THE ROLE OF MATERNAL FETAL MOVEMENT ASSESSMENT ON ANTEPARTUM FETAL TESTING AND PERINATAL OUTCOMES AMONG SELECTED HIGH-RISK PREGNANCIES AT THE KENYATTA NATIONAL HOSPITAL, 2014-2018

(A FIVE-YEAR RETROSPECTIVE COHORT STUDY)

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DECLARATION

This dissertation is my original work, written under theguidance of my supervisors and has not been presented for the award of a degree in any other university.References to work done by others have been indicated appropriately.

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DEDICATION

To my lovely wife, Maureen, our children Tamara Joy and Tilen Ajowi who have continued to give me hope and sense of direction during this journey.

Special thanks to my father who has supported me through most of my education.

LIST OF ABBREVIATIONS AND ACRONYMS

AFT   Antepartum fetal testing

ACOGAmerican Congress of Obstetricians and Gynaecologists

BMI   Body mass index

BPP   Biophysical profile

CSTContraction stress testing

CTG Cardiotocograph

FGR   Fetal growth restriction

FMA   Fetal movement assessment

GDMGestational diabetes mellitus

FKC   Fetal kick chart

IUFD   Intra-uterine fetal demise

KNH   Kenyatta National Hospital

MCA Middle cerebral artery

NICE   National Institute of Clinical Excellence, United Kingdom

NST Non-stress test

RFM Reduced fetal movements

RI   Resistive index

SGA Small for gestational age

UAUmbilical artery

UoN   University of Nairobi

OPERATIONAL DEFINITIONS

Antepartumfetal testing, surveillance techniques routinely used to assess the risk of fetal death (ACOG)

APGAR score, rapid scoring system used to assess the clinical status of a new-born infant. Comprises fivecomponents: 1) colour, 2) heart rate, 3) reflexes, 4) muscle tone, and 5) respiration, each of which is given a score of 0, 1, or 2(WHO definition)

Poor APGAR Score, total score of less than 7 at 5 minutes

Birth asphyxia, state of reduced oxygen delivery to the fetus or neonatal tissue manifesting as failure to initiate or maintain spontaneous respiration at birth. Usually denoted by APGAR score of seven or less at five minutes after delivery

Biophysical profile, an assessment of four discrete biophysical variables by ultrasound to determine fetal wellbeing. These include breathing, tone, movement and amniotic fluid volume. Each parameter is scored 2 or 0 with a score of 6 equivocal and 4 poor

Cardiotocography, method of continuous electronic fetal heart monitoring done through an ultrasound transducer attached to the mother's abdomen

Doppler velocimetry, Doppler assessment of blood flow through a fetal umbilical artery or Middle cerebral artery. It is used as a surveillance tool for high-risk pregnancies in the third trimester and an indicator of placental insufficiency

Early neonatal death, new-borndemise within three days of life

Fetal movement assessment (FMA), maternalfetal movement monitoring by subjective Perception

Fetal growth restriction (FGR), fetus with an estimated fetal weight < 10th percentile for that gestation

High-risk pregnancy,one that threatens the health or life of the mother or her fetus

New-born Unit, specialized neonatal care unit (NBU)

Prematurity, delivery of baby at gestation earlier than 37 weeks (WHO)

Post-term, pregnancy of gestation 42weeks and above (ACOG)

Reduced fetal movement (RFM),decreased perception of fetal movements by the mother

Small for gestation(SGA)infants are defined as having a birth weight that is less than that for 10% of the populationwhen plotted on a growth chart based on their gestational age and sex

Stillbirth, baby born with no signs of life at or after 28 weeks' gestation (WHO definition)

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ABSTRACT

Background

A high-risk pregnancy is that in which the life of the gravid woman or her fetus is threatened. Factorsassociated with high-risk pregnancy include; pre-existing medical conditions, pregnancy-related complications and inherent fetal health problems. Some of the commonest high-risk conditions include hypertensive disorders of pregnancy (HDPs), diabetes mellitus (DM) and post-term pregnancies whichaffect approximately8-10%, 16.2% and 5-10%of pregnancies in that order.Fetal surveillance tests such as maternal fetal movement assessment, fetal heart sound auscultation, cardiotocography (CTG) and ultrasound biophysical profile (BPP)and doppler velocimetry identify at-risk fetuses and therefore predict or prevent adverse perinatal outcomes.

Maternal fetal movement assessment (FMA)is a valuable test because it's easy to perform andinexpensive. Although FMA may not predictperinatal outcomes for all pregnancies, irrespective of the riskstatus, its role in high-risk pregnancies especially in low resource setting has not been fully described. In this study, we evaluated the antepartum fetal testing profile, early perinatal outcomes and the role of maternalfetal movement assessment in predicting adverse pregnancy outcomes specifically amongHDP,DM and post term pregnancies.

Objectives: To describe the antepartum fetal testing profile and perinatal outcomes and evaluate the role of maternal fetal movement assessment among selected high-risk pregnancies at Kenyatta National Hospital.

Methodology

Study Design: Records based retrospective cohort study

Sampling: Simple random sampling

Data collection: Standardpre‑coded and pretested data abstraction tools were employed to collect relevant data.

Statistical analysis: Continuous data variables were analysed as mean and standard deviation from the mean and t-test used to evaluate for association. For categorical variables, frequencies were obtained and compared using chi-square test. Relative risks werecalculated. A p-value of less than 0.05 was considered statistically significant.

Results: Between January 2014and December 2018 we examined records of 1372 women and 392(28.6%) werefound to be eligible. Thesecomprised 196(14.3%) records of women who reported normal fetal movements and 196 records of womenwho perceived reduced fetal movements. The mean age of the patients was 29.6 (standard deviation=6.2) years. A total of 140(35.7%) had hypertension, 67(17.1%) had diabetes mellitus, 132((33.7%) had post-term pregnancies and 53 women (13.5%) had more than one of these three conditions.

The most prevalent antepartum fetal test wasBPP (51.5%), followed by CTG (46.7%),umbilical artery resistive index (44.9%) and middle cerebral artery (MCA) resistive index (16.1%) in that order. The prevalence of fetal testing was significantly higher in the reduced fetal movement (RFM) group%) compared to normal fetal movement (NFM) group (CTG 60.2% vs 33.2%, BPP 67.3% vs 35.7%, umbilical artery RI 58.7%vs 31.1%, MCA RI 22.4 vs 9.7%), p < 0.05.

There were 55(14%) adverse perinataloutcomes, specifically,stillbirths,poor APGAR scores and early neonatal death. Theprevalence of these outcomes was higher in those who reported RFM 44(22%) vs11(6%) in the NFM group. Overall, the relative risk (RR)of adverse perinatal outcomes waselevated in those who had abnormal fetal testing compared tonormal testing. However this difference was not statistically significant(RR1.64,95% CI1.03-2.63,p

0.054)When we stratified by maternal fetal movement assessment, the association between abnormal fetal testing and adverse perinatal outcome remains statistically significant only in the RFM group(RR 2.55, 95% CI1.91-3.41, p < 0.001). There was no association between antepartum fetal testing and adverse perinatal outcome in the NFM group.

Conclusion: In the selected high-risk pregnancies, we found low rates of antepartum fetal testing withBPP as the most commonly performed test.The prevalence of fetal testing was higher when reduced fetal movements was reported. Abnormal fetal testing was associated with adverse perinatal outcome, more specifically in those with RFM suggesting RFM is an effect modifier of association between abnormal fetal testing and adverse perinatal outcome

Recommendations: Regarding high-risk pregnancies, protocols for antepartum fetal testing should be developed. Women with RFM and an abnormal fetal testshould be monitored closely due to high risk of adverse perinatal outcome.

Keywords: *High-risk pregnancies   Antepartum fetal testing   Adverse perinatal outcome*

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CHAPTER ONE: INTRODUCTION

1.1 Background

Perinatal morbidity and mortality are a major problem in low- and middle-income countries (LMICs) especially among high-risk pregnancies(1). Globally, the majority (98%) of stillbirths occur in LMICs(2). Sub-SaharanAfrica has an unacceptably high stillbirth rate of 28.7 per 1000 births(2). According to the 2014 Kenya demographic health survey (KDHS), the perinatal mortality rate is extremely high, at 29 per 1000 birtha far cry from the Every Newborn Action Plan that targetsa national stillbirth rate of 12 per 1000 live births by 2030(3). Although all pregnancies are potentially high-risk, a majority (88%) are uneventful with good perinatal outcomes (1). Pregnancies considered high-risk from the onset include those complicated by medical conditions such as hypertensive disorders of pregnancy (HDP), diabetesmellitus, placental abnormalities, preterm labour and post-term pregnancies(4). In high-risk pregnancies, diligent monitoring of the mother and fetus is required to optimize favorable outcomes(5).

Antepartum fetal tests are various techniques used routinely to evaluate the risk of fetal demise(5). These include maternal fetal movement assessment, cardiotocography (CTG), biophysical profile score (BPP) and doppler velocimetry of fetal umbilical artery and middle cerebral artery.

Maternal perception of fetal movements remains an important early indicator of the status of life and represents wellbeing throughout the pregnancy(6). Maternal concern over reduction or cessation of fetal movements(RFM) is a common problem which causes anxiety and has been noted to affect 15% of all pregnancies(7). RFM may be associated with adverse perinatal outcomes such as fetal growth restriction(FGR), preterm birth, intrauterine demise,

perinatal asphyxia, neonatal admission and early death(8)(9)(10)(11).Adjunct assessment of complaint of RFM with other objective fetal surveillance methods such as cardiotocography and ultrasound evaluations of the biophysical score and doppler velocimetry studies are associated with decision for early iatrogenic delivery geared towards improving perinatal outcome(12).

International guidelines direct that any woman in the third trimester of pregnancy should repeatedly be educated about the importance of monitoring fetal movements as RFM is one of the danger signs of pregnancy(13)(14). Both Royal College of Obstetricians and Gynecologists (RCOG)and American Congress of Obstetricians and Gynecologists(ACOG) recommend that any pregnant woman perceiving RFM should be offered further testing in the form of CTG and an ultrasound fetal BPP(13). ACOG guidelines go further and propose that suboptimal results from a non-stress test CTG or a modified BPP (non-stress test CTG and amniotic fluid index) be assessed with either a contraction stress test (CTG) or a biophysical score.

At KNH, pregnant women are educated on fetal movement assessment and those who perceive reduced fetal movements are evaluated further with an obstetric ultrasound and CTG. If those tests are normal, a fetal kick chart is maintained, commonly the "Cardiff count to 10". Currently, there is no evidence that any formal fetal movement counting protocol such as a kick chart is of greater value than the subjective maternal perception in the detection of fetal compromise (13)(15).

This study aims todescribe the antepartum fetaltesting profile, it's association with perinatal outcomes among selected high-risk pregnancies. Further the study seeks to evaluate if reduction in fetal movements influences the association between antenatal fetal testing and adverse perinatal outcomes. The findings will inform the utilization of antepartum fetal tests for high-risk pregnancies.

1.2 LITERATURE REVIEW

1.2.1 Background morbidities

Hypertensive Disorders of pregnancy encompass three related conditions, chronic hypertension, gestational hypertension and pre-eclampsia. Together they complicate about 10% of pregnancies. Chronic hypertension predisposes to pre-eclampsia which is characterized by abnormal placentation due to impaired trophoblastic invasion of the spiral arteries. Besides there is thrombosis, vascular endothelial damage and oxidative stress which lead to placental insufficiency(16)(17)(18).

Maternal hyperglycaemia complicates about 16% of pregnancies(19). is associated with hyperproliferation and hypervascularization of the placenta(20). This causes increased surface area especially in the periphery of the villous tree. Additionally, thickening of trophoblastic membrane occurs, resulting in increased diffusion distance between maternal and fetal systemic circulations. Impaired oxygen supply to placenta with attendant increase in oxygen demand by themacrosomic fetus then occurs. Furthermore, in type 1 diabetes mellitus there is slight edema of villous stroma and Hoffbauer cells leading to cytokine and interleukin release. These modify the metabolic and endocrine function of the placenta.

Prolonged pregnancy results in placental senescence and calcification which lead to metabolic and circulatory functions degradation(21). Genetic apoptosis is postulated to be responsible in placental metabolism and hormonal production changes.

1.2.2 Objective antepartum fetal testing methods

The existing methods of assessing fetal wellbeing include cardiotocography, ultrasound evaluation of biophysical profile score(BPP), modified BPP and doppler studies of the umbilical artery, middle cerebral artery and ductus venosus(12)(22). Cardiotocography is based on the principle that fetal hypoxia and acidosis can be predicted on fetal heart rate

tracings(22)(23). These include changes such as a reduction in beat to beat variability, fluctuations in baseline fetal rate. Presence of accelerations insinuates normal fetal neurological function while late, prolonged and variable decelerations are predictors of fetal compromise. A study conducted in India indicated performance of intrapartum CTG in predicting fetal hypoxia is as follows: sensitivity 47.5%, specificity 92.72%, positive predictive value of 63.33% and negative predictive value of 86.96%(24).

Ultrasound assessment of the biophysical profile can be a predictor of late changes following fetal compromise(25). The features it assesses include fetal movement, tone, breathing movement and amniotic fluid volume. Individual scores are aggregated with a score of 4 out of 8 and below being ominous while that of 6 out of 8 needing further evaluation. Ulah et al assessed the performance of sonographic biophysical profile in detecting fetal hypoxia and found the sensitivity to be 79.1%, specificity of 92.9%, positive predictive value of 98.55% and negative predictive value of 41.93%(26).

Modified biophysical profile is a combination of a non- stress test CTG and amniotic fluid volume. A large component of amniotic fluid comes from the fetal urine and in a compromised fetus oliguria and reduced amniotic exist.

Doppler velocimetry provides useful information on vascular impedance to blood flow(27). High impedance to blood flow is seen early in placental insufficiency while compensatory mechanisms lead to low impedance flow in the middle cerebral artery. Changes in the waveform of ductus venosus reflect changes in later stages of fetal compromise. The sensitivity, specificity, positive and negative predictive values of umbilical artery doppler in predicting adverse fetal outcomes was 43%, 83%, 33% and 88%(28). The middle cerebral artery predicted low APGAR scores(5 minutes) with a sensitivity of 69.6% and specificity of 72.8%(29).

Maternal fetal movement assessment remains the most common method for quantifying fetal movement(22). It is largely subjective however in United Kingdom, reduced fetal movement(RFM) has been associated with adverse perinatal outcomes rate of 25%(30).

1.2.3 Management of the selected morbidities

Management of gestational hypertension and pre-eclampsia without severe features-(adopted from ACOG)

Maternal and fetal findings

↓

37 0/7 weeks or more of gestation
  or
34 0/7 weeks or more of gestation
  with:
    Labor or rupture of membranes
    Abnormal maternal-fetal test
      results
    Ultrasonographic estimate of fetal
      weight less than 5th percentile
    Suspected abruptio placentae

— Yes → Delivery
      Prostaglandins
        if needed for
        labor induction

No ↓

Less than 37 0/7 weeks of gestation
Inpatient or outpatient management:
  Maternal evaluation: twice weekly
  Fetal evaluation
    With preeclampsia: twice
      weekly nonstress test
    With gestational hypertension:
      once weekly nonstress test

↓

37 0/7 weeks or more of gestation
Worsening maternal or fetal condition
Labor or premature rupture of membranes

↓

Delivery
  Prostaglandins if needed
    for labor induction

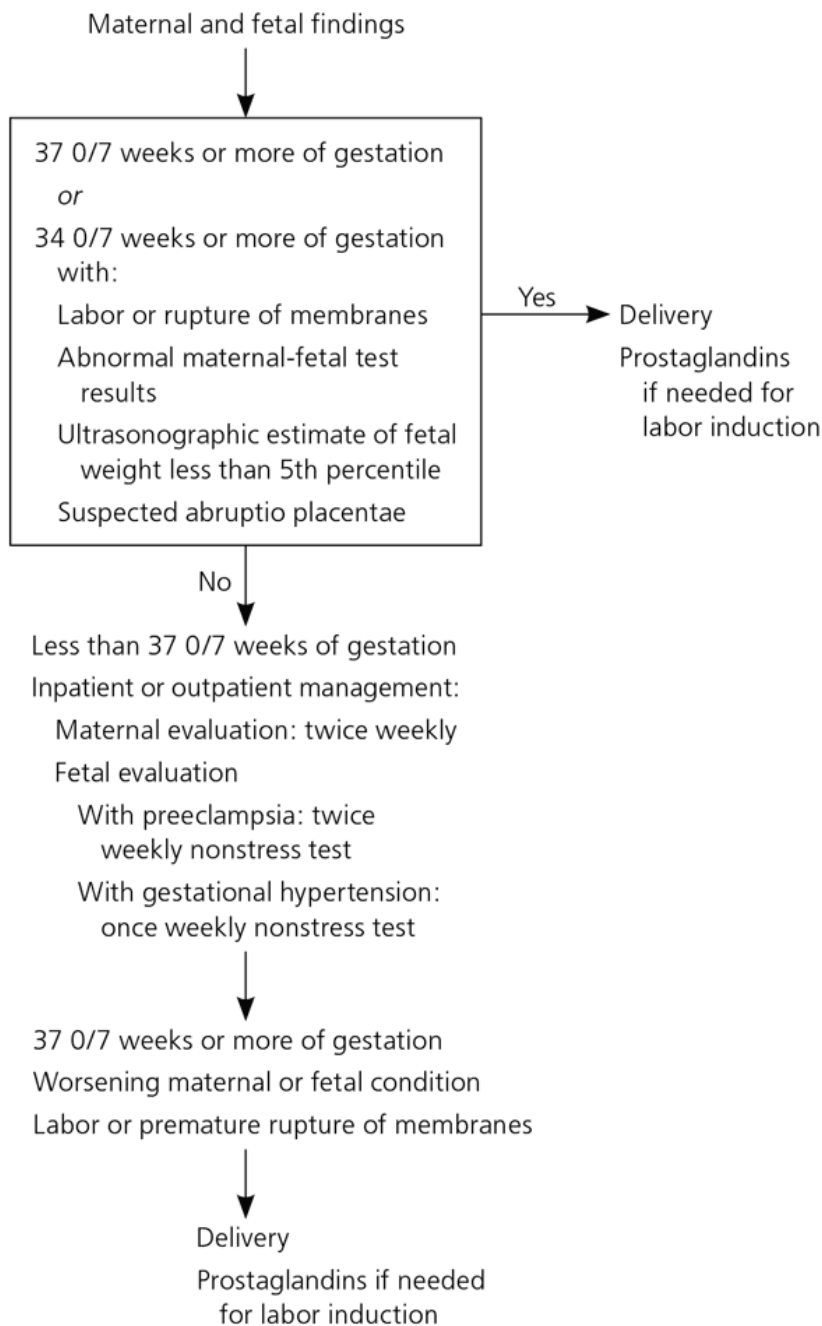**Figure 1.** Algorithm for management of gestational hypertension or preeclampsia without severe features.

Management of pre-eclampsia with severe feature

ACOG guidelines on hypertensive disorders in pregnancy, recommends fluid management (not exceeding 100ml/hour), seizure prophylaxis with magnesium sulphate, blood pressure control to less than 160/110 mmHg and expedited delivery based on disease severity and

gestational age. According to the same guidelines expectant management can be done in selected cases at gestation between 24 weeks to 34 weeks. Antenatal testing using CTG, amniotic fluid volume assessment and periodical fetal growth ultrasound are recommended. Acceleration of fetal lung maturity using antenatal corticosteroids is advised as well. Delivery is best in a hospital with NBU while the route and timing are based on maternal factors such as disease progression, parity, bishop's score on cervical examination and fetal parameters(gestational age, antenatal testing). Immediate delivery should be considered in eclampsia, pulmonary edema, abruptio placenta, resistant hypertension and worsening maternal or fetal condition. Delivery after 48 hours of antenatal corticosteroids administration is advised in thrombocytopenia (less than 100×103 per μL), transaminase levels two times the upper limit of normal, intrauterine growth restriction (less than 5th percentile), severe oligohydramnios, umbilical artery reversed end-diastolic flow, or new or worsening renal dysfunction

Management of Gestational Diabetes Mellitus (adopted from American Diabetes
Association/American family Physician)
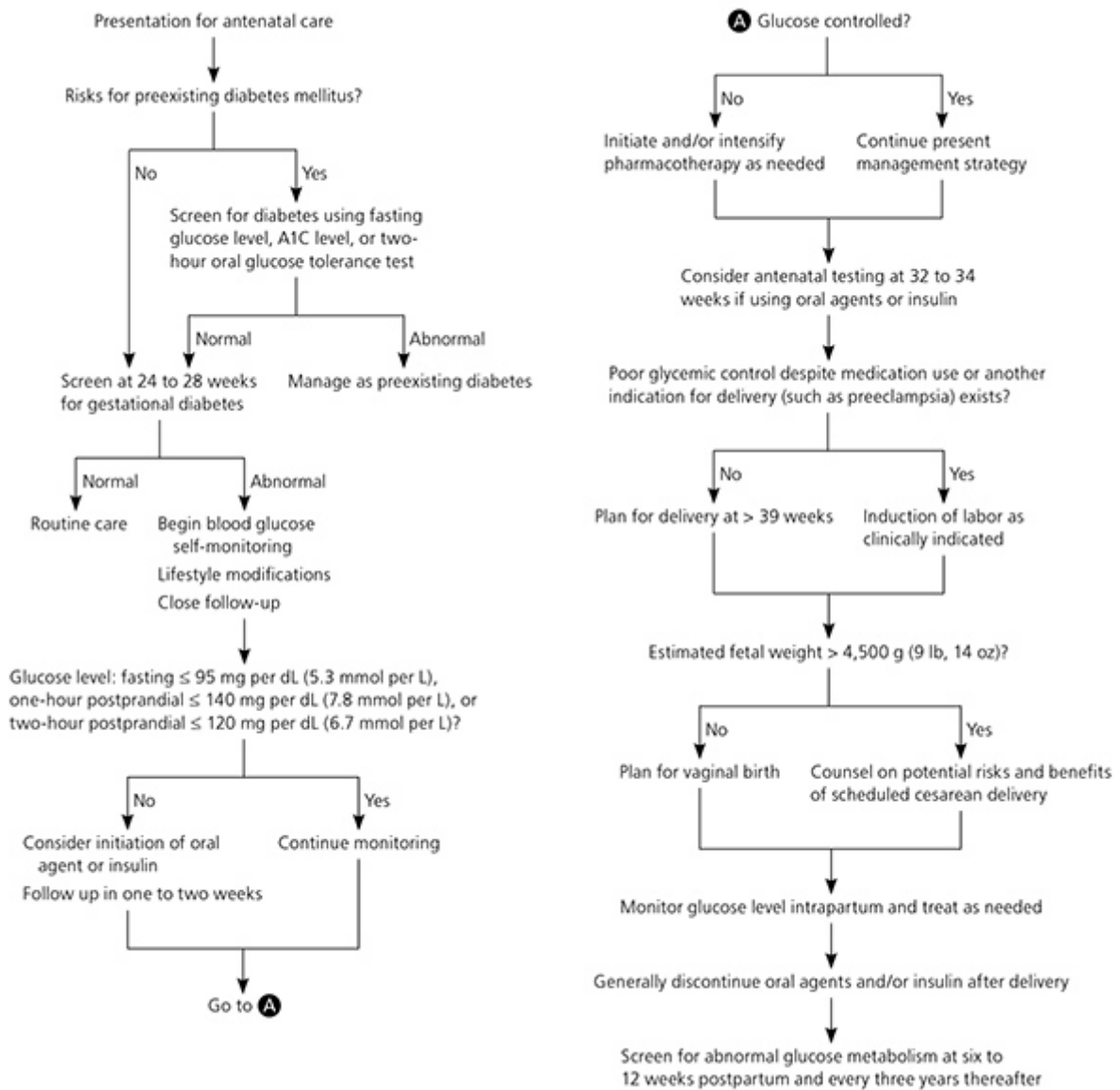
Figure 2. Management of gestational diabetes mellitus.

Management of late term and post term pregnancies (from American Family physician)

Management of Late-Term and Postterm Pregnancy

41 weeks' gestation, low risk

↓

Discussion of the risks
and benefits of induction

↓

Consider sweeping of the membranes
(if not done after 38 weeks)

Expectant management

↓

Antenatal testing: biophysical profile,
nonstress test/amniotic fluid index

↓

Oligohydramnios or
nonreassuring nonstress test?

Yes — No

Perform induction at > 41 weeks,
or for other indication

42 weeks' gestation

Figure 3

1.2.4 Global burden of Stillbirths

Global statistics about stillbirths have remained limited especially in worst affected regions. According to the 2016 Ending Preventable Stillbirthsreport, Lancet stillbirths' series, approximately 18.4 stillbirths per 1000 births occurred worldwide, down from 24.7and1000 in 2000(a 25.5% reduction). (10) This translates to 7,300 babies being born dead daily and 2.6million (uncertainty range 2.4-3.0 million) stillbirths annually. These statistics correlatewith those by Bhutta, Yakoob, Lawn et alwho estimated the global stillbirth rate of 2·65 million (uncertainty range 2·08 million to 3·79 million)(32).Majority (98%) of these stillbirthsoccur in low and middle income countries (LMICs) (33). From the same literature, a large proportion (77%) of these deaths occurs in South East Asia and Africa with only 3% contributed to by the high-income countries(33).

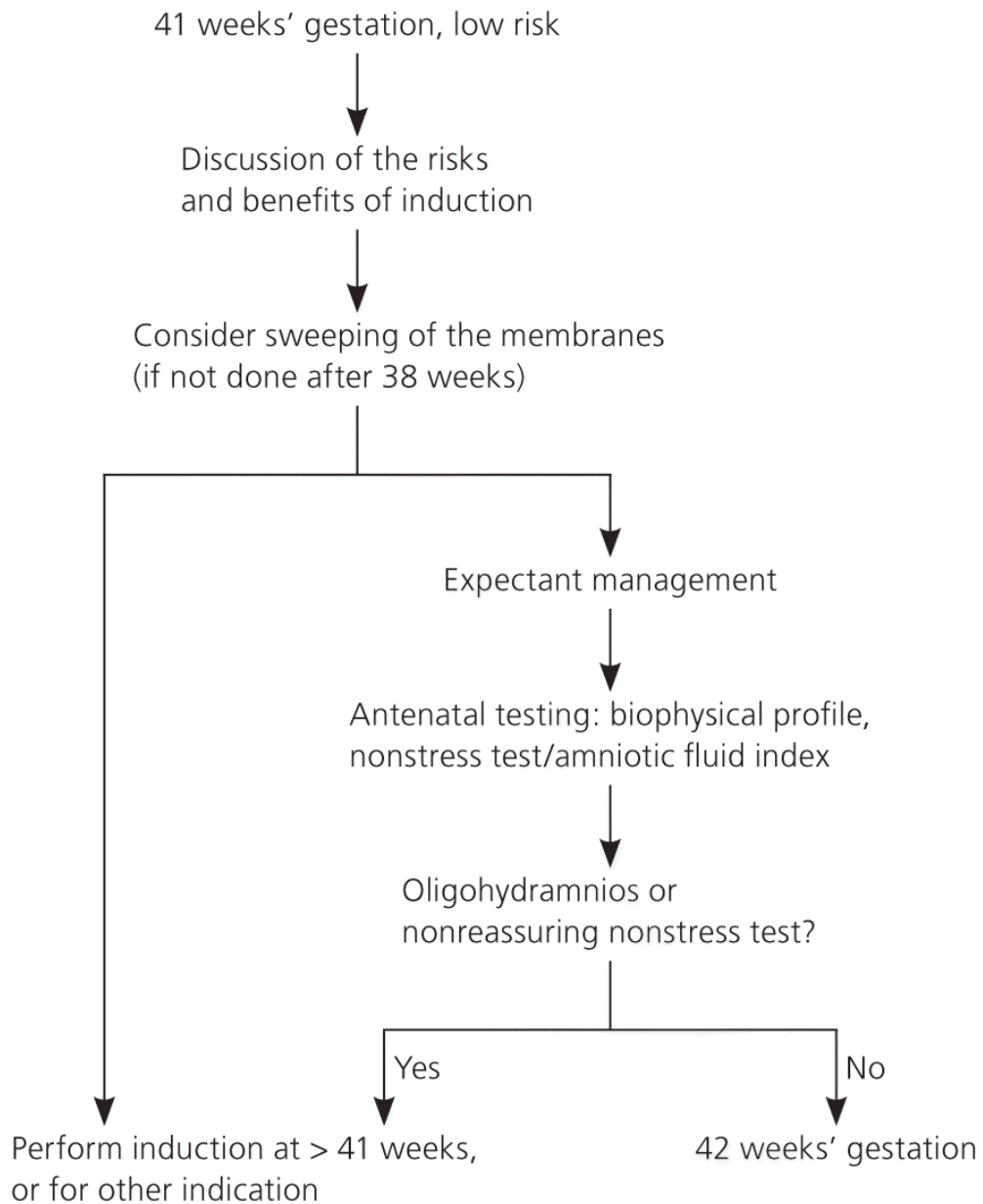According to the lancet series 2016, between the year 2000 and 2015, the average global stillbirth rate declined by 2 per cent from 24.7 per 1000 births to 18.4(19).However, this reduction is slowest when compared to the maternal mortality rate (3.0 per cent) and the under-five mortality rate (4.5 per cent)(33).The implications are that there is need to address this. Stillbirths remains a significant and understudied problem that now accounts for almost 50% of all perinatal deaths in the United State of America(34). In this setting, the risk factors for IUFD include low socioeconomic status, African-American race, advanced maternal age, obesity, smoking, previous history of fetal death. (8). Other contributing factors included pre-existing maternal diseases and fetal growth impairment (34)(36).

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obesity, smoking, previous history of fetal death. (8). Other contributing factors included pre-existing maternal diseases and fetal growth impairment (34)(36).

1.2.5 Regional perspective

Stillbirth rates for sub-Saharan Africa are approximated at between 28.7 to 32 per 1,000 births(32)(33)(37). Comparatively in high income countries 1 in 200 pregnancies at a gestation of 22 weeks and beyond end in a stillbirth or neonatal demise(36). The most recent of the systematic analysis indicates Rwanda as the best ranked East African country with 17 stillbirthsper1000 births. (33) In the same literature, Uganda is next with 21 stillbirths per 1000 births and Burundi is ranked last with 27 stillbirths per 1000 births.

1.2.6 Local perspective

The Lancet series on stillbirths 2016 estimated that Kenya had the second worst stillbirth rate in East Africa(31). The same series ranked Kenya eleventh among countries with the greatest number of stillbirths globally. Consistent with the global trend, the stillbirth rates in Kenya declined by 15 per cent from 26 per 1000 births in the year 2000 to 23and1000 births in 2015 according to that series. Despite the reduction in rate, the estimated number of annual stillbirths has increased by 10% from 32,000 to 35,000 over the same period. The Kenya Demographic Health Survey(KDHS) report 2014 indicates that Perinatal (Stillbirths plus early neonatal) mortality rate in Kenya stands at 29 deaths per 1000 live births(14).

At Kenyatta National Hospital, poor APGAR score and associated perinatal asphyxia is a major problem(38).A local study showed that by day 7 of life, 31.1% of infants with perinatal

asphyxia had died, 31.1% continued treatment, 6.7% discharged with sequelae and only 31.1% discharged with no sequelae(38).

1.2.7 Factors influencing the maternal perception of fetal activity

Maternal position at the time of assessment is important as most mothers recognize the movements best while lying down than when seated or in a standing position(16).Earlier studies have also demonstrated that fetal movements are best recorded during their peak activity period and this is more often than not in the afternoons and evenings(39)(40). A tranquil environment without distractions has been noted to improve identification of the fetal kicks by the gravid women(41). According to Cochrane database of systematic review 2015, fetal movements are best perceived and characterized with an empty bladder, mother lying on the side, relaxed and with hand on the abdomen during the specified counting period(42).

Some medicinesand recreational drugs depress fetal activity. For example, sedative drugs cross the placenta and are implicated in reduced fetal movements(43).A similar effect has also been shown with alcohol use and cigarette smoking(44)(45)(46)(47). Fluorinated corticosteroids used in accelerating fetal lung maturity may reduce fetal movements, but only, during the duration of administration(25)(49)(50).

Major fetal malformations affecting neurological development and limb formation can lead to a decreased perception of fetal movement(28). The in-utero position of the fetus may also influence the perception of fetal activity with 80% of reduced fetal movements in healthy fetuses found in the anteriorly positioned fetal spine (19).

There is inconclusive evidence on the effect of parity, gestational age, BMI, and site of placentation on maternal-fetal movement perception (29).Initially, it was thought that fetal activity reduces at term but so far there has been no substantial evidence supporting the reduction of fetal activity in term pregnancy(15)(53). This implies that women with perceived RFM should be assessed and closely surveyed no matter the gestation.

As pertains factors that stimulate fetal movements, controversy exists with some studies showing that an increasein maternal serum glucose concentrations is associated with improved fetal activity while others dispute these findings (32)(55).

1.2.8Fetal and perinatal outcomes associated with reduced fetal movements

In human beings, reduced fetal movements (RFM) are postulated to be a compensatory mechanism geared to reduce energy output in the context of reduced oxygen and nutrient supply to the fetus(56)(57)(58).Various studies have demonstrated that gravid women reporting reduced fetal movements are at increased risk of complications like fetal growth restriction(FGR), preterm delivery, IUFD, perinatal asphyxia, early Neonatal admission and death(9)(10)(11)(30). Other works of literature have shown that stillbirth rates tend to increase post RFM(59)(60).In a prospective cohort study involving 2,374 pregnancies presenting with maternal perception of RFM and 614 control cases, RFM were associated with adverse pregnancy outcome in 26% of the cases(9). These included preterm births and fetal growth restriction. It was also noted that none of the hospitals used for research had guidelines for the management of RFM.

In a recent prospective observational study, recruiting all women with singleton pregnancy at or beyond 28 weeks of gestation presenting with a subjective perception of RFM,47% belonged to a high-risk pregnancy. Among the high-risk pregnancies, 39% showed poor BPP

at the first presentation, 58% were delivered irrespective of their gestational age, out of which 32.75% had a poor perinatal outcome (50). Inanother prospective cohort study of women presenting with reduced fetal movements, 19% of gravid women who had a stillbirth presented at first contact with a live fetus (62). In the same study, it was noticed that where Intra Uterine Fetal Death (IUFD) occurred, it took place within a week of the first visit. Additionally, a retrospective study noted that a significant proportion, 55% of women experiencing stillbirths reported a form of reduced fetal movement before a diagnosis is made(60). Intrauterine fetal death (IUFD) has also been shown to be more often than not preceded by a reduction in fetal movements for over 24 hours in up to 50% of cases (63).A study assessing the clinical value of a 12-hour fetal movement assessment demonstrated that reduced fetal activity was associated with a high incidence of fetal asphyxia, and when fetal death occurred fetal kicks rapidly diminished and stopped 12 to 48 hours before death(64).This implies that timely intervention would give the at-risk fetuses a chance to live. The practice guidelines by Royal College of Obstetricians and Gynecologists (RCOG) suggests that clinicians should note the potential association of RFM with risk factors such as FGR, Small for gestation (SGA) fetus, placental insufficiency and congenital anomalies(13). Importantly, FGR is frequentlyunderdiagnosed complication despite it being one of the recognized precursors to fetal demise (54)(66).Philip.J. Dutton et al did a prospective cohort study that showed 22.1% of pregnancies complicated by the maternal perception of RFM ended with suboptimal perinatal outcomes(30),small for gestational age (SGA) being the most common.16.8% of SGA were term babies while 2.3 % of SGA were preterm babies. Furthermore, 4.1% had preterm deliveries and 0.7% required neonatal intensive care unit admission. A two-year cohort study of 200 gravid women in Zimbabwe indicated a good correlation between abnormal fetal kick chart and intra-uterine fetal demise in high-risk pregnancies(67). In the same study, antepartum death was 0.7% in those with normal fetal

kick charts and 43.7 % in those with abnormal kick charts. Low Apgar score was at 7.6% in those with normal fetal kick charts and 56.2% in those with abnormal fetal kick charts. The study also showed improved outcomes with early intervention.

Antepartum fetal surveillance in women experiencing reduced fetal movement has been demonstrated to offer the benefit of early identification of fetuses with growth restriction(6)(9)(68). Reliable evidence has also shown that perinatal outcomes improve with prompt recognition of fetal growth retardation(69). This is attributable to close surveillance and timely interventions such as emergency caesarean section. The efficacy of fetal movement monitoring tools in improving perinatal outcomes has been on evaluation for a long time (70). Numerous conflicting findings on the benefit of fetal movement assessment have emerged over the years. Recent high-quality studies in high income countries show that no formal fetal movement counting protocol demonstrated success in preventing perinatal mortality among the general population of pregnant women(42).

This disapproval started with a large RCT by Grant et al in 1989 which did not show any benefit of maternal-fetal movement assessment in routine antepartum care (71). Based on the results of this RCT, evidence-based care guidelines have since been unable to recommend fetal activity assessment as part of routine ante-partumfollow-up (72).The National Institute of Clinical Excellence(NICE), 2016 UK guidelines on antepartum care explicitly states that routine fetal movement counting should not be offered(73).Winje et al. conducted a prospective cohort study that compared fetal movement count in normal pregnancies and those that had suboptimal outcomes. The results were that a standard approach to fetal movement counting, applying the currently best-founded definition of RFM, was not useful as a screening tool for at-risk pregnancies in their population. A critical review of the RCT by

Grant highlighted various flaws in the study methodology. Chief among them was in randomization procedure as control women were in contact with those monitoring the fetal movements and in many instances were themselves advised to assess the movements(70).Furthermore, the comparatively low stillbirth rates reported during the study period was likely attributable to the "Hawthorns effect".

Though there appears to be lack of overwhelming evidence for formal fetal movement counting, more recent literature review suggests there is likely to be a benefit in maternal fetal activity monitoring(70)(72). The findings of a comparative cohort study done in Norway in 2010 indicated that the introduction of uniform fetal movement information and guidelines aimed at increasing maternal awareness and vigilance to decreased fetal activity had associated benefit in reducing late stillbirths(74).The stillbirth rate among women with perceived RFM fell during the intervention by 4.2% vs 2.4% previously. According to a study done in India, daily fetal movement assessment charts at term pregnancy helps in identifying at-risk fetus in low-risk pregnancies in the absence of any other risk factors necessitating early delivery(75). The results indicatedno perinatal mortality in 250 cases that were given daily fetal movement chart versus 2% perinatal mortality in the ninth month in the control group. This advantage can be extended in at-risk pregnancies which require more strict surveillance.

1.2.9 Fetal movements assessment protocols

There are many modalities for assessment of fetal movement counts but the count to 10 in two hours by patients was shown to be superior as it best correlates with Non-stress testing(76). According to Moore et al, the only numerical limit that has been derived from a total population and subsequently evaluated as a screening test in the same population is the

perception of 10 distinct movements during focused counting over a period of two hours ("Count to 10" method(77)). The count to 10isuser-friendly and compliance has also been shown to be better compared to other counting protocols.(78)(79)(80). ACOG guidelines 2014 considers the perception of 10 distinct movements in a period of up to 2 continuous or interrupted hours reassuring(5). The Society of Obstetricians and Gynaecologists of Canada (SOGC) Clinical Practice Guideline recommends daily fetal movement counting for all high-risk pregnancies. It further suggests that all pregnant women be educated on the significance of fetal movement in the third trimester and those who perceive a reduction of the same should perform daily fetal movement counting.

On the contrary, though fetal movement counting has long been advocated as a screening tool to identify the impaired placental function and fetal compromise, quantitative limits for decreased fetal movement perform poorly for screening purposes according to a study done in Malaysia(81). Winje et al conducted a prospective cohort study in Norway analysing the "Count to 10" fetal movement counting protocol and found that a standardized approach to fetal movement assessment, applying currently the best-founded definition of reduced fetal movement was not beneficial as a screening tool for high-risk pregnancies in their set up(15). Results of other studies have also advocated for a shift to the subjective perception of fetal activity as a screening tool (62). A similar position is taken by the Royal College of Obstetricians and Gynaecologists (RCOG) through its guidelines which recommend that fetal movement should be assessed by subjective maternal perception and discourages the use of fetal movement counting charts(13).

1.2.10 Correlation of fetal movement activity and other tests

From earlier studies in humans and animals, fetal heart rate pattern, level of activity and degree of muscular tone are sensitive to hypoxemia and acidemia (82)(83)(84). Reduction in gross body movement as a response to hypoxemia has been noted in experimental studies involving fetal lamb (37). This makes fetal movements an important indicator of fetal wellbeing and viability and by extension a marker of normal anatomy, cardiovascular and neurological integrity (5). Studies comparing the maternal perception of fetal movement with real-time ultrasonography assessment of fetal activity have shown a high correlation between the two antepartum testing methods (38). One such study has shown pregnant women can perceive 33-88% of ultrasound visualized fetal activity depending on the type and degree of movement(56). Earlier ultrasound studies also illustrated that sluggish, infrequent and absent fetal activity were signs consistent with fetal compromise(87).

In a case-control histological study of placentas by Warrander et al, a causal association between placental insufficiency and RFM was shown(88). This implies that women with RFM need further evaluation to rule out a fetal compromise. In fetuses with abnormal screening tests, various studies have shown reduced umbilical vein pH when compared to those with normal testing. In one such study, the mean umbilical vein pH in cases of RFM was 7.28+and- 0.11 and cessation of movements was correlated with a lower PH of 7.16+and- 0.08(89).

1.2.11 Management of abnormal fetal tests in the setting of reduced fetal movements

RCOG stipulates that cardiotocography (CTG) should be done in any pregnancy of 28 weeks and above gestation complicated by reduced fetal movement(13). Additionally, anultrasound should form preliminary investigations for reduced fetal movement (RFM) after a gestational

age of 28 weeks if the perception of RFM persists despite a normal CTG or if there are any additional risk factors for fetal growth restriction and stillbirth.

According to ACOG guidelines 2014, maternal perception of reduced fetal movement (RFM) should be evaluated by a non-stress test(NST), contraction stress test (CST), biophysical profile score (BPP), or modified BPP(71). It further stipulates cases of suboptimal results from an NST or a modified BPP be assessed with either a CST or a BPP. A BPP score of 6and10 is considered equivocal and based on the gestation should be evaluated further or delivery of the fetus done. At a term gestation (from 37 weeks onwards), prompt further evaluation and immediate delivery are recommended, whereas, in the preterm fetus, a repeat BPP should be performed in 24 hours. For a BPP score of 4 immediate delivery is usually indicated unless gestation is less than 32 weeks of which individualized management with extended monitoring is instituted. In most cases, a BPP score of fewer than 4 warrants immediate delivery. The guidelines from the Society for Maternal-Fetal Medicine recommends that if doppler velocimetry assessment shows absent end-diastolic flow, delivery should be planned for 34 weeks of gestation, and with a reversed end-diastolic flow, delivery is to be considered at 32 weeks of gestation.

Society of Obstetricians and Gynecologists of Canada (SOGC) clinical practice guidelines stipulate maternal perception of less than 6 fetal movements in 2 hours as non-reassuring and recommends further evaluation with an NST or ultrasound BPP for the same. A normal NST in a high-risk pregnancy should be followed by ultrasound for BPP and amniotic fluid volume assessment within 24 hours. An abnormal NST should be followed immediately by further testing involving ultrasound BPP, amniotic fluid volume evaluation and a CST.

1.3 Conceptual Framework
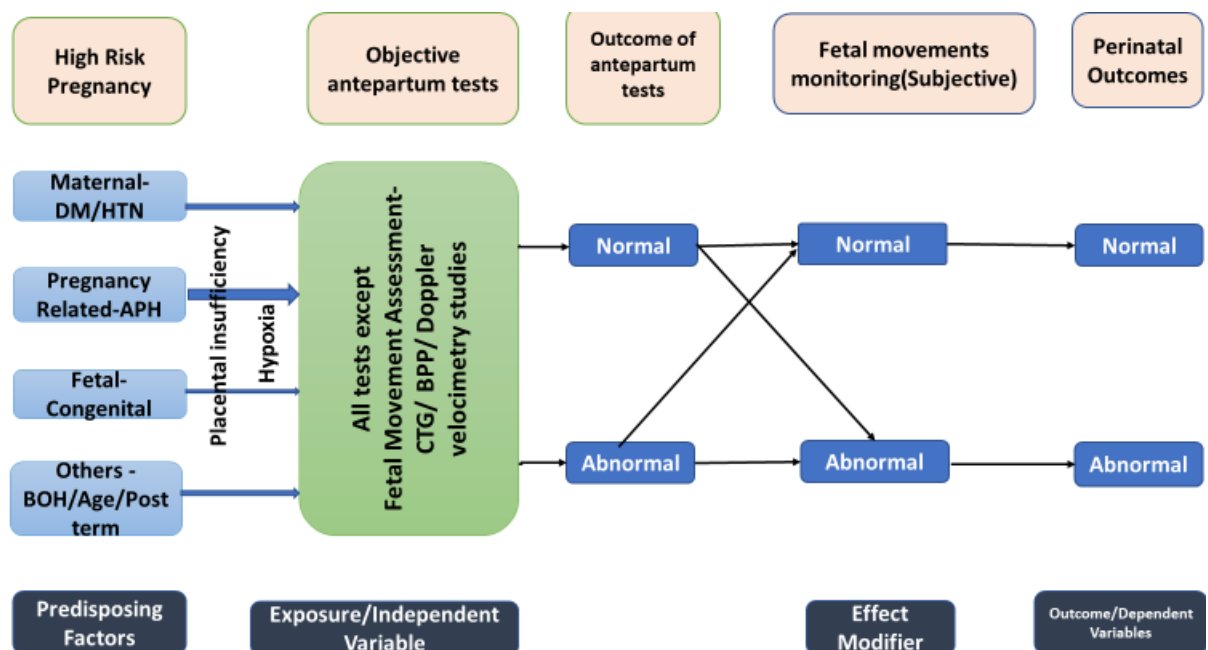
Figure 4: Conceptual Framework

Pre-existing and pregnancy-associated factors such as hypertensive disorders in pregnancy (HDPs), diabetes mellitus and post-term pregnancies are known to increase the risk status of pregnancy commonly by causing placental insufficiency.Subsequently, the placental insufficiency leads to fetal hypoxia and acidaemia with the resultant metabolic disturbancesleading to perinatalfeta morbidity and mortality, if not identified and managed in a timely manner.

In our setting, objective antepartum fetal tests used to identify fetuses at risk include cardiotocography and ultrasound assessment of fetal biophysical profile, umbilical and middle cerebral arteryvelocimetry.In cases of placental insufficiency, reduced fetal movements may arise due to shunting of blood to the brain and adrenal glands thus aiding in preservation of energy for more vital metabolic activities.Therefore, a combination of RFM

and an abnormal fetal test mayresult in adverse perinatal outcomes. Identifying fetuses at risk of adverse perinatal outcome can therefore help in timely intervention geared towards reduction of fetal perinatal morbidity and mortality in these selected high-risk pregnancies.

In this study we sought to evaluate the association between antenatal fetal testing (exposure variables), adverse perinatal outcomes (outcome variable) and the effect modification of fetal movement monitoring in this association

1.4 Justification of the Study

Adverse perinatal outcomes are a tragedy to immediate, extended family and the whole community of the affected individuals(90).The pregnant women affected by at-risk pregnancies also tend to present too late hence knowledge about fetal movements could help in timely consultation in cases of RFM(7)(62).

Estimated stillbirth rates have remained high in Sub Saharan Africa 32and1000(37). As per KDHS report 2014, the perinatal mortality rate in Kenya is high at 29 deaths per 1000 live births(3).This significantly falls short of the Sustainable Development Goals(SDGs), Every Newborn Action Plan(ENAP) target of 12 or fewer stillbirths per 1000 births in every country by 2030 (91).High-risk pregnancies contribute significantly to adverse perinatal outcomes hence there is need to improve their outcome(1)s.

A study conducted in the United Kingdom on knowledge and understanding of fetal activity by health professionals identified numerous inconsistencies(92). It is thought that a standard guideline of practice will go a long way to influence management with the resultant improvement in perinatal outcomes. According to Cochrane Systematic reviews, global consensus and guidelines for assessing reduced fetal activity are yet to be determined

(93).Likewise, in our local facility, KNH, there is no standard protocol guiding practice in antepartum surveillance of high-risk pregnancies.

RFM is one of the frequent maternal complaints during pregnancy, reported in about 15% of pregnancies(7). Unattended to, it may lead to adverse perinatal outcomes(94). Due to this, cessation or RFM is regarded as one of the danger signs pregnant mothers should consistently be educated during antepartum care. Maternal fetal movement assessment (FMA) is inexpensive, readily available and easy to perform in both outpatient and inpatient surveillance for fetal wellbeing.

It is unknown if reduced fetal movement can modify the association between abnormal fetal testing and adverse perinatal outcomes. A recent cross-sectional study done locally by Kikwai et al that assessed fetaloutcomes of pregnancies complicated by the maternal perception of RFM did not evaluate the role of maternal fetal movement assessment on antepartum fetal testing and the perinatal outcomes in high-risk pregnancies(95).

According to Cochrane Systematic Review, previous randomized controlled trials (RCTs) on the effects of fetal movement counting on fetal outcomes found no or little difference in preterm birth and stillbirth rates between those who used fetal kick charts and those who didn't.However, these studies were done in high-income countries with low stillbirth rates and the findings may necessarily not apply to settings such as ourswith high stillbirth rates. The WHO recommendations on antepartum care for positive pregnancy experience stipulate that maternal fetal movement monitoring should be conducted in high-risk pregnancies(96).Lastly, objective antenatal fetal testing may not completely predict or

prevent adverse perinatal outcome thus a more available test such as fetal movement monitoring can be added to them.

1.5 Research Question

What is the fetal testing profile, the association between antenatal fetal testing and perinatal outcomes and the role of maternalfetal movement assessment in selected high-risk pregnancies at Kenyatta National Hospital?

1.6 Null hypothesis

There is no role of maternal fetal movement assessment in high-risk pregnancies and no association between antenatal fetal testing and perinatal outcomes.

1.7Objectives of the Study

1.7.1 Broad Objective

To describethe fetal testing profile,perinatal outcomes and evaluate the role of maternal fetal movement assessment in selected high-risk pregnancies at Kenyatta National Hospital.

1.7.2 Specific Objectives

Among selected high-risk pregnancies undergoing maternal fetal movement assessment at KNH: -

1. To describe the antepartum fetal testing (AFT) profile. The AFTs will includefetal movement assessment (FMA), cardiotocography (CTG), ultrasound biophysical profile scoring (BPP) and doppler velocimetry in antepartum surveillance for specific high-risk pregnancies.

2. To determine the association between antepartum fetal testing and adverse perinatal outcomes.

3. To evaluate if maternal fetal movement assessment modifies the association between other antepartum fetal testing methods and adverse perinatal outcomes by estimating the relative risk of adverse perinatal outcomes in high-risk pregnancies with normal versus reduced fetal movements.

CHAPTER TWO: METHODOLOGY

2.1 Study design

The study was a hospital-based, retrospective cohort study. Medical records ofwomenwith the selected high-risk pregnanciesdocumented maternal fetal movement assessmentand perinataloutcomes were assessed.Charts of women who had reported their fetal movements as normal or reducedwere considered and evaluation of the outcomes of interest such asstillbirth, poor APGAR score, neonatal demisewithinthree-days, NBU admission, prematurity and low birth weights ascertained.Antepartum fetal tests carried out to further evaluate the mothers were also assessed.These included cardiotocography and ultrasound tests of fetal biophysical profile score, umbilical artery and middle cerebral artery resistive indices.

2.2 Study site and setting

The study was conducted at the Kenyatta National Hospital (KNH) wheremedical records from the medical records registry were retrieved for review. KNH is in Upper Hill area, Nairobi County-Kenya. It serves as the largest referral hospitalin Kenya. Embedded within it is the University of Nairobi, School of Medicine. The hospital bed capacity is 1800 and on average, 10,000 obstetric deliveries are conducted annually. The Reproductive Health Department is staffed with over 60 Consultant Obstetricians. Linked to the labour ward are two maternity theatres and anew-bornunit with a bed capacity of 60.The hospital hassix CTG machines, six ultrasound machines andan operational laboratory. All these services are available for 24hours. The records department is well staffed with about 20 well-trained employeescharged with records management.

Women presenting with a newly diagnosed high-risk pregnancy or an elevation in the risk statusof the pregnancy are usually admitted for further evaluation and management. During

the day, these women come in through the routineantepartum clinics and casualty department. They are then admitted either in the labour ward or antepartum clinics based on the index assessment. At night, the women proceed directly to the labour ward, from which evaluation and management are instituted. Gravid women with high-risk pregnancies are commonly subjected to an admission obstetric ultrasound and a CTG (for those in the third trimester of pregnancy). Those who are clinically stable or undergoing conservative management are transferred to the antepartum wards for continued care or discharge. At admission and during their stay in the hospital, pregnant women are regularly probed on the status of fetal movements and those who report reduced perception of the same are oftenevaluated with objective antepartum fetal tests.Additionally, those who report persistently reduced perception of fetal movements despite normal fetal testing are taught on how to use and maintain a Cardiff- count to 10 fetal kick charts.

2.3 Study population

Charts of pregnant women previouslyadmitted to the KNHantepartum wards with the selected high-risk pregnancies and later proceeded to deliver at the facility were assessed. The high-risk conditions includeddiabetes mellitus, hypertensive disorders, post-termpregnancy. Thestudy period wasfrom 1st January 2014to 31st December 2018

2.4 Recruitment procedure

Records of the pregnancies complicated by the selected conditions were identified using the International Statistical Classification of Diseases and Related Health Problems 10th Revision(ICD-10)A screening tool was thenbe used to identify medical records of women who had the selected high-risk conditions and met the inclusion criteria. It was mandatory the records have, maternal feedback on perceived fetal movements and perinatal outcomes.We

then randomly sampled all files starting from the most recent date until we reached the required sample size.
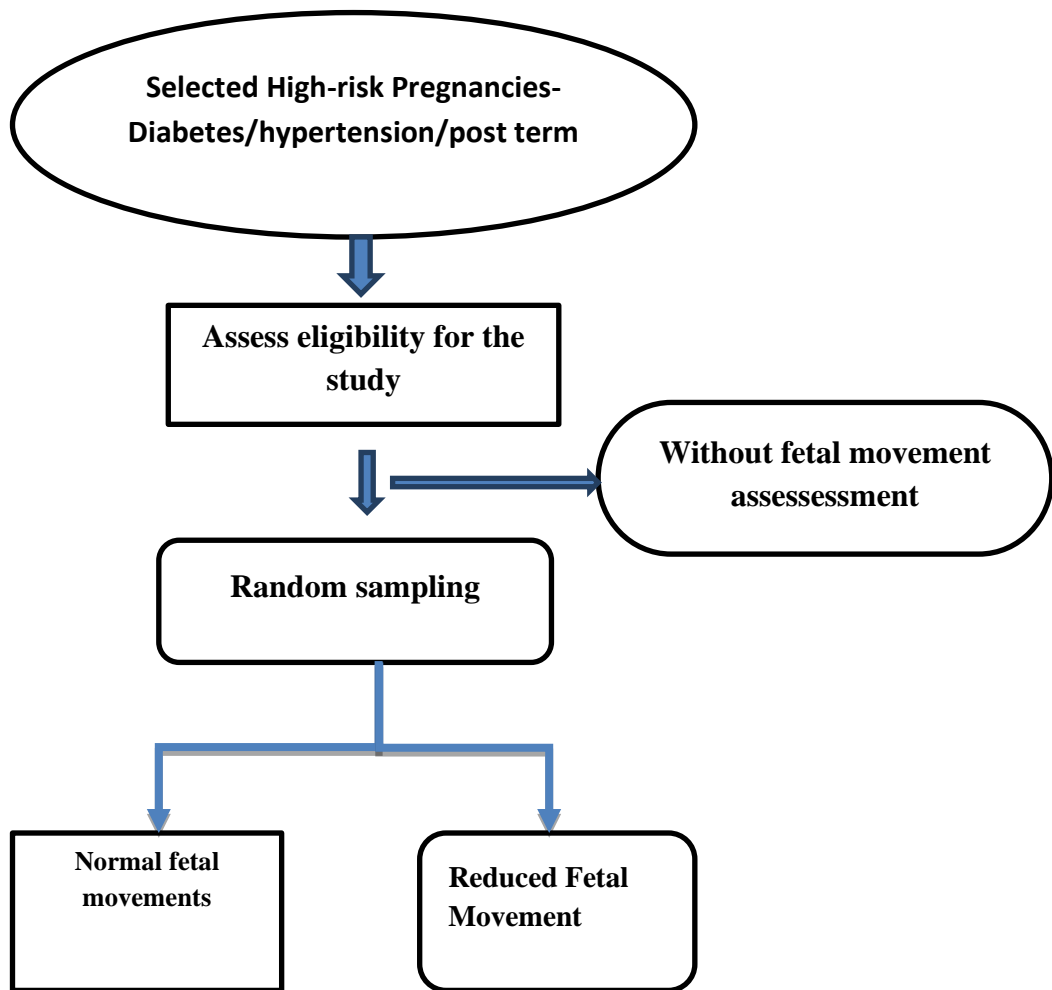
Figure 5: Study procedure

2.4.1 Inclusion criteria

Pregnant women were eligible if they were aged at least 14 yearsby the time they delivered. Participants had to bein the late second trimester of pregnancy, from 28weeks and beyond.The gestation was determined based on the bestavailable obstetric estimate which was projected fromthelast normal menstrual period, date of conception or embryo transfer, ultrasound, symphysis-fundal height or date of a first pregnancy test. Women were only eligible if they had high-riskpregnanciescomplicated bydiabetes mellitus, hypertensive

disorders and post-term pregnancy.Besides, only files with the key variablesof reduced or normal maternal perception of fetal movements and perinatal outcomes were selected.

2.4.2 Exclusion criteria

Pregnantwomen who presented in active labour, those with emergencyobstetric conditions, antepartum diagnosed congenital anomalies, as well as multiple order gestations,were also excluded.Post-partum women who were referred after delivering in other health facilities were eligible.

2.5 Sample size determination

The main outcome of this study is the ability of the antepartum monitoring to pick out patients who would otherwise have adverse perinatal outcomes if no fetal movement monitoring was done; in this study, and for calculation of the sample size, low APGAR score will be used. In a study done by De Muylder in Zimbabwe, 7.6% of the babies had low APGAR score despite a normal fetal movements chart while 25% had low APGAR score with reduced fetal movement chart. In this study, we postulate that fetal monitoring reduces the incidences of low APGAR score by 17.4%

Therefore, for us to detect a 17.4% difference in low APGAR score outcomes in our setting, we estimated using Donners' sample size formula $n = \dfrac{2\left(z_{1-\alpha_{/2}}\sqrt{2\bar{p}(1-\bar{p})} + z_{1-\beta}\sqrt{p_c(1-p_c)+p_a(1-p_a)}\right)^2}{(p_c - p_a)^2}$ [Allan Donner; Stat. Medicine (1984), using statcalc software that we would need to study a total of 140 womenper group to achieve an 80% power to detect the stated difference of 17.4% at a two-sided alpha=0.05 level of significance.

Where $\bar{p} = (p_C + p_a)$ and2 ($Z_{0.25} = 1.960$, and $Z_{0.8} = 0.842$).

Assuming the non-response rate due to poor documentation of 10%, the recalculated sample size will be:

1and1-0.1*140

=156 (minimum sample) for each of the groups (Normal vs Reduced foetal movement on assessment). However, we were able to achieve a sample size of 196 per group

2.6 Sampling procedure and technique

The estimated number of patients with the selected high-risk pregnancies from January 2014 to December 2018 was determined from the medical registry. A screening tool was used to select files that meet the inclusion criteria.Simple random sampling was employed until a sample size of196 for each group, reduced fetal movement vs normal fetal movement.

2.7 Sources and methods of the recruitment

The research team comprised the principal investigator and two research assistants, a clinical officer specializing in reproductive health and amidwife, both based at the KNHantepartum wards. The principal investigator trained the research assistants on good clinical research practice, study procedures, documentation procedure in the patient records and then supervised data collection.

2.8 Data variables

In this study, the exposure (independent) variables were reduced and normal fetal movements. The other variables included the various antepartum fetal surveillance tests available in our set-up. These included cardiotocography, biophysical profile scores and doppler velocimetry tests (umbilical and middle cerebral artery resistive indices).On the other

hand, the outcome variables included perinatal outcomes such as 5 minutes APGAR scoring, the status of life at birth and early neonatal demise. Other secondary outcomes assessed included birth weight, NBU admission rate and prematurity.

2.9 Data collection and management (see appendix- data collection tools)

A standard pre-coded and pre-tested data abstraction tool with sections for baseline, socio-demographic details, obstetric history, antepartum fetal surveillance tests and delivery details were used for data collection. Collected data was reviewed daily, first by the research assistants then followed by the principal investigator to ensure completeness.First data entry was made into the MS Excel databaseby the principal investigator to create a clinical database. The completed data abstraction tools were transferred to the data management team, comprisingthe statistician and a data entry clerk who did second data entry. The first and second data entries were compared, errors listed and fixed by the principal investigator and the statistician. The generated clean data was entered into a research database. Statistical analysis using SPSS (Version 21.0, Chicago-Illinois) was done from this database.

2.10 Data quality assurance

Data quality assurance was enhanced continuously throughout the study period to maximize the validity and reliability of the findings.The research assistants underwent training and random checks of the filled data abstraction tool done throughout the data collection process. Piloting of the questionnaire conducted to ensure it covered the objectives of the study. Daily

data entry was done daily and evaluation of the accuracy of transferred data performed as shown in figure 3.

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│  PrincipalInvestigator   │
│  (PI)                    │
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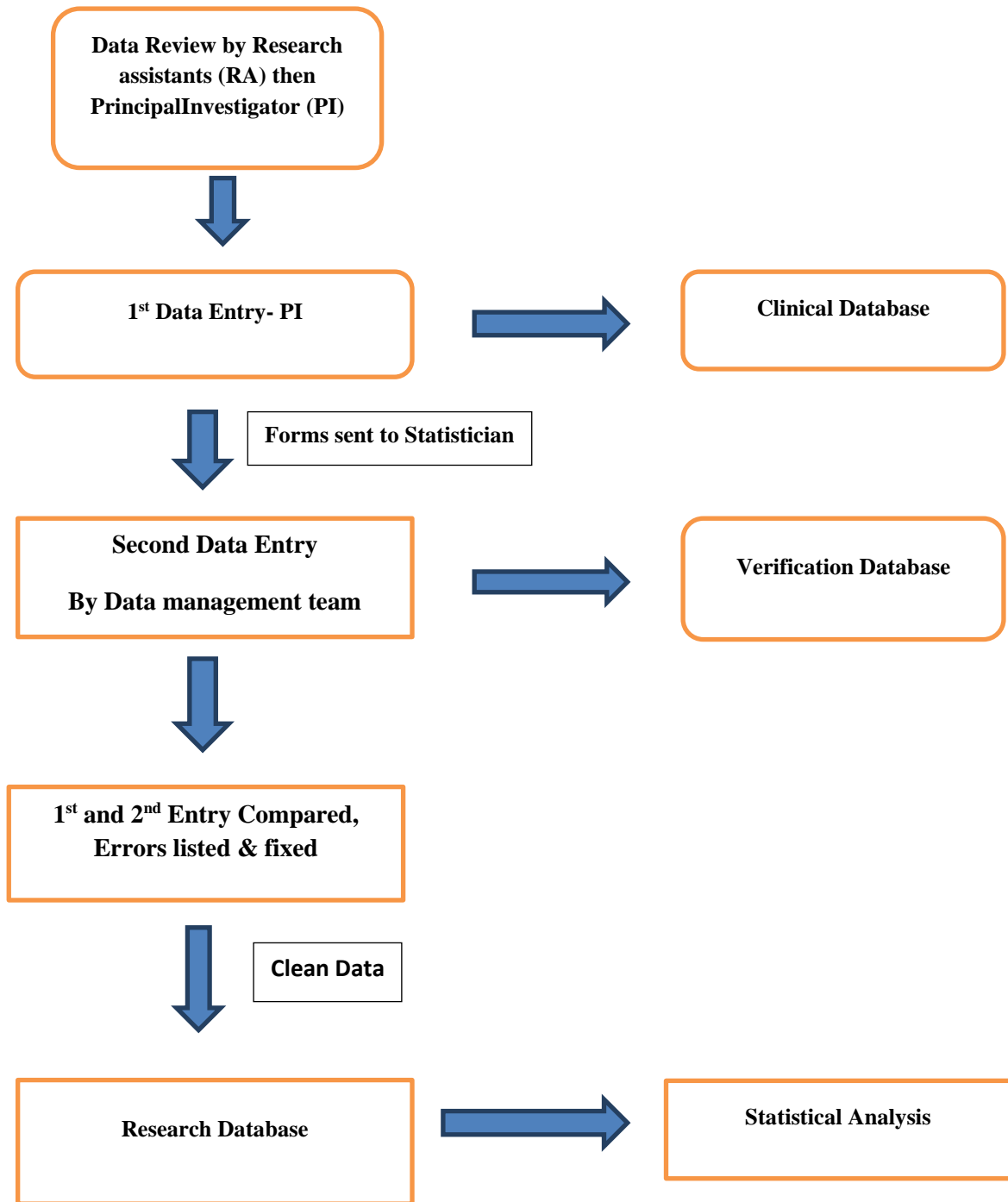
Figure 6- Summary of Data Quality Control

2.11 Data analysis methods

Continuous data variables were analysed as mean and standard deviation from the mean and t-test used to evaluate for association. For categorical variables, frequencies were obtained and compared using chi-square test. Relative risks were calculated. A p-value of less than 0.05 was considered statistically significant.

For objective 1, we described the prevalence of various antepartum fetal tests available as a percentage of allselected pregnancies. Since these are not mutually exclusive, we described them as a percentage alone and as a combination.

For objective 2, we estimated the association between abnormal tests that were associated with various perinatal outcomes. The testswerebiophysical profile, cardiotocography, doppler velocimetrystudies (umbilical artery and middle cerebral artery) and the outcome variableswere stillbirths, poor APGAR Score and early neonatal demise.Otheroutcomes that were assessed includedprematurity, low birth weightand NBU admission rates.

For objective 3 we evaluated whether the association seen in objective 2 above was different between pregnant women who reported normal versus reduced fetal movementby comparing

the risk estimates and testing for effect modification using Mantel Haenszel test of homogeneity. Data and results of the analysis were presented in the form of pie-chartsand tables.

2.12 Research ethics

The proposal development was done with the help of the supervisors, reviewed by the Department of Obstetrics and Gynaecology and approved by the KNH- UON Ethics and Research Committee (ERC) on 30th October 2018, protocol number**P552/08/2018.** As this was a record based retrospective study, we did notrequire consent from the participants. Nonetheless, consent for data extraction from medical records was obtained from the Departmentsof Reproductive Health as well as that of Health Research Programs, KenyattaNational Hospital. The study subjects' identity, characteristics and clinical information were kept confidential throughout the process of data collection by deidentification.

2.13 Study results dissemination plan

The findings of this research studywere presented to the Department of Obstetrics and Gynaecology, University of Nairobi. A copy of the final report will be submitted to the KNH Research and Programs department and KNH-UON Ethics and Research Committee. The findings of the study will be sent to peer review journals for possible publication. Policy briefs will be shared with key stakeholders both at the KNH and the Ministry of Health to scale down the recommendations into action points.

2.14 Limitations of the study

The major study limitations included, inaccurate data recording due toincomplete, inconsistent documentation and unlegiblehandwriting.These were few due to more documentation in high-risk pregnancies compared to the low-risk ones. Also, a restriction was done and only files with complete relevant andlegible documentation were sampled.Interobserver variation in interpretation of CTG is likely to be present however resident doctors have standard reference tracer charts pinned on the labour ward wall. The residents also undergo modular teaching on CTG interpretation and enlist consultants to help with any abnormal tracing. The ultrasounds are largely performed by sonographers and resident students. The differences in reporting APGAR scores is another limitation though the mid-wives have an APGAR scoring chart for referencing inthe delivery rooms and theatre.

CHAPTER THREE: RESULTS

3.1 Introduction

The findings of the study are presented in this chapter. The main objective of the study was to determine the antepartum fetal testing profile, perinatal outcomes associated with abnormal testsand the role of maternal fetal movement assessment inselected high-risk pregnancies at Kenyatta National Hospital.Between January 2014and December 2018, we examined records of 1372 women and found that 392(28.6%)were eligible. These comprised 196 (14.3%) records of women who had normal fetal movements and 196 records of women who perceived reduced fetal movements. (See figure 2)
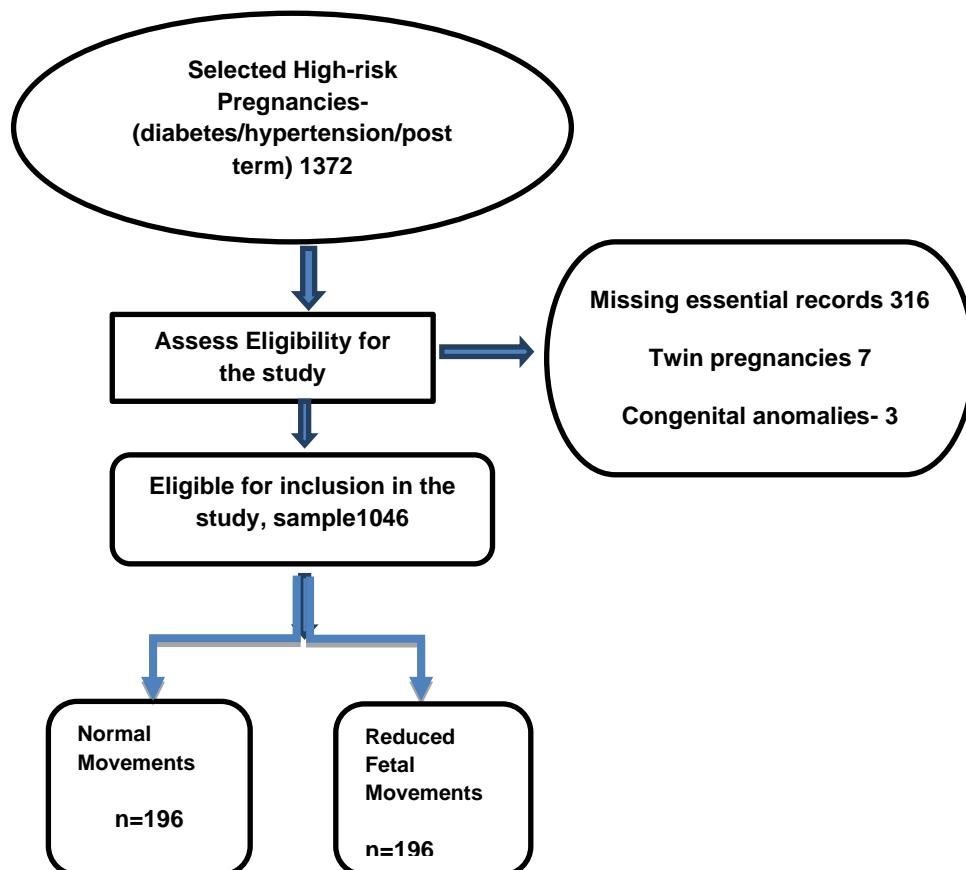
Figure7. Study flow chart of the participants

3.2 Patient characteristics

This section describesparticipant characteristics. We have described characteristics such as the distribution of the high-risk conditions, baseline and reproductive characteristics.

3.2.2 Prevalence of selected high-risk conditions in pregnancy

As illustrated in table 1, a total of 140(35.7%)study participants had hypertensive disorder of pregnancy (HDP), 67(17.1%) had diabetes mellitus (DM), 132((33.7%) had a post term pregnancy and 53 (13.5%)women had a combination of these disorders.Among the selected women, a combination of DMand an HDP was present in 32(8.2%) women followed by post term and HDP in17(4.3%) women with a post term pregnancy and DM identified in 4(1%) study participants. There were no significant statistical differences in the distribution of the high-risk disorders except in post term: RFM 33.7% versus normal fetal movement 25%, p <0.001

Table 1: Selected high-risk pregnancies by maternal perception of fetal movements

	Normal fetal movement N=196	Reduced fetal movement N=196	p-value
Post Term Pregnancy	83 (42.3)	49 (25)	<0.001
DM	29 (14.8)	38 (19.4)	0.227
Hypertensive Disorder	62 (31.6)	78 (39.8)	0.092
Combinations			
DM and Hypertensive Disorder	12 (6.1)	20 (10.2)	0.140
Post Term and Hypertensive Disorder	8 (4.1)	9 (4.6)	0.804
Post Term Pregnancy and DM	2 (1.0)	2 (1.0)	1.000

3.3.3 Baseline socio-demographic characteristics of the study participants

The mean age of the patients was 29.6 (standard deviation= 6.2) years. Majority of the women had a secondary school level of education orhigher, 77% in both groups. Most of the women were married (85.5%) distributed as 90.3% in the normal fetal movement group compared to 80.6% in the RFM group.This difference was statistically significant, p-value 0.006. More than half of the women (54.3%) were employed. Among the unemployed, 49.5% were in RFM group while 41.8% were in the normal fetal movement group.As pertains the participants' age, level of education and employment, no statistically significant difference was seen between the two groups.

Table 2: Comparison of socio-demographic characteristics of women with the selected high-risk pregnancies at KNH from 2014-2018 by maternal perception of fetal movements

Characteristics	Normal movements N=196 n (%)	Reduced Movements N=196 n (%)	p-value
Mean age 29.6(SD 6.2)			
Median 29.0(IQR=9)			
Age in years			
18-25	64 (32.7)	50 (25.5)	0.119
26-35	99 (50.5)	100 (51.0)	0.920
36-45	33 (16.8)	46 (23.5)	0.102
Education			
Primary	45 (23.0)	45 (23.0)	1.000
Secondary	82 (41.8)	79 (40.3)	0.758
Tertiary	69 (35.2)	72 (36.7)	0.752
Marital status			
Married	177 (90.3)	158 (80.6)	0.006
Single	19 (9.7)	38 (19.4)	Ref
Employment			
Employed	114 (58.2)	99 (50.5)	0.128

Unemployed	82 (41.8)	97 (49.5)	Ref

3.3.4 Reproductive (obstetric) characteristics of the study participants

As shown in table 3, more women in the RFM group had a previous pregnancy (77.4%) when compared to those in the normal fetal movement group (72.6%). The difference seen was however not statistically significant. Miscarriagein the previous pregnancy was more common in RFM group 15.8% vs 8.2% (p-value 0.023). There were no significant differences seen in the outcomes of previous pregnancies such as stillbirth (RFM 9.2%, NFM 6.1%) and early neonatal demise (RFM 5.1%, NFM 5.6%).

Overall, more women delivered at term (70.7%)compared to preterm 29.3. %. However preterm deliveries were2.5-foldmorelikely to occur in the RFM group(41.8% vs 16.8%)., p<0.001. The rate of induction of labour was low in both groups (19.1%) but significantly higher in the RFM group 21.4% vs normal fetal movement 16.8%, (p-value 0.0114).

Vaginal delivery rates were generally low at 16.1% of all pregnancies. These findings were comparable in the two groups, 15.3% in NFM group vs 16.8% in RFM. Nearly four-fifths (79.6%) of the study participants had an emergency caesarean delivery and no statistical difference was noted between normal and RFM groups, 77% vs 81.1% respectively (p=0.875).

Significantly fewer women had elective caesarean deliveries in RFM group, 2.0% compared to NFM 7.7 %(p=0.016). Almost one third (29.1 %) of the neonates born were low birth weight (<2500g) with about three-fold incidence in the RFM group, 42.9% vs 15.3%. (P-value<0.001).

Table 3: Comparison of reproductive (obstetric) characteristics of women with selected high-risk at KNH from 2014-2018 by normal and reduced fetal movements

Characteristics	Normalfetal movements N=196 n (%)	Reducedfetal movements N=196 n (%)	p-value
Parity			
Primigravida	54 (27.6)	44 (22.4)	0.243
Multigravida	142 (72.4)	152 (77.6)	
Number of living children			
None	17 (8.7)	25 (12.8)	0.191
One and above	179 (91.3)	171 (87.2)	
ANC visits			
<4	144 (73.5)	145 (74)	0.909
>4	52 (26.5)	51 (26)	
The outcome of last pregnancy			
Miscarriage	16 (8.2)	31 (15.8)	0.023
Stillbirth	12 (6.1)	18 (9.2)	0.200
Neonatal demise	11 (5.6)	10 (5.1)	0.988
Uneventful	103 (52.6)	93 (47.4)	Ref
N/A(Primigravida)	54 (27.6)	44 (22.4)	0.679
Gestation at delivery			
<37	33 (16.8)	82 (41.8)	<0.001
≥37	163 (83.2)	114 (58.2)	
Onset of labour			
Spontaneous	32 (16.3)	16 (8.2)	Ref
Induced	33 (16.8)	42 (21.4)	0.014
Indicated for C/S delivery	131 (66.8)	138 (70.4)	0.022
Mode of delivery			
SVD	30 (15.3)	33 (16.8)	Ref
Emergency C/S	151 (77)	159 (81.1)	0.875
Elective C/S	15 (7.7)	4 (2.0)	0.016
Birth weight			
<2500	30 (15.3)	84 (42.9)	<0.001
≥2500	166 (84.7)	112 (57.1)	

3.3 Profile of antepartum fetal testing (AFT)

This section presentsa comparison ofantepartum fetal testingprofile in women with high-risk pregnanciesperforming self-fetal movement monitoring.The AFTsincludedcardiotocography (CTG), ultrasound Biophysical Profile Scoring (BPP), doppler Velocimetrystudies (Umbilical artery Resistive Index and Middle Cerebral artery resistive Index).We described the prevalence of various individual Antepartum Fetal Tests available as a percentage of all pregnancies. We described these as individual and a combination of tests.

Among women with selected high-risk conditions (table4), ultrasound biophysical profile was the most prevalent antepartum surveillance test (51.5%) followed by CTG (46.7%) and umbilical artery resistive index (44.9%). MCA resistive index was the least performed test (16.1%).In women who reported reduced fetal movements the prevalence of the surveillance tests was significantly higher (CTG 60.2%, BPP 67.3%, umbilical artery RI 58.7%, MCA RI 22.4%. This would likely mean that a pregnant woman presenting with reduced fetal movements will likely have more investigations as compared to her peers who perceives normal fetal movements.

Table 4:Comparison of foetal testing profile in selected high-risk pregnancies at KNH from 2014-2018 by normal and reduced fetal movements

	Normal(N=196) n (%)	Reduced(N=196) n (%)	p-value
CTG Performed	65 (33.2)	118 (60.2)	<0.001
BPP Performed	70 (35.7)	132 (67.3)	<0.001
Umbilical RI Performed	61 (31.1)	115 (58.7)	<0.001
MCA Performed	19 (9.7)	44 (22.4)	0.001

3.4 Association of antepartum fetal testing (AFT) and perinataloutcomes

This section presents the results of comparison of the proportions of adverse perinatal outcomes (Stillbirths, poor APGAR and early neonatal death combined) in the two groups and association between the antepartum fetal testing and perinataloutcomes.

Overall,the more serious adverse perinatal outcomes of stillbirths, poor APGAR score or early neonatal deaths were seen in 14% of the study participants. However,as shown in figure 5, the incidence was morein high-risk pregnancies with reduced fetal movement (22%) when compared to those with normal fetal movements (6%), RR 1.77, 95% CI 1.49-2.12, p<0.001.
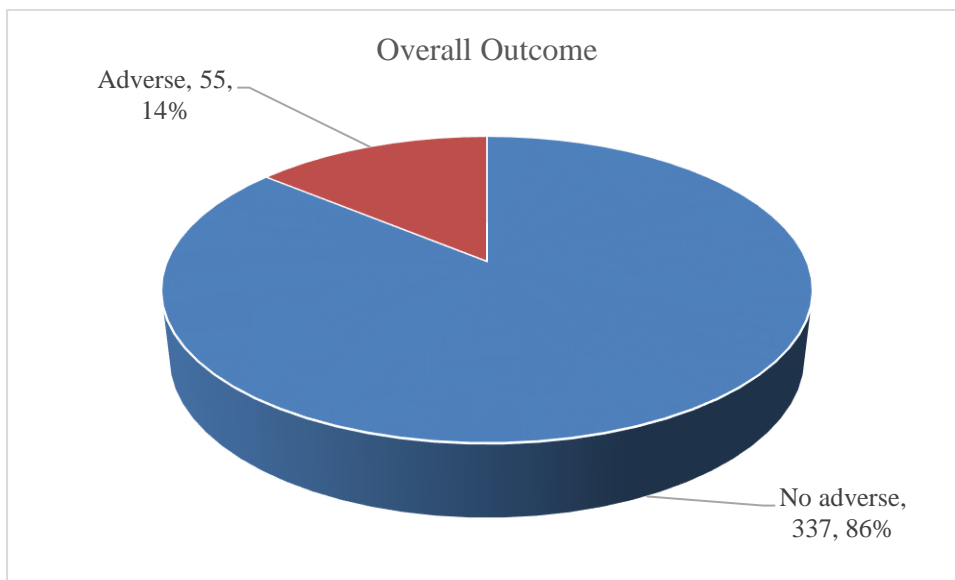
*** *Stillbirths, poor 5-minute APGAR and early neonatal death*

Figure8: Incidence of perinatal outcomes*** among the selected high-risk pregnancies at KNH, 2014-2018
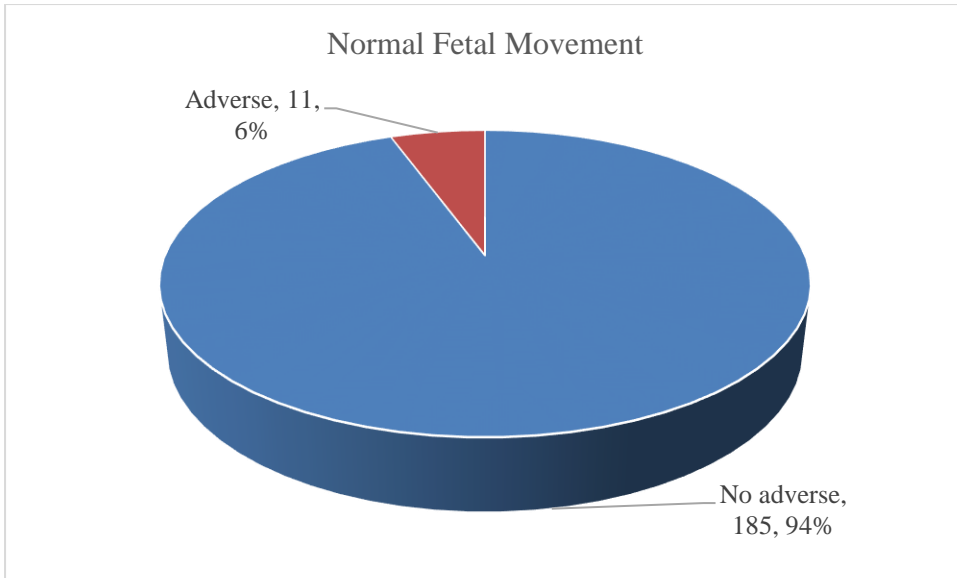
Figure 9.Incidence of adverse perinatal outcomes in selected high-risk pregnancies with normal fetal movements
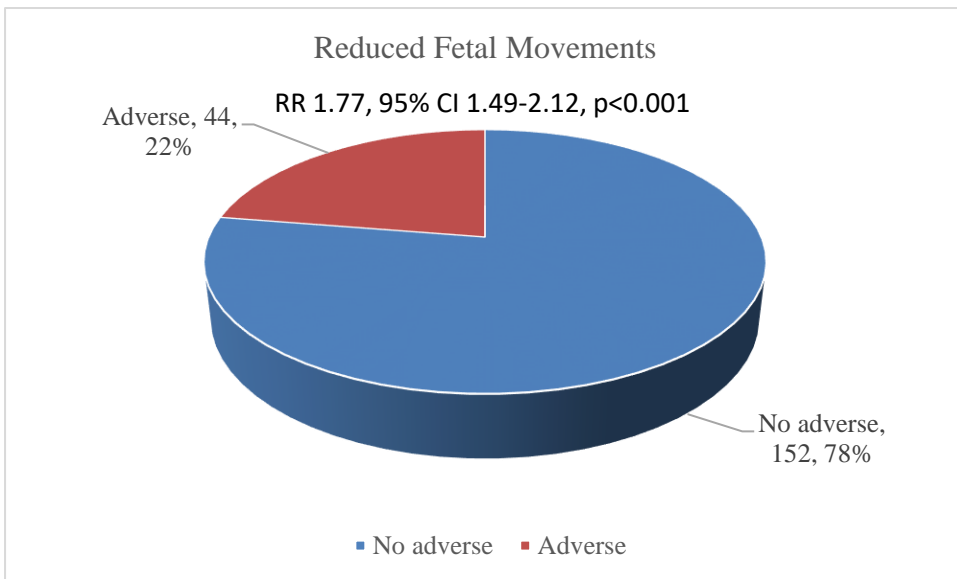

Figure 10:Incidence of adverse perinatal outcomes in selected high-risk pregnancies with perception of reduced fetal movements

Association betweenantepartum fetal testing and adverse perinatal outcomes

As illustrated in table 5, there was a tendency to have an adverse perinatal outcome if at least one of the antepartum tests was abnormal compared to when all the tests were normal. However, this difference was not significant statistically, RR 1.64, 95% CI 1.03-2.63, p= 0.054.

Table 5: Association betweenantepartum fetal testing and adverse perinatal outcomes when surveillance tests are aggregated

The aggregate of all tests	Adverse outcomes	perinatal	RR(CI)	p-value
	Yes	No		
Abnormal AFT	36	78	1.64 (1.03-2.63)	0.054
Normal AFTs	21	257	Ref	

3.5 Effect modification of maternal fetal movement assessment (FMA) on fetal testing

This section presents the results of the evaluation of FMA if at all it modifies the association between other antepartum fetal testing methods and adverse perinatal outcomes.

When we stratified the association above by maternal fetal movement assessment, the association between abnormal fetal testing and adverse perinatal outcome was statistically significant only in the RFM group (RR 2.55, 95% CI 1.91-3.41, p < 0.001). There was no association between antepartum fetal testing and adverse perinatal outcome in the NFM group (table 7)

Table 6:Association betweenantepartum fetal testing and adverse perinatal outcomes in normal fetal movements

The aggregate of all tests	Adverse outcomes	perinatal	RR(CI)	p-value
	Yes	No		
Normal FM				
Abnormal AFT	2	32	0.88 (0.24-3.27)	0.847
Normal AFTs	11	151	Ref	

Table 7: Association betweenantepartum fetal testing and adverse perinatal outcomes in reduced fetal movements

The aggregate of all tests	Adverse outcomes	perinatal	RR(CI)	p-value
	Yes	No		
Reduced FM				
Abnormal AFT	34	46	2.55 (1.91-3.41)	<0.001
Normal AFTs	10	106	Ref	

CHAPTER 4: DISCUSSION

This study presents a retrospective evaluation of theantepartum fetal testing profile, associated perinatal outcomes and the role of maternal fetal movement assessment.Themain findings in this study were that in the selected high-risk pregnancies, ultrasoundbiophysical profile score was the most performed antepartum fetal testing method followed by cardiotocography, umbilical artery resistive index and middle cerebral artery resistive index in that order.

Adverse perinatal outcomes were significantly more likely to occur in high-risk women who perceived reduced fetal movements. Another findingof note was a suboptimal prevalence of antepartum fetal testing in women with the high-risk conditionsand increased incidence of testing whenever perception of reduced fetal movement was reported. Additionally, high-risk women perceiving reduced foetal movements were more likely to have had a history of prior pregnancy, miscarriage in their last pregnancy compared to their counterparts experiencing normal fetal movements. They were also more likely to undergo interventions such as induction of labour and emergency caesarean delivery.

Possible reasons for the low prevalence of antepartum testing could be in that our settingwe haveinadequate resources to patient ratios.These resources could be personnel and equipment used for fetal testing.Additionally, the lack of local guidelinesfor routine fetal testing and continuous electronic fetal monitoringin high-risk conditions could have some contribution.High- risk conditions generally increase the risk of fetal death through placental insufficiency and resultant fetal compromise. Maternal perception of reduced fetal movement is a late sign which signifies irreversible fetal compromise hence higher rates of adverse events in the RFM group when compared to the women who had normal fetal movements.

More low birth weights neonates seen in RFM group could also be attributed to interventions such as early iatrogenic delivery geared towards optimizing fetal outcomes whenever abnormal testing is realized. Furthermore, high-risk medical conditions like hypertensive and diabetic disorders are also associated with the small for gestational age- IUGR complex.

A local cross-sectional study done in 2010 found that the prevalence of admission CTG for women who presented with reduced fetal movements was 71.9% while that of BPP was 54.6%. The higher CTG prevalence could possibly be because CTG machines were readily available in the labourward (admission point) while the other antenatal wards had to source the machines from labour ward. Froen et al in Norway through audits of stillbirths illustrated that maternal perception of RFM was associated with increased perinatal mortality, need for emergency delivery and low neonatal Apgar scores at delivery. These findings correlate with ours(97). In a cohort study done in the UK, it was demonstrated that pregnancies with the reduced fetal movements were more likely to have higher rates of induction of labour, low neonatalAPGAR scores at 5 minute and NBU admission(10). These findings can be correlated with what we found in our setting. Contrary to our findings this same study found that RFM was more common in primigravida women and there was no difference in caesarean delivery rates in RFM and normal fetal movement groups. RCOG guidelines on reduced fetal movementsadvocates for CTG as the first test for assessment of reduced fetal movement at a gestation of 28 weeks and above. In this study, the prevalence of CTG use was less than 50%. In comparison, Claire Mc Carthy et al in the UK found a prevalence of CTG use in patients presenting in an emergency department with reduced fetal movements to be 97.9%. (47) In the same study utilization of ultrasound biophysical profile score was 69.7%. In our study, biophysical profile scoring was done in over half of the high-risk pregnancies, 51.5%. A local study on perinatal outcomes of women presenting with reduced fetal

movements found an association between abnormal fetal testing and adverse perinatal outcomes(95). Low APGAR scores were more prevalent in those with abnormal CTG compared to normal CTG tracing 22.7% vs 7% respectively (p 0.011).Stillbirths were also commoner among those who had abnormal CTG 4.5% versus 1.1% (p 0.002)

This study is the first one of its kind in Kenya as it focused on the subset of the population with high-risk pregnancies. By auditing care of these women, we can address the various gaps in their management. However, the limitations in this study are that due to its retrospective nature many factors that are likely to beconfounders could not be controlled for inter-observer variability and interpretation of test results of the fetal surveillance tests could not be ruled out.

CONCLUSION

In the selected high-risk pregnancies, we found low rates of antepartum fetal testing with BPP as the most commonly performed test. The prevalence of fetal testing was higher when reduced fetal movements were reported. Abnormal fetal testing was associated with adverse perinatal outcome, more specifically in those with RFM suggesting RFM is an effect modifier of association between abnormal fetal testing and adverse perinatal outcome.

RECOMMENDATIONS

Regarding high-risk pregnancies, protocols for antepartum fetal testing should be developed. This will standardize the care provided to this subgroup of pregnantwomen, who ordinarily require more diligence in management. Women with reduced fetal movement and an abnormal fetal test should be monitored closely due to high risk of adverse perinatal outcome. This could possibly result in improved neonatal outcomes

Study Timelines

	Feb-Jun 2018	July 2018	Aug 2018	Sept 2018	Oct 2018	Jan-Apr 2019	May 2019	June 2019	July 2019
Proposal Development	■								
Proposal Presentation		■							
Ethics Committee Review			■	■	■				
Data Collection						■			
Data analysis							■		
Result Presentation								■	
Publishing									■

Study Budget

Components	Unit of Measure	Duration and Number	Unit Cost (Kshs)	Total Cost (Kshs)
Personnel				
Research Assistant	**1 Pax**	**33 Days**	**1500.00**	**49,500.00**
Statistician				**30,000.00**
Printing				
Questionnaires	**1 Copy**	**2 Copies**	**10.00**	**20.00**
Final Report	**1 Copy**	**80 Pages**	**10.00**	**800.00**
Photocopying				
Questionnaires	**430 Copies**	**2 pages**	**3.00**	**2,580.00**
Final Report	**5 Copies**	**80 pages**	**3.00**	**1,200.00**
Final Report Binding	**6 Copies**	**1**	**500.00**	**3,000.00**
Other costs				
ERC Fees				**2,000.00**
Records Access Fee				**1,500.00**
Poster Printing				**2,500.00**
Training	**3 Pax**	**1 day**	**500.00**	**1,500.00**
Total				94,600.00

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Appendices

Appendix 1- More analysis

Table 8: Comparison of combinations of fetal testing profile in selected high-risk pregnancies at KNH from 2014-2018 by normal and reduced fetal movements

Combined testing	Normal(N=196) n (%)	Reduced(N=196) n (%)	Total(N=392) n (%)	p-value
CTG and BPP	32 (16.3)	85 (43.4)	117(29.8)	<0.001
CTG, BPP and Umbilical RI	29 (14.8)	71 (36.2)	100(25.5)	<0.001
CTG, BPP, Umbilical RI and MCA RI	9 (4.6)	28 (14.3)	37(9.4)	0.001
BPP and Umbilical RI	59 (30.1)	108 (55.1)	167(42.6)	<0.001
BPP, Umbilical RI and MCA	17 (8.7)	41 (20.9)	58(14.8)	0.001

Table 9: Associationbetween antepartum fetal testing and perinatal outcomes in selected high-risk pregnancies at KNH from 2014-2018

	Perinatal Outcome***			
CTG	**Adverse**	**Good**	**RR**	**p-value**
Abnormal	19	45	2.34 (1.63-3.33)	<0.001
Normal	9	110	Ref	
BPP				
Abnormal	22	27	3.89 (2.53-5.97)	<0.001
Normal	13	140	Ref	
Umbilical RI				
Abnormal	23	25	4.47 (2.98-6.73)	<0.001
Normal	7	121	Ref	
MCA				
Abnormal	12	17	1.77 (1.07-2.90)	0.038
Normal	6	28	Ref	
Fetal movement				
Abnormal	44	152	1.77 (1.49-2.12)	<0.001
Normal	11	185	Ref	

*** Aggregated perinatal outcomes of stillbirths, poor APGAR score and early neonatal death

Table 10: The association between maternal perception of reduced fetal movementsandadverse perinatal outcomes in selected high-risk pregnancies at KNH from 2014-2018

Outcome	Fetal Movements				
		Reduced	Normal	RR	p-value
APGAR Score < 7	Yes	38	6	6.3 (2.7-14.6)	<0.001
	No	158	190		
Stillbirths	Yes	23	1	23.0 (3.1-168.6)	<0.001
	No	173	195		
Neonatal Deaths	Yes	11	5	2.4 (0.8-6.8)	0.083
	No	167	191		
Low Birthweight (less than 2500)	Yes	84	30	2.8 (1.9-4.0)	<0.001
	No	112	166		
Prematurity	Yes	82	33	2.5 (1.7-3.5)	<0.001
	No	114	163		
NBU admission	Yes	75	53	1.6 (1.2-2.1)	0.002
	No	103	143		

Appendix2: Data abstraction Tool

Date   Patient ID

Role of Fetal Movement Assessment on Antepartum Fetal Testing of High-Risk Pregnancies- PI: Dr Ajowi D

Maternal Demographics	
Age (Years)	
Weight (Kg)	
Height(M)	
Level of Education	□ Primary □ Tertiary □ Secondary
Employment status	□ Employed □ Unemployed
Marital status	□ Single □ Married
Residence	□ Urban □ Rural
Obstetric History	Parity No. of living children-------- No Of ANC attended□ 4 and above □1-3 □0
Outcomes of the last pregnancy	□ Miscarriage □ Neonatal Demise

	□ Stillbirth	□ Uneventful
Selected Existing Risk Factor		□ DM
	□ Post Term Pregnancy	□ Hypertensive Disorder
Antepartum Surveillance Method	Perceived fetal movement □ Normal	□Reduced
	CTG	□Normal □Abnormal □ Not performed
	BPP	□Normal □Abnormal □ Not Performed
	Umbilical RI	□Normal □Abnormal □ Not Performed
	MCA RI	□Normal □Abnormal □ Not Performed
Gestation at delivery	□ Very Preterm (28-<32 weeks) □ Moderately Preterm 32-<34weeks □Late Preterm 34-<37 weeks	□ 37-<39 weeks □ 39-<41 weeks □ 41-<42 weeks □ >42 weeks

Onset of Labour	□Spontaneous □Induced	□Indicated for C/S delivery	
Mode of delivery	Vaginal C-section	□ SVD □Emergency	□ Vacuum Delivery □ Elective
Perinatal outcome	BWT	___g	
	Health Status	□Alive	Stillbirth □ MSB □ FSB
	5 min APGAR score	□ <7	□ ≥7
	NBU admission	□Yes □ No	Early NeonatalDemise □Yes □No

Appendix 3: Letter to ERC

Dr Ajowi Duncan,

College of Health Science,

Department of Obstetrics &Gynaecology,

The University of Nairobi.

The Chairperson,

Ethics, Research and Standards Committee,

Kenyatta National Hospital and University of Nairobi,

P.O. Box 20723,

NAIROBI

Dear Sir,

RE: SUBMISSION OF MASTER'S DEGREE RESEARCH PROPOSAL FOR APPROVAL

I wish to submit my research proposal for approval by your committee. I am currently a 3rd-year student pursuing a master's Degree in Obstetrics and Gynaecology at the University of Nairobi, College of Health Sciences.

Yours Sincerely,

DrAjowi Duncan

Post graduate student

Appendix 4: KNH-UoN ERC Approval

Ref: KNH-ERC/A/385

31st October   2018

Dr. Duncan Ochieng Ajowi
Reg. No. H58/81036/2015
Dept. of Obstetrics and Gynecology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Ajowi,

RESEARCH PROPOSAL – THE ROLE OF FETAL MOVEMENT ASSESSMENT ON ANTEPARTUM FETAL TESTING AND EARLY NEONATAL OUTCOMES AMONG SELECTED HIGH-RISK PREGNANCIES AT THE KENYATTA NATIONAL HOSPITAL; A FIVE YEAR RETROSPECTIVE DESCRIPTIVE COHORT STUDY   (P552/08/2018)

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 31st October 2018 – 30th October 2019.

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.

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