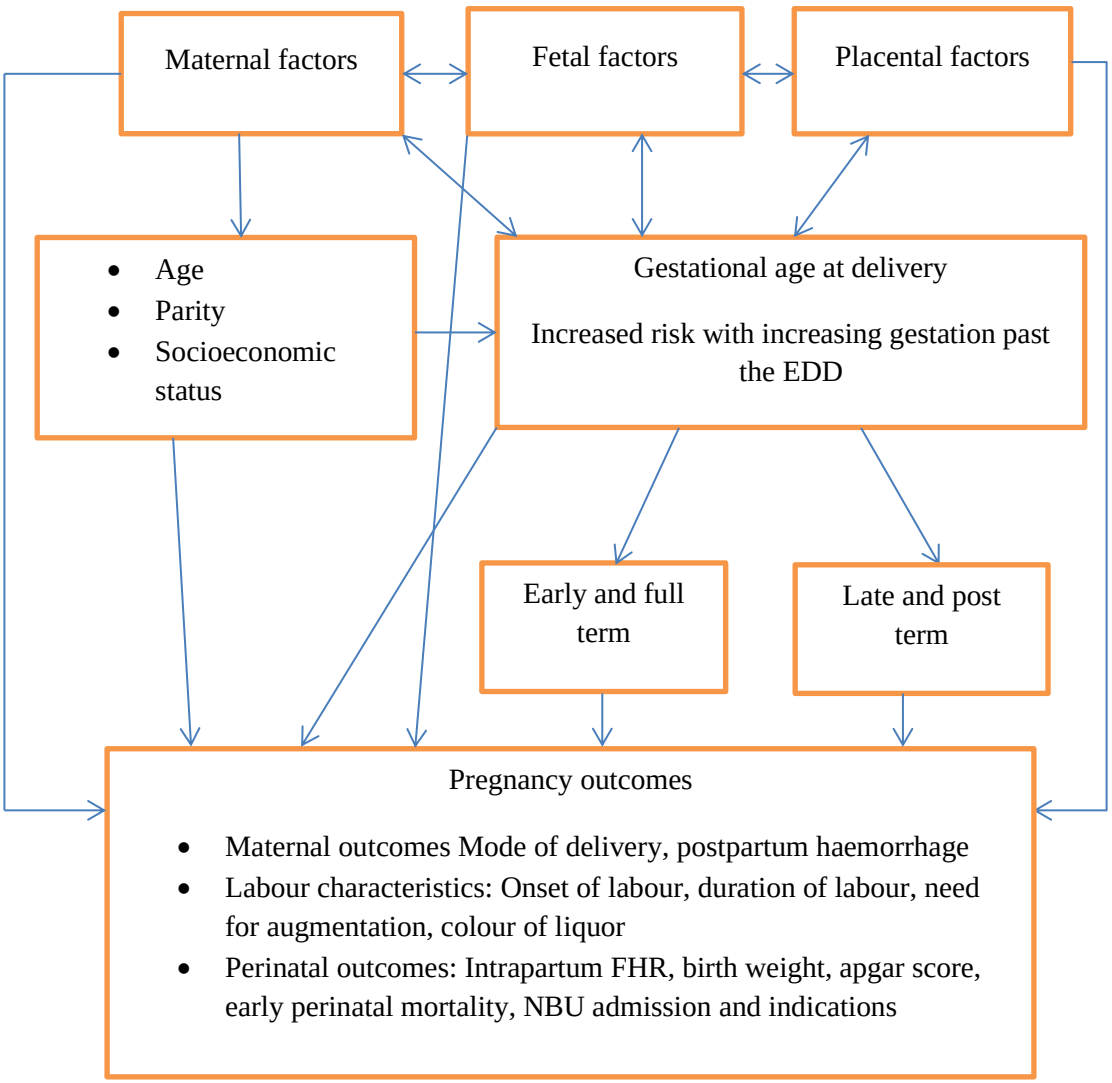
accordance with these WHO recommendations(28) NICE guidelines advise; in uncomplicated singleton pregnancies, offer induction of labour at 41 0/7 weeks, to take place then or as soon as possible afterwards (29). According to a Cochrane review on IOL for improving birth outcomes for women at or beyond term , a policy of labor induction rather than expectant management was associated with less perinatal deaths, and fewer caesarean deliveries, NBU admission rates were lower and less babies had Apgar score below 7 at five minutes(30). The ARRIVE trial evaluated outcomes for elective IOL at thirty nine weeks versus expectant management in otherwise healthy low risk nulliparous women with no medical or obstetric indication for IOL and found no statistically significant difference in their primary perinatal outcomes but significantly lower rate of caesarean delivery(31). A meta-analysis of 6 cohort studies done to compare elective IOL at 39 weeks with expectant management demonstrated that elective IOL was associated with a significantly lower risk of caesarean delivery, maternal peripartum infection and perinatal adverse outcomes that included respiratory morbidity, intensive care unit admission and mortality(32). Taking into account this findings, ACOG and SMFM recommend that it is acceptable for clinicians to give nulliparous women with low-risk pregnancies the option of IOL once they have completed thirty nine weeks taking into account the values and preferences of the pregnant woman, the resources available (including personnel), and the setting in which the intervention will be implemented. A collaborative discussion on risks and benefits with shared-decision making should take place with the pregnant woman(33,34).

THEORETICAL FRAMEWORK

Research has shown that there are varied pregnancy outcomes, both maternal and perinatal, depending on the gestation at delivery at term and beyond with increasing evidence demonstrating that once at term, as a pregnancy continues past the expected due date, there's increased risk of both maternal and perinatal complications during pregnancy, labour or following birth(19–21). There is risk of placental insufficiency due to placental aging as the pregnancy continues, increased risk of oligohydramnios which is associated with umbilical cord compression, poor tolerance of labor and fetal distress, meconium passage may also occur leading to meconium aspiration syndrome, fetal hypoxia, fetal acidosis and abnormal intrapartum fetal heart rate (14,19). There's increased risk of macrosomia which can result in shoulder dystocia, obstetrical trauma and increased rates of instrumental and caesarean delivery (14,19,24). Greater perinatal morbidity and mortality are also noted with increasing gestation due to the above complications(4,19,24).

CONCEPTUAL FRAMEWORK

Figure 1: Schematic Conceptual Framework



Narrative

This framework indicates that the study is concerned with the association of gestational age at delivery (early and full term in comparison to late and post term) and pregnancy outcomes these being labour characteristics, maternal outcomes and perinatal outcomes. These can be influenced by socio demographic factors as well as maternal, fetal and placental factors. Similar pregnancy outcomes as indicated will be assessed for both groups and then compared to check for differences.

JUSTIFICATION

As pregnancy continues past the expected due date, there's greater risk of maternal and perinatal complications during pregnancy, labour or following birth and this is especially so for late and post term pregnancies(19–22). Management options may include induction of labour or expectant management with fetal antenatal monitoring(26). At KNH induction of labour is offered as per national guidelines if one is certain the woman is at or beyond forty one weeks gestation(28).

Currently, there is limited published data on pregnancy outcomes at early term, full term, late term and post term gestations in our setting. This study aimed to compare the pregnancy outcomes of women who delivered between 37 0/7 and 40 6/7 weeks of gestation to those who delivered at 41 0/7 weeks and beyond at KNH. The findings from this study will help add information to local data available on outcomes of low risk pregnancies at term and beyond. Recognition of variation in morbidity as gestation increases at term will help clinicians consider interventions at appropriate time to minimize these. These findings will also help clinicians have evidence based information when counseling patients on various management options available at and beyond term with concomitant risks versus benefits as demonstrated, especially so as there is shifting of practice towards earlier elective induction of labour(29,33,34). Information on the outcomes of pregnancy at the various gestations at and beyond term especially in relation to morbidity and mortality involved is important, and will be useful in revising or formulating health policies, guidelines and Standard Operating Procedures in our set up further strengthening on appropriate timing of interventions with the aim of achieving positive pregnancy outcomes.

RESEARCH QUESTION

Is there any difference in pregnancy outcomes in women who delivered between 37 0/7 and 40 6/7 weeks of gestation compared to those who delivered at 41 0/7 weeks and beyond at KNH between 2017 and 2019?

NULL HYPOTHESIS

There is no difference in pregnancy outcomes in women who delivered between 37 0/7 and 40 6/7 weeks of gestation compared to those who delivered at 41 0/7 weeks and beyond at KNH between 2017 and 2019.

BROAD OBJECTIVE

To compare the pregnancy outcomes in women who delivered between 37 0/7 and 40 6/7 weeks of gestation to those who delivered at 41 0/7 weeks and beyond at KNH between 2017 and 2019.

SPECIFIC OBJECTIVES

Among women at 37 0/7 to 40 6/7 weeks of gestation and in comparison to those at 41 0/7 weeks and beyond, to determine their:

1. Maternal outcomes
2. Perinatal outcomes
3. Association between gestation at delivery and pregnancy outcomes, adjusted for socio demographic and obstetric characteristics.

METHODOLOGY

STUDY DESIGN

This was a comparative cross-sectional study in which the pregnancy outcomes of women who delivered at a gestation between 37 0/7 and 40 6/7 weeks and those who delivered at 41 0/7 weeks and beyond between 1st January 2017 and 31st December 2019 were analyzed using their case records and their outcomes compared. This design was suitable for this study as it was able to capture multiple variables in the comparative groups at a specific point in time and could determine the association between the exposure and outcome of interest simultaneously.

STUDY SITE AND SETTING

The study was conducted at the Maternity unit and the Health Information and Records department of KNH. KNH is a national teaching and referral hospital located in Nairobi County. The maternity unit caters for about 10,000 deliveries annually. The unit consists of a labor ward, 2 maternity operating theatres, 3 antenatal/postnatal wards and antenatal/postnatal clinics and a dedicated critical care unit. Obstetric patients who need admission are admitted through labour ward and antenatal clinic. IOL is offered if one is certain the woman is at or beyond forty one weeks. Current guidelines do not recommend elective IOL prior to forty one weeks in uncomplicated pregnancies. Those undergoing induction of labour or are already in labour are monitored within the labour ward where deliveries are also carried out. Following delivery, immediate postpartum care is given at labour ward and then mother and baby are transferred to the postnatal wards for postnatal care after review by the doctor. KNH Records department has a centralized filing system that is largely paper based. Each service delivery point within KNH has a designated Health Records and Information Officer working from a unit within the service delivery point. Each client/patient is allocated a unique identifying

number at the initial service point and this serves as a reference for that particular client within the hospital for all services and subsequent visits.

STUDY POPULATION

Women who delivered at Kenyatta National Hospital at a gestation of 37 0/7 weeks and beyond between 1st January 2017 and 31st December 2019.

ELIGIBILITY CRITERIA

Inclusion Criteria

- Women with low-risk pregnancies who delivered at 37 0/7 weeks gestation and beyond based on their LNMP and/or an obstetric scan done before 24 weeks of gestation. Gestation by dates was accepted unless the LNMP was unknown or there was a discordance of more than 10 days on scan upon which the gestation by scan was used.
- Women with singleton pregnancy.

Exclusion Criteria

- Women who were uncertain of their LNMP and with no early pregnancy obstetric scan.
- Women with adverse medical conditions in pregnancy such as HIV, diabetes mellitus, any hypertensive disorder, anemia, pulmonary diseases, thyroid or cardiac disease.
- Women with incomplete case records.
- Women with malpresentations.
- Women with prior caesarean delivery.

SAMPLE SIZE

Sample size calculation was done using Kelsey's formula for comparing two proportions(35).From study done by Singh et al in India that looked at some pregnancy outcome parameters similar to ours, NICU admission for birth asphyxia was 6.09% among

term and 17.6% in prolonged pregnancies in this study(23). These findings were used to calculate our sample size as shown below.

$$\boldsymbol{n = \frac{2\left(Z_{\frac{\alpha}{2}} + Z_{\beta}\right)^{2} P(1-P)}{(P_1 - P_2)^{2}}}$$

n = Desired sample size

$\boldsymbol{Z_{\frac{\alpha}{2}}}$ = value from standard normal distribution corresponding to desired confidence level = 1.96 for 95% CI

$\boldsymbol{Z_{\beta}}$= 0.842 (From Z table) at 80% power

$\boldsymbol{P_1 - P_2}$ = Difference in proportion of pregnancy outcomes in the two groups

$\boldsymbol{P =}$ Pooled prevalence = (Prevalence in group $\boldsymbol{P_1}$+ Prevalence in group $\boldsymbol{P_2}$**)** / 2

$$\boldsymbol{n = \frac{2(1.96 + 0.842)^{2} 0.11845(1 - 0.11845)}{(0.176 - 0.0609)^{2}} = 124}$$

n = 124 women per group, therefore minimum total sample size was 248.

This was adjusted by a factor of 10% to cater for missing data bias from studies using medical records(36). Therefore 137 women were required per group giving a total sample size of 274.

SAMPLING PROCEDURE

Upon obtaining ethical approval, the study participants were recruited from the delivery registers obtained at the health records office situated in the labour ward. Delivery registers were checked to identify women who were documented to have had gestation of 37 0/7 weeks and beyond and delivered between 1st January 2017 and 31st December 2019. Their unique identifying numbers were used to get their case records which were checked to see if they met the inclusion criteria. Stratified random sampling technique was used with 3 strata made up from the years 2017, 2018 and 2019 with at least 56 participants in each study arm from 2017,

37 from 2018 and 44 from 2019, numbers proportioned to the ratio of number of deliveries in the 3 years at KNH. Simple random sampling was then employed in each of these years.

STUDY VARIABLES

Exposure Variables

Socio demographic characteristics

- Age
- Education level
- Marital status
- Employment status

Obstetric characteristics

- Parity
- Gestational age

Outcome variables

Maternal outcomes and labour characteristics

- Onset of labour- spontaneous or induced
- Need for augmentation
- Colour of liquor
- Postpartum haemorrhage.
- Mode of delivery- SVD, instrumental, caesarean.
- Duration of labour

Perinatal outcomes

- Intrapartum FHR
- Birth weight

- Early Perinatal mortality - stillbirths and 1st 24 hour neonatal deaths
- NBU admission and indications.
- Minute 5 Apgar score

DATA COLLECTION AND MANAGEMENT

Data was collected from patients' case records using a data retrieval form (Appendix 1). Two clinical officer interns were recruited as research assistants to aid in the collection of data. They were trained on data collection before commencing the study, first by observation followed by collection of data under supervision. Patients' unique identifying numbers were used to retrieve their case records from KNH Records department. To maintain confidentiality, a study number was assigned to each eligible case record and used henceforth.

Quality Assurance Procedures: Strict adherence to the study protocols on recruitment of study participants was done. We used standardized methods of determining gestational age, that is, Naegele's rule and/or an obstetric ultrasound done before 24 weeks of gestation to ensure validity. Pre testing of the data collection tool was done on 10 cases to ensure standardization in filling and correction of any errors or ambiguities was done before data collection began so as to ensure reliability. Participants' unique identifying numbers were entered into a register upon recruitment for serialization. This register was checked daily for any double entries and if found, one of the data collection forms was withdrawn and discarded. The Principal Investigator counter checked the serialized data retrieval forms daily for completeness and if satisfactory transferred the data onto Excel soft copy using the same serial number in case need to counter check data for errors arises. Hard copy forms were stored safely and confidentially by the Principal Investigator. Soft copy was in a password protected computer.

DATA ANALYSIS

A Microsoft form was used for data entry and management. Data was counter checked then exported to SPSS v25 for analysis. Socio-demographic characteristics, perinatal outcomes, and maternal outcomes that were categorical were summarised and presented as frequencies and proportions, while those that were continuous were presented as means with standard deviations. Comparison of the socio-demographic and obstetric characteristics, perinatal outcomes as well as maternal outcomes between the two groups was done using Chi-square test and logistic regression at 95% confidence interval. Tests were considered significant where the p-value < 0.05.

ETHICAL CONSIDERATIONS

Approval was obtained from UON Department of Obstetrics and Gynaecology and the KNH-UoN ERC before collection of data began. Permission was also sought from the in charges of the KNH Obstetrics & Gynaecology and Records departments. All data sheets did not contain names of participants or their hospital in-patient numbers for confidentiality purposes. Participants' file numbers and assigned study numbers were used for record purposes. All used forms and the serialization register were stored safely and confidentially by the Principal Investigator, soft copies were in a password protected computer. No patients were interviewed for this study hence no informed consent was needed.

STUDY RESULTS DISSEMINATION PLAN

Findings from the study will be presented to the KNH/UON Departments of Obstetrics & Gynaecology, in scientific conferences and published in peer-reviewed journal.

STUDY STRENGTHS AND LIMITATIONS

Strengths

The comparative nature of the study enabled us to capture multiple variables in the comparative groups at a specific point in time and enabled us to determine the association between the exposure and outcome of interest simultaneously.

The study employed stratified random sampling technique to reduce bias.

Multivariable logistic regression models were used during data analysis to control for potential confounders.

Limitations

The study findings might not be generalised as the study was carried out in one facility.

This was a cross sectional study design and as such showed association and not causal effect.

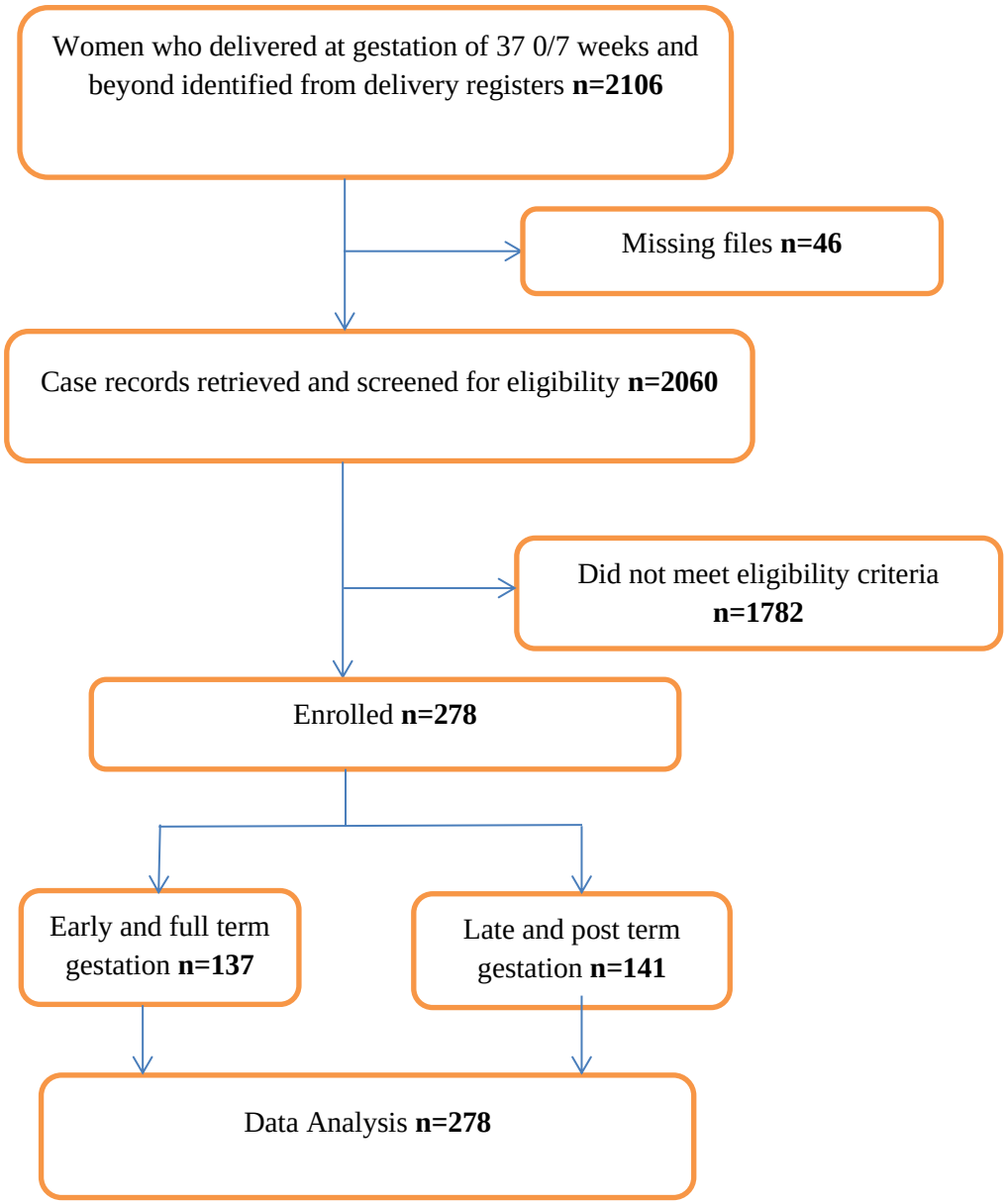
The study grouped together women in early and full term gestation and compared their outcomes to those in late and post term gestation groups and this combination of groups may have affected study outcomes, for this we suggest further studies that evaluate outcomes in each group independently so as to reduce bias.

Non-differential misclassification bias of gestational age might have occurred in the two groups. To mitigate this, we compared the EDD given by LNMP with that of an early obstetric scan so as to come up with the best obstetric estimate of the due date.

RESULTS

2106 case records were identified from delivery books for retrieval and screening for eligibility. Out of this, 46 files were missing giving a retrieval rate of about 98%. Out of the 2060 files retrieved, 1740(approximately 84%) had no early pregnancy scan and out of the remaining 320 files, 42 were excluded because of having other medical conditions, incomplete records, malpresentations or prior caesarean delivery.

Figure 2: Recruitment Flow Chart



Maternal Characteristics

Two hundred and seventy eighty (278) were evaluated, 137 who delivered at a gestation of 37 0/7- 40 6/7 and 141 who delivered from 41 0/7 weeks gestation. A comparison of their demographic characteristics is presented in table 1. Participants who delivered at 37 0/7- 40 6/7 weeks of gestation were slightly older with a mean age of 26.9±5.5 years compared to those who delivered from 41 0/7 weeks gestation (26.6±5.2 years) but the age difference was not statistically significant. Moreover, participants who delivered at 37 0/7- 40 6/7 weeks gestations compared to those who delivered from 41 0/7 weeks were more likely to be single, have a secondary education than primary, and multiparous but the difference was not statistically significant.

Table 1: Maternal characteristics

Variable	**37 0/7 - 40 6/7 (N=137)**	**41 0/7 and beyond (N=141)**	**OR (95% CI)**	**P value**
Age, Mean (SD)	**26.9 (5.5)**	26.6 (5.2)		0.720
Marital status, n (%)				
Single	**25 (18.2)**	23 (16.3)	1.13 (0.61-2.11)	0.689
Married	112 (81.8)	117 (83.0)	Reference	
Divorced/separated	0 (0.0)	1 (0.7)	-	-
Education level, n (%)				
None	0 (0.0)	1 (0.7)	-	-
Primary	19 (13.9)	18 (12.8)	Reference	
Secondary	**62 (45.3)**	58 (41.1)	1.01 (0.49-2.07)	0.973
University/tertiary	56 (40.9)	64 (45.4)	0.82 (0.40-1.69)	0.618
Employment, n (%)				
Casual	8 (5.8)	8 (5.7)	1.12 (0.38-3.21)	0.842
Salaried	25 (18.2)	28 (19.9)	Reference	
Self employed	39 (28.5)	47 (33.3)	0.92 (0.47-1.83)	0.834
Unemployed	65 (47.4)	58 (41.1)	1.25 (0.65-2.43)	0.489
Parity, n (%)				
Nulliparous	65 (47.4)	68 (48.2)	0.87 (0.47-1.58)	0.649
Primiparous	38 (27.7)	42 (29.8)	0.82 (0.41-1.61)	0.564
Multiparous	**34 (24.8)**	31 (22.0)	Reference	

Maternal outcomes and labour characteristics

Table 2: Comparative analysis of maternal outcomes and labour characteristics

	41 0/7 and beyond (N=141)	**37 0/7-40 6/7 (N=137)**	**OR (95% CI)**	**P value**	**AOR (95% CI)**	**P value**
Colour of liquor						
Clear	113(81.3)	111(81.8)	Reference			
Meconium stained	26 (18.7)	26 (19.0)	0.98 (0.54-1.76)	0.953	1.05(0.55-1.98)	0.878
Onset of labour						
Induction of labour	69 (51.5)	34 (25.4)	3.12(1.88-5.17)	**<0.01**	3.17(1.86-5.41)	**<0.01**
Spontaneous onset of labour	65 (48.5)	100(74.6)	Reference			
Duration, Mean(SD)						
1st stage(hrs)	5.93(3.3)	6.08 (6.0)	-	0.424	-	0.427
2nd stage(min)	17.37(11.9)	15.79(9.2)	-	0.586	-	0.221
Augmentation						
Yes	56 (44.1)	49 (37.4)	1.32 (0.81-2.15)	0.274	1.25(0.74-2.12)	0.390
No	71 (55.9)	82 (62.6)	Reference			
Mode of delivery						
Caesarean	48 (34.0)	23 (16.8)	2.56 (1.46-4.54)	**<0.01**	2.89(1.54-5.42)	**<0.01**
SVD	92 (65.2)	113 (82.5)	Reference			
Vacuum	1 (0.7)	1 (0.7)	1.22 (0.06-23.5)	0.884	2.01(0.11-36.4)	0.636
Blood loss (Mls), Mean (SD)	314.7(153.2)	271.3(153.9)		0.019		
Caesarean	494.8(95.8)	508.7(231.4)		0.784		
SVD	222.0(73.5)	223.2(65.7)		0.901		
Vacuum	200.0	250.0		-		

Maternal outcomes and labour characteristics are presented in table 2. After adjusting for socio demographic characteristics, participants who delivered from 41 0/7 weeks of gestation

compared to 37 0/7-40 6/7 weeks gestation were 3.17-fold (95% CI=1.86-5.41) more likely to undergo induction of labour (P<0.01) and 2.89-fold (95% CI=1.54-5.42) more likely to deliver via a caesarean section (P<0.01). The status of liquor, duration of first and second stage of labour and the need for labour augmentation were comparable among women who delivered from 41 0/7 weeks of gestation compared to 37 0/7-40 6/7 weeks gestations before and after adjusting for socio demographic characteristics. Mean blood loss was comparable between the two groups irrespective of mode of delivery.

Indications for caesarean sections

Table 3: Indications for caesarean sections

	41 0/7 and beyond (N=48)	**37 0/7-40 6/7 (N=23)**	**OR (95% CI)**	**P value**	**AOR (95% CI)**	**P value**
Non-reassuring fetal status	16(33.3)	10(43.5)	0.65 (0.25-1.73)	0.406	0.60 (0.17-2.05)	0.421
Prolonged labour	4 (8.3)	1 (4.3)	2.00 (0.29-25.4)	0.539	1.99 (0.18-21.6)	0.569
Poor progress	8 (16.7)	5 (21.7)	0.72 (0.22-2.31)	0.605	0.60 (0.13-2.67)	0.506
Cervical dystocia	2 (4.2)	2 (8.7)	0.45 (0.06-3.10)	0.438	0.31 (0.02-3.45)	0.341
Obstructed labour	3 (6.3)	1 (4.3)	1.46 (0.20-9.83)	0.744	3.13 (0.24-39.4)	0.377
Meconium-stained liquor grade III	7 (14.6)	3 (13.0)	1.13 (0.25-4.37)	0.861	0.87 (0.15-4.83)	0.877
Meconium-stained liquor grade II	4 (8.3)	5 (21.7)	0.32 (0.09-1.31)	0.112	0.30 (0.05-1.64)	0.168
Failed induction	8 (16.7)	3 (13.0)	1.33 (0.33-5.03)	0.693	1.22 (0.25-5.88)	0.802

Indications for caesarean sections among patients who delivered from 41 0/7 weeks of gestation compared to 37 0/7- 40 6/7 weeks were similar (table 3). Patients who delivered from 41 0/7 weeks of gestation compared to 37 0/7- 40 6/7 weeks were more likely to undergo a caesarean

section (CS) due to prolonged labour, obstructed labour, meconium-stained liquor III, and failed induction but the difference was not statistically significant before and after adjusting for demographic characteristics. Moreover, patients who delivered from 41 0/7 weeks of gestation compared to 37 0/7 to 40 6/7 weeks were less likely to undergo a caesarean section because of non-reassuring fetal status, poor progress, cervical dystocia, meconium-stained liquor II but the difference was not statistically significant.

Perinatal outcomes

Table 4: Comparative analysis of perinatal outcomes

	41 0/7 and beyond (N=141)	**37 0/7-40 6/7 (N=137)**	**OR (95% CI)**	**P value**	**AOR (95% CI)**	**P value**
Intrapartum FHR			-		-	
Mean (SD)	139.4(4.9)	138.4(4.2)	Reference	0.332		0.480
Regular	134 (95.7)	135 (98.5)	3.02(0.72-14.9)		3.60(0.65-19.9)	
Irregular	6 (4.3)	2 (1.5)		0.160		0.142
Fetal viability						
Stillbirth	2 (1.4)	0 (0.0)	-	-	-	-
Live birth	139(98.6)	137 (100)	Reference			
Birth weight						
Mean (SD)	3434.4 (463.9)	3245.0 (423.4)	-	**<0.01**	-	**<0.01**
<2500g	1(0.7)	4(2.9)	0.26(0.02-1.63)	0.204	0.28(0.03-2.57)	0.260
2500-3999g	123(87.2)	130(94.9)	Reference			
>4000g	17(12.1)	3(2.2)	5.98(1.85-19.61)	**0.002**	6.03(1.71-21.28)	**0.005**
Apgar at 5 mins						
0-6	5(3.5)	1(0.7)	5.00(0.67-59.31)	0.106	6.00(0.67-53.43)	0.108
7-10	136(96.5)	136(99.3)	Reference			
NBU admission						
Yes	15 (10.6)	8 (5.8)	1.92(0.80-4.49)	0.146	1.82(0.73-4.55)	0.199
No	126 (89.4)	129(94.2)	Reference			
EPMR						
Yes	2 (1.4)	2 (1.5)	0.97(0.15-6.27)	0.976	1.18(0.15-8.88)	0.868

No	139 (98.6)	135 (98.5)	Reference			

FHR – Fetal Heart Rate, EPM – Early Perinatal Mortality

As shown in table 4, average birth weight was significantly higher when delivery was at 41 0/7 weeks gestation and beyond [3434.4 (463.9) grams] compared to 37 0/7-40 6/7 weeks gestation [3245.0 (423.4) grams] before adjusting for socio-demographic characteristics ($p<0.01$) and after adjustment ($p<0.01$). The odds of giving birth to a baby with macrosomia compared to one with normal birth weight was 5.98-fold higher (95% CI=1.85-19.61) when delivery was from 41 0/7 weeks compared to 37 0/7- 40 6/7 weeks before adjustment for socio demographic characteristics ($p=0.002$) and 6.03-fold (95% CI=1.71-21.28) higher after adjustment. Poor Apgar score (0-6) at 5 minutes was more likely among children born from 41 0/7 weeks compared to 37 0/7- 40 6/7 before [OR=5.00 (0.67-59.31)] and after adjusting for socio demographic characteristics [OR=6.00 (0.67-53.43)] but the difference was not statistically significant. Intrapartum fetal heart rate, need for NBU admission, and early perinatal mortality were comparable between the two groups before and after adjusting for socio-demographic characteristics.

Indications for NBU admission

Table 5: Indications for NBU admissions

	41 0/7 and beyond (N=15)	**37 0/7-40 6/7 (N=8)**	**OR (95% CI)**	**P value**	**AOR (95% CI)**	**P value**
Birth asphyxia	3 (20.0)	3 (37.5)	0.41 (0.07-2.36)	0.362	0.02 (0.00-3.91)	0.155
Respiratory distress syndrome	8 (53.3)	2 (25.0)	3.42 (0.45-19.88)	0.191	14.6 (0.16-1270.6)	0.238
Meconium aspiration	1 (6.7)	1 (12.5)	0.50 (0.02-10.7)	0.636	0.68 (0.01-48.5)	0.861

Neonatal sepsis	1 (6.7)	2 (25.0)	0.21 (0.01-2.26)	0.213	0.01 (0.00-5.22)	0.165
Macrosomia	2 (13.3)	0 (0.0)	-	-	-	-

As shown in table 5, indications for NBU admissions among children delivered from 41 0/7 weeks compared to 37 0/7- 40 6/7 weeks were similar. Children delivered from 41 0/7 weeks of gestation compared to 37 0/7- 40 6/7 weeks were more likely to be admitted to NBU due to respiratory distress and macrosomia but the difference was not statistically significant before and after adjusting demographics. The odds of NBU admission due to birth asphyxia, meconium aspiration, and neonatal sepsis were lower among children delivered from 41 0/7 weeks compared to 37 0/7- 40 6/7 weeks but the difference was not statistically significant before and after adjusting demographics.

DISCUSSION

Prolonged pregnancy is a subject of interest because of its confirmed association with increased maternal and perinatal morbidity and mortality(19–22). In this study, participants who delivered at 41 0/7 weeks and beyond compared to those who delivered at 37 0/7 - 40 6/7 weeks gestation were 3-fold more likely to undergo induction of labour. This is consistent with findings by Hovi et al(14). This could be explained by the routine practice of offering induction of labour to women who are at forty one weeks gestation and beyond (27).

Participants who delivered at 41 0/7 weeks and beyond compared to those who delivered at 37 0/7 - 40 6/7 weeks gestation were about 3-fold more likely to deliver via a caesarean section. Similar results were noted in studies by Caughey et al(19,21),Singh et al(23)Marahatta et al(24) and Hovi et al(14). Increased rates of caesarean delivery may be due to the increased risk of macrosomia, prolonged labour and meconium passage that may occur in prolonged pregnancies(14,19,24). In this study, it was noted that patients who delivered at 41 0/7 weeks and beyond compared to those who delivered between 37 0/7 and 40 6/7 weeks were more likely to undergo a caesarean section due to prolonged labour, obstructed labour, meconium-stained liquor III, and failed induction.

The status of liquor, duration of labour, need for labour augmentation and mean blood loss were comparable in the two study groups. This contrasts with the study by Hovi et al in which meconium staining was more common in the post term group and duration of labour was longer in cases with prolonged pregnancies as well (14). This may be explained by the practice of active management of labour that involves routine artificial rupture of membranes with augmentation of contractions with synthetic oxytocin and charting progress of labour on a partograph(37).

Average birth weight was significantly higher when delivery was at 41 0/7 weeks and beyond. The odds of giving birth to a baby with macrosomia compared to one with normal birth weight

was 6-fold higher when delivery was at 41 0/7 weeks and beyond compared to 37 0/7- 40 6/7 weeks. This was consistent with studies by Marahatta et al and Hovi et al (14,24). This is because although placental function decreases as the pregnancy prolongs past the expected due date, the total placental area increases and hence exchange of nutrients usually continues to support fetal growth.

There were no statistically significant differences between the two groups in the occurrence of poor Apgar scores and this was consistent with findings by Hovi et al(14).

Early perinatal mortality as well as need for NBU admission was comparable between the two groups. This was consistent with the study by Hovi et al(14) where they did not demonstrate any difference in perinatal mortality and morbidity as well as rate of admission to NBU in the study groups. This result was however inconsistent with studies by Singh et al, Marahatta et al and Caughey et al which showed increased rates of stillbirth and perinatal mortality in late and post term pregnancies (19,23,24).

Maternal demographic characteristics were comparable between the two groups demonstrating no association between maternal age, marital status, parity, education level and employment status with variation in gestational length. This was consistent with findings by study done by Endere at St. Mary's Mission Hospital, Nairobi(12).

A secondary finding that we noted as we were evaluating case records for eligibility is that out of the 2060 case records that we screened, 1740 had no early ultrasound scan done before 24 weeks translating to approximately only 16% of them having a record of an early scan. In comparison, Matiang'i et al(38) in a study on barriers and enablers that influence utilization of ultrasound screening services among antenatal women in Kisii and Kajiado counties found only 21% of antenatal women had scans done before 24 weeks gestation. This was in contrast to a study by Hovi et al in Finland(14) in which approximately 95% of pregnant women had

undergone ultrasound screening in the first trimester. This could be due to low resources in our setting as well as fewer women having access to ultrasound before 24 weeks(7,39).

CONCLUSION

This study showed increased fetomaternal risks in late and post term gestations in comparison to early and full term gestations.

Late and post term pregnancies are associated with increased rates of induction of labour. This could be explained by the routine practice of offering induction of labour to women at 41 weeks and beyond in accordance with national guidelines adopted from WHO recommendations.

Late and post term pregnancies are associated with increased rates of caesarean deliveries mainly due to prolonged labour, obstructed labour, meconium stained liquor grade III and failed induction. They are also associated with increased risk of macrosomia when compared to early and full term pregnancies. All these come with increased risks of both maternal and perinatal morbidity and mortality.

RECOMMENDATIONS

Management of pregnancies that progress past due date should include counselling regarding risks associated with increasing gestational age.

Induction of labour should continue to be offered at confirmed gestation of 41 0/7 weeks or beyond in accordance with national guidelines.

Women who opt for expectant management should be monitored closely in the antepartum and intrapartum period as gestation advances because of the increased risks demonstrated.

Performance of routine early pregnancy scans is encouraged so as to improve on the accuracy of gestational age estimation. This will facilitate proper planning of delivery and provision of timely interventions in the pregnancy with the aim of reducing morbidity especially those associated with late and post term pregnancies.

TIMELINES

Time Frame Gantt chart

	Jan-May 2020	June 2020	July-Oct 2020	Nov-Feb 2021	Mar-May 2021	June 2021	July-Aug 2021
Proposal Development							
Proposal Presentation							
Ethics Approval							
Data Collection							
Data Analysis							
Results presentation							
Final dissertation							

BUDGET

ITEM	**COST IN KSH**
Stationery and printing costs	10,390
ERC Fees	2,000
Statistician's fees	24,000
Research assistants	52,500
Total(Ksh)	**98,890**

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APPENDICES

Appendix 1: Data Retrieval Form

Serial number……..

Date……..

Section A: Socio demographic data

1. Age……
2. Marital status
   (a) Single [ ]
   (b) Married [ ]
   (c) Separated/divorced [ ]
   (d) Widowed [ ]
3. Education level
   (a) None [ ]
   (b) Primary [ ]
   (c) Secondary [ ]
   (d) Tertiary [ ]
4. Employment status
   (a) Unemployed [ ]
   (b) Self-employed [ ]
   (c) Salaried [ ]
   (d) Casual [ ]

Section B: Obstetric Data

1. Parity before delivery…….. + ……
2. LNMP…… Uncertain [ ]

   EDD by dates……

   Early pregnancy ultrasound EDD …….. Difference with dates…….

   Final EDD…….

   Delivery date…….

   Estimated gestation in weeks and days at delivery……..
3. Number of ANC visits…….
4. Medical conditions during the pregnancy…….
5. Maternal outcomes:
   a) Onset of labour:

      (i) Spontaneous [ ]

      (ii) Induced [ ]

   b) Need for augmentation (i) Yes [ ] (ii) No [ ]

   c) Duration of labour

      (i) First stage in hours……

      (ii) Second stage in minutes…….

   d) Colour of liquor at time of membrane rupture:

      (i) Clear [ ] (ii) Meconium stained [ ]

   e) Mode of delivery:

      (i) SVD [ ] (ii) Vacuum [ ]

      (iii) Caesarean [ ] Indication……..

   f) Estimated blood loss…….

   g) Final maternal outcome

(i) Alive [ ]

(ii) Dead [ ] Cause……..

6. Perinatal outcomes

a) Intrapartum FHR (bpm) ……..(i) Regular [ ] (ii) Irregular [ ]

b) Viability

(i) Live [ ] (ii) Fresh still birth [ ] (iii) Macerated still birth [ ]

c) Birth weight (grams)…….

d) Apgar score at 1 minute…….

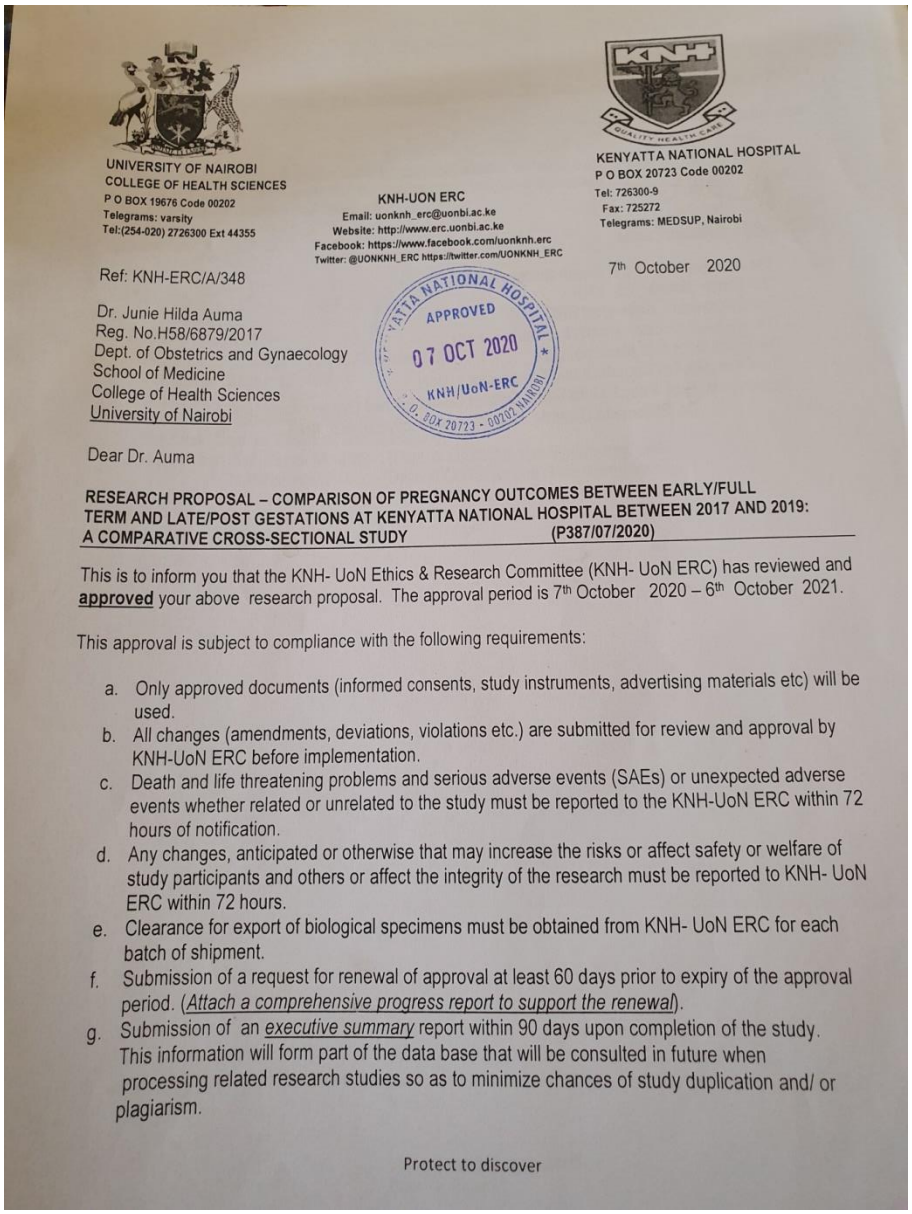
e) Apgar score at 5 minutes……..

f) NBU admission: (i) Yes [ ] Indication…….....

(ii) No [ ]

g) Early perinatal mortality: (i) Yes [ ] (ii) No [ ]

Appendix 2: KNH-UoN ERC Approval



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/348

7th October 2020

KENYATTA NATIONAL HOSPITAL APPROVED 07 OCT 2020 KNH/UoN-ERC P.O. BOX 20723 - 00202 NAIROBI

Dr. Junie Hilda Auma
Reg. No.H58/6879/2017
Dept. of Obstetrics and Gynaecology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Auma

RESEARCH PROPOSAL – COMPARISON OF PREGNANCY OUTCOMES BETWEEN EARLY/FULL TERM AND LATE/POST GESTATIONS AT KENYATTA NATIONAL HOSPITAL BETWEEN 2017 AND 2019: A COMPARATIVE CROSS-SECTIONAL STUDY (P387/07/2020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 7th October 2020 – 6th October 2021.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

Protect to discover

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept.of Obstetrics and Gynaecology, UoN
Supervisors: Prof. Patrick Muia Ndavi, Dept.of Obstetrics and Gynaecology, UoN
Dr. Philomena Owende, Dept.of Reproductive Health, KNH

Appendix 3: KNH Study Registration Certificate

KNH/R&P/FORM/01

KENYATTA NATIONAL HOSPITAL
P.O. Box 20723-00202 Nairobi

Tel.: 2726300/2726450/2726565
Research & Programs: Ext. 44705
Fax: 2725272
Email: knhresearch@gmail.com

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
   DR. JUNIE HILDA AUMA
2. Email address: hildajunie@gmail.com Tel No. 0721 872612
3. Contact person (if different from PI) N/A
4. Email address: N/A Tel No.: N/A
5. Study Title
   COMPARISON OF PREGNANCY OUTCOMES BETWEEN EARLY/FULL TERM AND LATE/POST TERM GESTATIONS AT KENYATTA NATIONAL HOSPITAL BETWEEN 2017 AND 2019. A COMPARATIVE CROSS-SECTIONAL STUDY
6. Department where the study will be conducted OBSTETRICS AND GYNAECOLOGY
   (Please attach copy of Abstract)
7. Endorsed by KNH Head of Department where study will be conducted.

   Name: DR M. EMITI Signature [signature] Date 11/11/2020
8. KNH UoN Ethics Research Committee approved study number P387/07/2020
   (Please attach copy of ERC approval)
9. I JUNIE HILDA AUMA commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Medical Research.

   Signature [signature] Date 09/11/2020
10. Study Registration number (Dept/Number/Year) Obs/14181/2020
    To be completed by Medical Research Department)
11. Research and Program Stamp KENYATTA NATIONAL HOSPITAL 19 NOV 2020

All studies conducted at Kenyatta National Hospital **must** be registered with the Department of Medical Research and investigators **must commit** to share results with the hospital.

Appendix 4: KNH HOD Approval

KENYATTA NATIONAL HOSPITAL
P.O. BOX 20723, 00202 Nairobi

Tel.: 2726300/2726450/2726550
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OFFICE OF HEAD OF DEPARTMENT, OBSTETRICS $ GYNAECOLOGY
EXT.43370

KNH/HOD-OBS&GYN/07/VOL.1 Date: 11th November, 2020

Dr. Junie Hilda Auma
Reg. No.H58/6879/2017
Dept. of Obsterics & Gynaecology
School of Medicine
College of Health Sciences
University of Nairobi

RE: COMPARISON OF PREGNANCY OUTCOMES BETWEEN EARLY/FULL TERM AND LATE/POST TERM GESTATIONS AT KNH BETWEEN 2017 AND 2019; A COMPARATIVE CROSS-SECTIONAL STUDY (P387/07/2020)

This is to inform you that the department has given you permission to conduct the above study which has been approved by ERC.

Liaise with Senior Assistant Chief Nurse - Incharge Labour ward In-charge in Obstetrics and Gynaecology to facilitate your study.

You will be expected to disseminate your results to the department upon completion of your study.

Dr. Maureen Owiti
For: HOD-OBSTETRICS & GYNAECOLOGY

Cc. Incharge - Labour Ward