FACTORS ASSOCIATED WITH ADVERSE PREGNANCY OUTCOMES AMONG HOME AND HEALTH FACILITY DELIVERIES IN LAMU COUNTY, KENYA: A COMPARATIVE CROSS SECTIONAL STUDY

By

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Declaration

I declare that this is an original write up and it does not duplicate any previously written or published material to the best of my knowledge. Where reference was made from other sources, the source literature has been cited. This is a product of my own work done with the guidance of my supervisors.

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This is to certify that this dissertation is the original work of Dr. Hind. A. Maawiya, Master of Medicine student in the Department of Obstetrics and Gynecology, Registration Number H58/75090/2014 University of Nairobi (2014 – 2018). The research was carried out in Lamu County under supervision of the department of Obstetrics and Gynecology, School of Medicine, College of Health Sciences, University of Nairobi. It has not been presented in any other university for award of degree.

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ABBREVIATIONS

APH---------- Antepartum hemorrhage

CHU---------- Community health units

CHW ---------- Community health workers

ERC ---------- Ethics research committee

FGR ---------- fetal growth restriction

FGR ---------- Fetal growth restriction

FSB ---------- fresh still birth

GBV ---------- gender based violence

IUFD ---------- Intra uterine fetal demise

KDHS ---------- Kenya demographic health survey

KNH ---------- Kenyatta national hospital

L.E ---------- Lamu East

L.W ---------- Lamu West

MNM ---------- maternal near miss

MSB ---------- macerated still birth

PPH ---------- postpartum hemorrhage

UNFPA ---------- United Nations fund population authority

UoN ---------- University of Nairobi

UW---------- University of Washington

WHO ---------- World health Organization

WWF---------- world wild life fund

ABSTRACT

Background

There has been rising concern on the number of maternal and neonatal deaths in Lamu County with no published article on the factors contributing to such poor outcomes. Compounding this problem are the unique features specific to Lamu County: the fact that it is an archipelago, shortage of staff linked to the recent terror attacks, the cultural aspects of Lamu County and the narrow roads as well as sparsity of tarmacked land. This study aimed to evaluate the socio-demographic, economic and cultural factors associated with place of delivery, role of preexisting medical conditions and obstetric emergencies on adverse pregnancy outcomes and to determine if there is any difference in the factors associated with adverse pregnancy outcomes depending on place of delivery i.e. hospital versus non-hospital. The adverse outcomes assessed were: premature deliveries, early onset neonatal sepsis, still births, intra uterine fetal demise (IUFD), maternal death, blood transfusion of 2 or more units, hysterectomy done due to post-partum hemorrhage (PPH) and pregnancy related stroke.

Broad objective

To determine the factors contributing to adverse pregnancy outcomes following health facility and home deliveries at gestational age of 28 weeks or higher in Lamu County in the year 2017.

Methodology:

Study design

This was a comparative cross sectional study in which factors associated with adverse pregnancy outcomes and place of delivery were determined among 185 facility and 215 home deliveries between February and October 2017 in Lamu County, Kenya in 2017.

Study site

Hospital setting: post-natal wards of: King Fahad, Faza, Mpeketoni County hospitals, Witu and Kiunga health centers. (All the public hospitals in the County that provide a minimum of basic obstetric care)

Home setting: 4 randomly selected divisions; deliveries were traced through community health workers in the area.

Study population

A community survey of female residents of Lamu County who delivered either at home or in a health facility in the year 2017 at gestation age of 28 weeks or greater.

Sample size

Using Fleiss formula for comparative cross sectional study; the sample size was approximated to be 400 participants after adjusting for attrition.

Data collection

A structured questionnaire in line with the study objectives was used.

Data analysis

Data analysis was conducted using SPSS (IBM version 20). Continuous variables were summarized using means and standard deviations or medians and interquartile ranges for skewed variables. Categorical variables were summarized using counts and proportions and compared between those with and without adverse pregnancy outcomes or home versus facility delivery using Pearson's chi-square tests or Fisher's exact tests as appropriate. Statistical significance was based on an alpha cut-off level of 0.05.Multivariable analysis was conducted using logistic regression for binary outcomes after adjusting for confounders. Odds ratios and 95% confidence intervals were reported from the multivariable analysis.

Significance of the study

Since there is no published article on the factors contributing to adverse pregnancy outcomes despite a high MMR and IMR of almost double the national rate. Also home deliveries are more prevalent than health facility deliveries in the County as per K.D.H.S 2014 54 versus 56% respectively. This study will help in identifying the key areas that need dire attention and also act as a baseline research and key indicators for and interventions in the County.

Results

Between February 2017 and October 2017 we interviewed 400 participants: 185 following a hospital delivery and 215 following a non-hospital delivery. In Lamu County, women that are more likely to deliver at home are: older (≥30yrs), with a prior normal vaginal delivery, multiparous (>3), with a low level of education and a low level of income. The overall prevalence in adverse outcomes did not differ statistically between women who had a hospital or a non-hospital delivery. However, occurrence of severe PPH with transfusion of two or more units of blood in the index pregnancy, was almost twice more common following a home delivery (54.5% Vs 23.3% P 0.014). Also, obstetric emergencies (OR 19.94, 95% CI 9.47-41.98, P 0.001), pre-existing medical conditions like hypertension (OR 12.53, 95% CI 4.12-38.09, P 0.001), diabetes, anemia and epilepsy (OR 11.07, 95% CI 3.57-34.27, P <0.001), social characteristics like teenage pregnancies and single parenthood, distance to the nearest health facility of >5Km (OR 3.63, 95% CI 1.27-10.38, P 0.016) ; were associated with adverse maternal and perinatal outcomes.

Conclusion: In Lamu County, a home delivery was more common among women who were: older (≥30yrs), with a prior normal vaginal delivery, multiparous (>3), low education and income level. Contributors to adverse outcomes were: obstetric emergencies, pre-existing medical conditions like hypertension, diabetes, anemia and epilepsy, social characteristics like teenage pregnancies, single parent-hood and distance to the nearest health facility of >5kms.
Interventions to reduce adverse outcomes should focus on: education on need for hospital delivery, upgrading of health centers to provide comprehensive obstetric care, as well as working with traditional birth attendants to act as ambassadors in referring patients in labor to deliver in a hospital setting.

CHAPTER 1

1.1 Introduction

Pregnant women, their families and care providers desire normal pregnancy, with limited interventions and good maternal and perinatal outcomes specifically, a healthy newborn and mother. Sadly, some pregnancies result in adverse maternal and perinatal outcomes such as low birth weights, preterm births, fetal growth restriction (FGR), intrauterine fetal demise (IUFD), congenital anomalies, perinatal deaths and maternal death. In addition most women prefer to deliver in an environment favorable to the physical and emotional well-being of both the mother and the baby. While health care providers consider facility delivery as the most ideal setting for ensuring optimum pregnancy outcomes, some pregnant women and their families prefer home deliveries as more friendly and only seek care when they develop complications.

Risk factors for such poor outcomes include: child spacing, poverty, age (<15 and >35 years) quality of prenatal care, poor maternal nutrition, body mass index >25, smoking, drug abuse and alcohol consumption during pregnancy. A study by Kazaura et al demonstrated factors associated with neonatal mortality as parity, marital status, maternal age, race, smoking, birth weight, labour complications, antenatal care, previous poor birth outcomes (stillbirths, neonatal deaths, maternal morbidity like H.I.V and malaria infection), preexisting medical conditions and socio economic factors.

In Kenya some strategies like beyond zero campaign, free maternity care, health care devolution and county system of governance have been introduced in order to address these adverse outcomes; however, disparities still remain within counties especially in neonatal outcomes and maternal near misses/deaths.

1.2 Statement of the problem

There is a disproportionately high burden of maternal and perinatal mortality and morbidity in sub-Saharan Africa compared to the rest of the world. According to the World Health Organization (WHO), in comparison to the developed world a woman's lifetime risk of dying during pregnancy or childbirth in Sub Saharan Africa is 1 in 3700 and almost 97-99% of the estimated 3-4 million stillbirths and 3 million neonatal deaths that occur yearly globally occur in low and middle income countries. In 2015, about 830 women globally were reported to have died each day due to complications of pregnancy and child birth with most of these deaths occurring in low resource settings and most of which could have been prevented. In the same year there were 2.6 million reported stillbirths globally and 2.7 million deaths of neonates, majority of these deaths occurred in developing countries and about half of them in the intrapartum period. From a WHO systematic review hemorrhage, hypertension and sepsis were responsible for more than half of maternal deaths worldwide (1).

Another contributor to adverse pregnancy outcomes is adolescent and teenage pregnancy. Each year about 16 million adolescents (15-19 years of age) give birth worldwide with 95% of the deliveries occurring in developing countries (2). The rate of teenage pregnancies is the third highest in coast province in Kenya with 20.8% of teenagers having begun childbearing (3). In low and middle income countries complications of child birth and pregnancy are the leading cause of death among adolescents; also perinatal deaths are 50% more common among teenage mothers in comparison to mothers aged 20 to 29 years. It is thus a growing realization that teenage pregnancies contribute to a number of adverse pregnancy outcomes like maternal and perinatal deaths, low birth weights and a vicious cycle of ill health and poverty (2).

The current Kenya maternal mortality ratio (MMR) is at 360/100,000 live births in comparison to the ratio in 1990 of 530/100,000 live births. However this slow decline has not met the targets of the fifth millennium development goal with disparities in the counties. More so given that the third goal of the sustainable developmental goals targets to reduce the global MMR to less than 70 per 100,000 live births. According to the United Nations fund for population activities (UNFPA) 98.7% of the maternal deaths reported in Kenya occur in 15 out of 47 counties, with Lamu County ranking seventh with a MMR of 676/100,000 live births (4). A similarity noted among these counties is the lack in continuity in care. From the 2014 Kenya demographic health survey (KDHS) statistics of Lamu County it was noted that 95.7% of pregnant women had attended at least one visit from a skilled provider, 62.2% went on to receive four or more antenatal care (ANC) visits, 47.3% were delivered by a skilled birth attendant and 43.9% delivered in a health facility. The major challenge according to a baseline survey by AMREF; with regard to access to health care is poor road infrastructure and inadequate transport facilities. The nearest distance to a health facility of any kind is about 5Kms with only about 6kms of the road network being tarmacked making transportation by road during the rainy seasons almost impossible. Travelling by boat is at times impossible depending on the tides of the sea waves.

The total fertility rate in Lamu county is at 4.3 as compared to the national fertility rate of 3.9 with a contraceptive prevalence rate of 42.2% which is still low compared to the national rate of 58% and also in comparison to twenty two other counties with their rates being higher than the national contraceptive prevalence rate (3).

Doctor to patient ratio, a key determinant of quality of care is low in LMICs including Kenya. However, the situation is worse in Lamu County where the doctor to patient ratio in Lamu County is 1: 6,500 according to the counties' statistics in comparison to the WHO recommended ratio of 1:435. Also, Lamu County has a high infant mortality rate of 72/1000 live births compared to the national rate of 39/1000 live births (3).

This study aimed to identify the factors associated with choice of place of delivery given that more than half 54% of the women in Lamu County deliver at home, to determine the factors associated with adverse pregnancy outcomes in Lamu County in home and hospital deliveries as well as to assess if there is any difference in the factors contributing to adverse pregnancy outcomes comparing home versus hospital deliveries in order to employ targeted interventions. One of the areas of concern has been the recent terror attacks in the region and its impact on maternal and child health in terms of acquiring health personnel and access to health services. Up until early 2015 there has been no obstetrician/ gynecologist despite numerous attempts by the County to advertise for the position as well as other specialties. This study will therefore inform the reproductive health team and county leadership on the status of maternal health and potential interventions to address adverse outcomes.

CHAPTER 2: LITERATURE REVIEW

2.1 Factors and adverse outcomes associated with choice of place of delivery

From several studies, reasons for choice on place of delivery differ in developed versus developing countries, with home deliveries in developed countries being mostly planned. According to a systematic review of 45 studies it was shown that: in developed countries sociodemographic and economic characteristics of women that had a home birth were: older >25-35 years, medium-high socio economic status, multiparous, non-Hispanic whites, living in rural areas, with a masters' degree education, late initial antenatal attendance of 4 months or more and with the largest distance from a hospital. In developing countries, most women that deliver at home were shown to have a lower level of education, less wealth, multiparous, living in rural areas and having received little or no pre-natal care (5)

From the above mentioned systematic review, outcomes following home and hospital deliveries in Netherlands, Canada and United States of America (U.S.A) were noted to be similar. This was attributed to the low risk nature of the pregnancies of women that opted for home deliveries, skilled birth attendants and a highly integrated and prompt health care system of referral(5)

A different study in the U.S.A showed that neonatal mortality following planned home birth was higher compared to hospital deliveries i.e. 10/10,000 live births and 3.2/10,000live births respectively. This was attributed to higher infection rates following a home delivery(6)

A study done in a tertiary hospital in India, on women admitted following a home birth delivered by traditional birth attendants in 79% of the cases and 11% by relatives or friends, the most common adverse outcome was post-partum hemorrhage accounting for 50.6% of the adverse outcomes compared to 26% following delivery in a health facility under skilled birth attendants

(7) Obstetric complications (PPH, puerperal sepsis and hypertension) were reported in 38% of participants in a community survey in rural Hyderabad Pakistan following home deliveries(8)

A systematic review of nine population based cohort studies in sub Saharan Africa on adverse pregnancy outcomes based on place of delivery concluded that perinatal mortality was higher following a non-hospital delivery compared to hospital delivery i.e. 70/1000 versus 56/1000 live births. However, maternal mortality ratio (MMR) was consistently higher across two out of three studies that reported maternal deaths as an adverse outcome. Following a hospital delivery, the MMR was 945/100,000 live births versus 599/100,000 live births in non-hospital deliveries. The reason attributed to this result was: those seeking hospital care were more likely to have complicated cases thus at higher risk of mortality(9)

In Kenya, a study in the rural coast of Kilifi County showed that a larger distance to a health facility was associated with a home birth (10) Similarly, in another study among pastoralist women in Laikipia and Samburu Counties, larger distance to a health facility, poor roads, economic constraints, low level of education and poor staff attitudes were associated with a home delivery (11)

With regard to Lamu County, various unique aspects were demonstrated in a study on unique challenges faced by health non-governmental organizations in the health system of Lamu County mostly due to the fact that the County is an archipelago.

The main challenges noted were lack in continuity of care (mostly attributed to the terrain and poor accessibility to health institutions of some locations in the County), social beliefs making people shy away from seeking treatment (skeptism towards HIV/AIDS) and working with the existing health care system (12). Another study on determinants of male involvement in

attending mother and child health clinics established an almost nil pattern in male attendance and attributed it to: poverty level (men being predominantly the bread winners in the family would rather look for a source of food for the day), the social outlook; men who accompany their wives to the health facility are considered to be weaklings in the community and religious aspect; avoiding mingling with women as they would be predominant in such a gathering(13)

2.2 The global situation: Individual risk factors associated with adverse pregnancy outcomes

From a W.H.O systematic analysis carried out between the years 2003 and 2009, 73% of all maternal deaths are due to direct obstetric causes with the commonest being hemorrhage, hypertensive disorders and sepsis (1). Similar results were obtained from a cross-sectional study done in India that showed a near miss to mortality ratio of 5.8:1 with hemorrhage being the most frequent cause followed by hypertensive disorders, sepsis and raptured uterus. Admission to the intensive care unit was at a rate of 42.34% (14). Another cross-sectional study in Indonesia showed a higher rate of near misses in public (17.3%) versus private (4.2%) facilities with hemorrhage being the most common followed by hypertensive disorders (15). Taking a look at the fetal outcomes and the possible risk factors; a systematic review of 142 studies on factors associated with stillbirths in low and middle income countries identified poverty, lack of education, maternal age(<20years/ >35years), previous history of a stillbirth, prematurity, low birth weight and parity (1/ >5) as factors associated with stillbirths.

Maternal HIV infection with low CD4 count, maternal syphilis, diabetes, malaria, birth asphyxia and trauma (3-25%), congenital anomalies (2-33%), placental causes (7-42%), umbilical problems (2-33%), amniotic and uterine factors (6-10%) accounted for the following percentages of stillbirths (16). A study in in a tertiary hospital in Moradabad India, tried to merge the two aspects above i.e. obstetric emergencies and fetal outcomes (stillbirths 34.7%, neonatal ICU admissions

74% and ventilator support 25.7%) and the possible risk factors identified were: maternal illiteracy and ignorance being major contributors of poor fetal outcomes. The most common obstetric emergencies were pregnancy induced hypertension, obstructed labor, antepartum hemorrhage and anemia (17). Another study done in Karnataka, India in a rural community on obstetric emergencies showed the commonest obstetric emergencies in the area to be PPH, APH and obstructed labor with the probable risk factors being teenage pregnancies (44.3%), pregnancy induced hypertension and anemia (18).

Another systematic review involving 15 studies demonstrated that most of the complications associated with teenage pregnancies are in relation to the newborn i.e. significantly greater occurrence of preterm deliveries, low birth weights and neonatal deaths. The probable risk factors for the above outcomes were: inadequate prenatal care, poverty, smoking, marital status and low education level (19).

Similarly, a population based study in Taiwan between 2001 to 2010 on adverse pregnancy outcomes (stillbirths, preterm birth, low birth weight, neonatal death, macrosomia, congenital anomalies and small gestational age [SGA]) in relation to maternal age, showed increased occurrence of adverse birth outcomes in extremes of age: (<14years and >44years) with still births, preterm labor, low birth weight, SGA being more common in teenage pregnancies and congenital anomalies and macrosomia occurring more often in the older age group >43 years. Neonatal deaths occurred more commonly among both extremes of age (20). Also, retrospective case control study in California concluded that all teenage pregnancies are associated with poor obstetric outcomes i.e. greater neonatal and infant mortality rates, preterm deliveries and low birth weights less than 2500gms (21). As such strong evidence is available on the impact of extremes age on pregnancy outcomes.

Delays in making the decision, access and provision of health care have been associated with adverse maternal and perinatal outcomes. For instance, a cross sectional multi-center study in Brazil identified delays contributing to poor obstetric outcomes (maternal near misses and maternal death). The delays identified were: accessibility to a health facility (34.6%), quality of medical care (25.7%) and delay in seeking health care (10.2%). However, it's worth taking note that in 53.8% of all subjects a kind of delay was identified. Among the maternal deaths and near misses in 84% and 68% of the mothers at least one delay was identified respectively (22).

Also of much significance are preexisting medical conditions as shown in various research articles such as: a systematic review on preconception and pregnancy glycemic profile showed that the rate of stillbirth and pre-eclampsia is double in patients with type 1 diabetes whereas perinatal deaths and small for gestational age were higher in type 2 diabetic patients; preterm deliveries, fetal malformations, macrosomia, miscarriages and cesarean section rates were comparable between the two groups (23). There is an eight fold relative risk in developing pre-eclampsia superimposed on chronic hypertension than pre-eclampsia in the general population according to a meta-analysis of 55 studies from 25 countries on chronic hypertension and pregnancy outcomes; pooled incidences of the outcomes were as follows: superimposed pre-eclampsia 25.9%, caesarean section rate 41.4%, pre-term delivery 28.1%, low birth weight <2.5kgs 16.9%, neonatal unit admission 20.5% and perinatal deaths at 4% (24) .

In Yorkshire a study conducted showed an incidence of 5.2 per 1000 women for severe pre-eclampsia/ eclampsia, with 39 per 10,000 women developing serious complications, 23 per 10,000 women requiring ICU admission and a neonatal mortality rate of 47.2 per 1000 live births (25). Also, a meta-analysis involving 52 cohort studies showed a significant association of maternal HIV infection with low birth weight (pooled odd ratio of 1.73) and preterm deliveries (pooled odd

ratio of 1.56). Use of antiretroviral agents did not seem to alter the association above (26). In relation to heart diseases and birth outcomes, a systematic review on outcomes of pregnancy in women with congenital heart diseases (CHD) demonstrated that complex CHD were associated with higher preterm deliveries and small for gestational age neonates with high neonatal mortalities attributed to the preterm births (27)

2.3 Situation in Sub-Saharan Africa

Out of the 830 daily global maternal mortality deaths 550 occurred in Sub Saharan Africa and 180 in Southern Asia, compared to only 5 occurring in developed countries; making the risk of a woman in a developing country dying from a maternal related cause during her lifetime 33 times higher than a woman living in a developed country (1)

Similar to the W.H.O systematic review on maternal deaths is a study done at Muhimbili referral hospital in Tanzania which showed that the top three causes of maternal deaths in the hospital over a 6 year period of retrospect analysis were direct causes i.e. eclampsia, post-partum hemorrhage however unlike in the W.H.O report it was then followed by anemia rather than sepsis(28). Another study in rural Gambia, taking a look at neonatal outcomes i.e. stillbirths in surviving patients with antepartum hemorrhage, pre-eclampsia/eclampsia, prolonged/obstructed labor or severe anemia; identified an association of stillbirths with delays associated in accessing skilled health care. In all the patients at least one delay was identified. First delays (delays in making a decision and delays in recognizing danger signs) occurred in 30% of the cases, second delays (issues related to transport, distance and poor infrastructure) in occurred in 50% of the cases and third delays (delays in receiving blood transfusion) occurred in 20% of the cases (29) Still on neonatal outcomes, a study done in Zimbabwe showed that lack of prenatal care and rural residency have associations

with low birth weights (30). This study established almost a similar correlation to a study in Nigeria that demonstrated that teenage pregnancy is a high risk pregnancy with most of them 78.9% occurring in teenagers from a low socio economic class and the prevalent complications amongst them being anemia (33.5%), low birth weight (17.8%), pre-eclampsia (12.4%),preterm labor (11.5%) and stillbirth (2.5%).

In both studies the poor outcomes were linked to lack of adequate prenatal care among teenage pregnancies probably due to lack of financial resources (31)

With relation to infections and preexisting medical conditions several studies such as: a cross-sectional study in Tanzania showed women with placental malaria to be three times more likely to develop maternal anemia and four times more likely to have premature deliveries (32) Another study done in northern Tanzania showed that the most prevalent parasitic infection was malaria (17%), with increased odds of 13% of having a preterm delivery (33)

2.4 Situation in Kenya

Consistent findings have been demonstrated from the studies in sub Saharan Africa as well as locally as seen in a study on pathways of the determinants of unfavorable birth outcomes (preterm births, low birth weights and cesarean section deliveries) in Kenya identified antenatal care as the central link relating sociodemographic factors to birth outcomes (34) Another study in Keiyo district Kenya, on factors contributing to adverse pregnancy outcomes in public hospitals showed that low education level, un employment, single parenthood, preexisting medical conditions, experience of obstetric emergencies, caesarean and vacuum deliveries poor staffing and poor staff attitudes as contributors of poor obstetric outcomes in the region i.e. stillbirths, miscarriages, preterm birth, low birth weight, fetal growth restriction and perinatal deaths (35). At a rural area in Msambweni in coast province, Kenya a study on barriers to a hospital delivery identified lack

of resources (funds, access to transport), health workers' attitude and ignorance as major barriers (36)

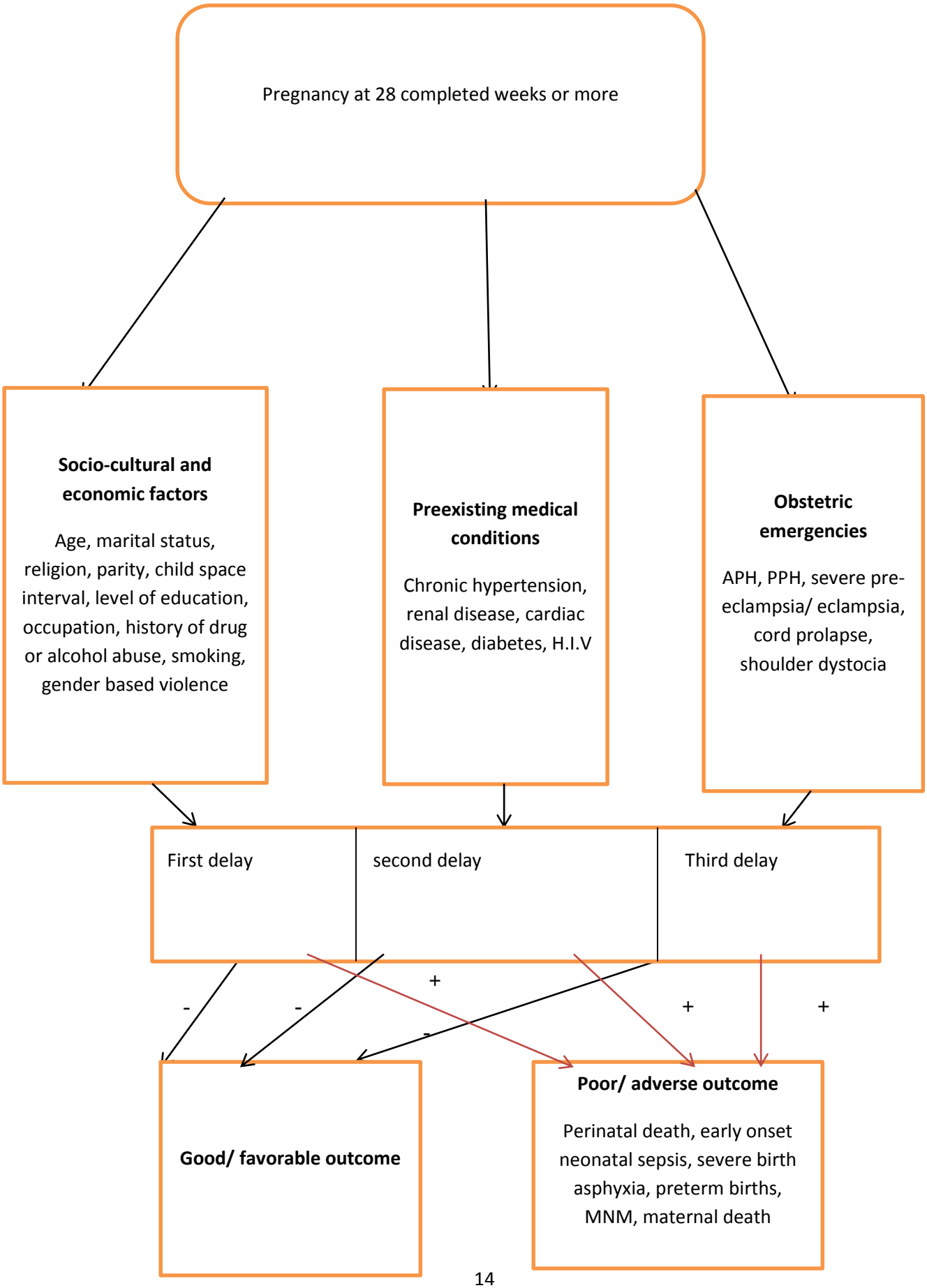
In comparison to the developed world; poverty, education level seem to be major factors associated with poor pregnancy outcomes for instance, a case control study done at the Moi teaching and referral hospital (MTRH) factors associated with maternal mortality were: low education level, no skilled birth attendance, admission with co morbid conditions, patients admitted as a referral, no antenatal clinic attendance, history of other medical conditions and patients with pre-eclampsia (37) Another study at MTRH hospital showed a stillbirth rate of 30.5 per 1000 live births of which 72.2% were fresh stillbirths whereas the commonest probable cause of death was intrapartum asphyxia and commonest mode of delivery was vaginal hence implying on need for proper antenatal and intrapartum care in improving such outcomes (38) Also, in Nairobi, Kenya a study in two urban slums shows a link between poverty and adverse maternal outcomes. Associations with minimal educational background, delays in seeking skilled delivery care, poor nutrition and early teenage pregnancies were made (39)

Globally teenage pregnancies have been shown to have poorer pregnancy outcomes for instance; a study done in south Nyanza on determinants and consequences of early teenage pregnancies; with the measured consequences being pregnancy wastage and preterm deliveries, it was observed that about half of the live births were preterm deliveries with a higher incidence among rural residents, those with low educational attainment, very young mothers(13 years or less), unmarried teenagers and those having their first pregnancy (40)

Throughout many articles various factors have been shown to contribute to poor pregnancy outcomes like: preexisting medical conditions, infections, socio demographic characteristics, delays in seeking, access and provision of health care and obstetric emergencies, with different factors having more impact in different regions around the globe. Thus along these lines it makes it necessary to make enquiries and answer questions specific to each County in the country.

2.5 Conceptual framework:

In developing countries like Kenya, a pregnancy at 28 completed weeks is considered viable; thus the outcome of such a pregnancy should generally be good (healthy mother and baby). However there is an interplay of several risk factors i.e. socio-cultural and economic factors (age, marital status, parity, level of education, occupation, religion, drug abuse, alcohol consumption and smoking in a pregnant state), obstetric emergencies (pre-eclampsia/eclampsia, cord prolapse, obstructed labor, antepartum hemorrhage, post-partum hemorrhage) and preexisting medical conditions (chronic hypertension, diabetes, renal disease, cardiac disease, H.I.V, anemia); which if dealt with accordingly and in good time would most probably give a good outcome. Delays in care i.e. first delay: delay in identifying danger signs and making the decision to seek health care, second delay: delay in reaching the health facility or/ and delay in receiving appropriate treatment, contribute to adverse maternal and perinatal outcomes.


Pregnancy at 28 completed weeks or more
Socio-cultural and economic factors
Age, marital status, religion, parity, child space interval, level of education, occupation, history of drug or alcohol abuse, smoking, gender based violence
Preexisting medical conditions
Chronic hypertension, renal disease, cardiac disease, diabetes, H.I.V
Obstetric emergencies
APH, PPH, severe pre-eclampsia/ eclampsia, cord prolapse, shoulder dystocia
First delay
second delay
Third delay
-
-
+
-
+
+
Good/ favorable outcome
Poor/ adverse outcome
Perinatal death, early onset neonatal sepsis, severe birth asphyxia, preterm births, MNM, maternal death

2.6 Justification:

There has been rising concern on the number of still births, maternal deaths and quality of maternal health care in the County necessitating the launch of a programme by UNFPA in six counties including Lamu. It is aimed at reducing maternal and child mortality with the Counties' rates being almost double the national rates. Furthermore, there is no published research article that has investigated the loopholes in the County coupled with the fact that Lamu County has various unique features that call for a research specific to Lamu County in order to adequately address the above issue I.e. it is an archipelago, there is no access to the interior of the mainland by vehicles, recent terror attacks and the cultural aspect of the inhabitants of Lamu County. Also, the proportion of women who deliver at home under traditional birth attendants in Lamu County is more than half about 54% as per KDHS 2014 data. Thus, this study aims to identify the socio demographic and economic characteristics associated with home deliveries, to assess the factors associated with adverse pregnancy outcomes among women of Lamu County and to determine if there's any difference in the factors comparing home and hospital deliveries. Throughout the years a lot of money has been directed towards improving pregnancy outcomes in Lamu County however the progress has been staggering; will help in providing a baseline from which other studies can stem up from, making it a good reference to policy makers.

2.7 Research question

What are the factors associated with adverse pregnancy outcomes following health facility and home deliveries at a gestational age of 28 weeks or higher in Lamu County in the year 2017?

2.7 Broad objective: To determine the factors associated with adverse pregnancy outcomes following health facility and home deliveries at 28 completed weeks or higher gestational age in Lamu County in the year 2017.

2.8 Specific objectives

Among home and facility deliveries in Lamu County, Kenya to:

1. Determine socio demographic, economic and cultural factors associated with health facility and home deliveries.

2. Determine the association of preexisting medical conditions and adverse pregnancy outcomes.

3. Assess the association of obstetric emergencies and adverse pregnancy outcomes.

4. Evaluate any differences in factors associated with adverse pregnancy outcomes.

CHAPTER 3: METHODOLOGY

3.1 Study design:

Comparative cross sectional study on factors associated with adverse pregnancy outcomes among female residents of Lamu County delivering either at home or in a health facility. It was quantitative in nature with the aid of a structured interviewer guided questionnaire and eventually coded into numerical data and analyzed.

3.2 Study site:

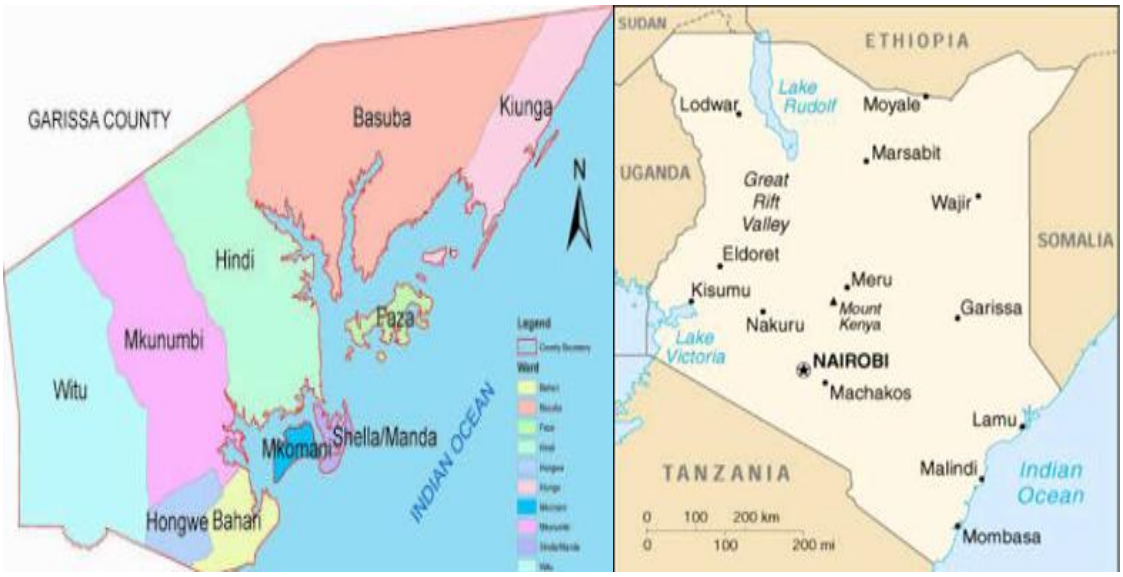
Lamu is an archipelago in Kenya, comprised of the mainland (Amu) and over 65 other islands. It is located in the Northern coast of Kenya bordering Kilifi County in the Southwest, Garissa County to the North, Somalia to the Northeast and Indian Ocean to the South. It lies 1^0 40' and 2^0 30' South, longitude 40^0 15' and 40^0 38' South. It has a population of 101,539 (2009 census). The main indigenous groups are Bajoun, Arabs, Orma and the Boni. The County has two constituencies Lamu East (L.E) and Lamu West (L.W) with a land surface area of 6,273.1km. Lamu West comprises of: Amu (mkomani), Hindi, Mkunumbi, Shela, Witu, Bahari and Hongwe, while Lamu East comprises of Faza, Kiunga and Basuba. Lamu County has a total of 42 hospitals i.e. one County referral hospital on the mainland (king fahad), two sub district hospitals (faza, and mpeketoni hospitals), 5 health centers, 20 dispensaries, 13 medical clinics and one nursing home; 33 of them being government owned (Lamu County statistics). King Fahad hospital (referral hospital in the County: level 5 hospital) is in Amu. There are two ambulances on the mainland with the other at Mokowe which links the County to other coastal areas of the country. Amu is comprised of narrow roads hence access to the interior by vehicles is impossible thus a patient is brought to the shore by being carried by relatives or being ridden on the back of a donkey. The rest of the county access is either by boat or dhows which are dependent on the sea tide and some places are accessible by road. However since the stretch of tarmacked road is only 6kms; the rest

being earth during rain seasons access becomes a big challenge worsened by the fact that the only all-terrain jeep available does not belong to the County instead, it belongs to the world wildlife fund (WWF) hence is available when not already in use by the WWF(41). Thus health care accessibility in Lamu County might pose a unique challenge especially in emergency situations. Given the small population of residents of Lamu, we embarked on a countywide study to identify factors associated with adverse pregnancy outcomes and place of delivery.

Box 1: showing the population of Lamu County as per electoral ward (Kenya national bureau statistics)

Electoral ward	Total population
Faza (L.E)	13,384
Kiunga (L.E)	4,103
Basuba (L.E)	1,052
Shella (L.W)	2,935
Mkomani (L.W)	18,660
Hindi (L.W)	10,039
Mkunumbi (L.W)	11,710
Hongwe (L.W)	9,084
Witu (L.W)	12,983
Bahari (L.W)	15,516

Box 2: Map of Lamu County showing its divisions



3.3 Study population

Female residents of Lamu County: aged 14 years or more, having delivered in the year 2017 at gestation age of 28 completed weeks or more; meeting the inclusion criteria.

Inclusion criteria

- Age14 years or more (emancipated minors)
- Gestation 28 completed weeks or more.
- Resident of Lamu County (a woman who has lived in the County for a year prior to delivery)

- Hospital setting: all women who delivered from 28 weeks gestation during the study period in the labor or antenatal wards of King fahad, Faza, Mpeketoni hospitals, Witu and Kiunga health centers. (interviewed within a month of delivery)
- Community setting: Included women whose most recent delivery (within a month of the time of data collection) was a home delivery or occurred while on route to the hospital.
- All the above were interviewed after having given consent. However, a participant who met the above criteria and passed away, consent was sought from the next of kin.

Exclusion criteria:

- Non-residents of Lamu.
- Maternal death from unconfirmed pregnancies.

3.4 Sample size

Sample size was calculated using Fleiss formulas (42)

$$n_1 = \frac{\left[C_{\alpha/2}\sqrt{(r+1)\bar{P}\bar{Q}} = \pi r^2 - C_{1-\beta}\sqrt{rP_1Q_1 + P_2Q_2}\right]^2}{r(P_2 - P_1)^2}$$

$$m = \frac{m'}{4}\left[1 + \sqrt{1 + \frac{2(r+1)}{m'r|P_2 - P_1|}}\right]$$

m=n_1=size of sample from population 1; n2=size of sample from population 2

P_1=proportion of disease in population 1; P_2=proportion of disease in population 2

α= "Significance" = 0.05 β=chance of not detecting a difference = 0.2

1-β = Power = 0.8 r = n2/n1 = ratio of exposed to unexposed

P = (P1+rP2)/(r+1); Q = 1-P; n1 = m n2 = r m

If 1- α is 0.95 then cα/2 is 1.960; α/If 1- β is 0.80 then c1-beta is -0.842

Proportion of facility (unexposed) deliveries = 46%

Proportion of home (exposed) deliveries = 54%

P_1 = estimated proportion of adverse pregnancy outcomes (obstetric complications in facility deliveries in Nepal, India) in the unexposed (facility deliveries) population = 24%.

P2 = estimated proportion of adverse pregnancy outcomes (obstetric complications in rural Hyderabad, Pakistan) in the exposed (home deliveries) population = 38%.

The number of home deliveries estimated in this study was 197 participants while 169 were facility deliveries. After adjusting for attrition the calculated sample size was 185 and 215 for health facility and home deliveries respectively.

3.5 Data collection tool:

Structured interviewer guided questionnaires based on the study objectives were used (see appendix 3) to assess participants' sociodemographic, cultural and economic characteristics, obstetric history, medical history and pregnancy outcomes. Study assistants were trained on study details and on how to fill the questionnaire as well as recruit eligible participants.

3.6 Data collection procedure:

Permission was first sought from the Lamu County executive commissioner of health and from the medical superintendents of all the health facilities where data was collected from as well as from the individual participants.

Health facility setting: All women meeting the inclusion criteria who delivered in the five health facilities i.e. Kiunga, Faza, mpeketoni, witu and King Fahad hospital (providing a minimum of basic obstetric care) during the period of data collection were recruited simultaneously across the five health facilities until the desired sample size was achieved i.e. 185 participants. This is based on 2014 KDHS statistics that show that 46% of deliveries in the County are in health facilities

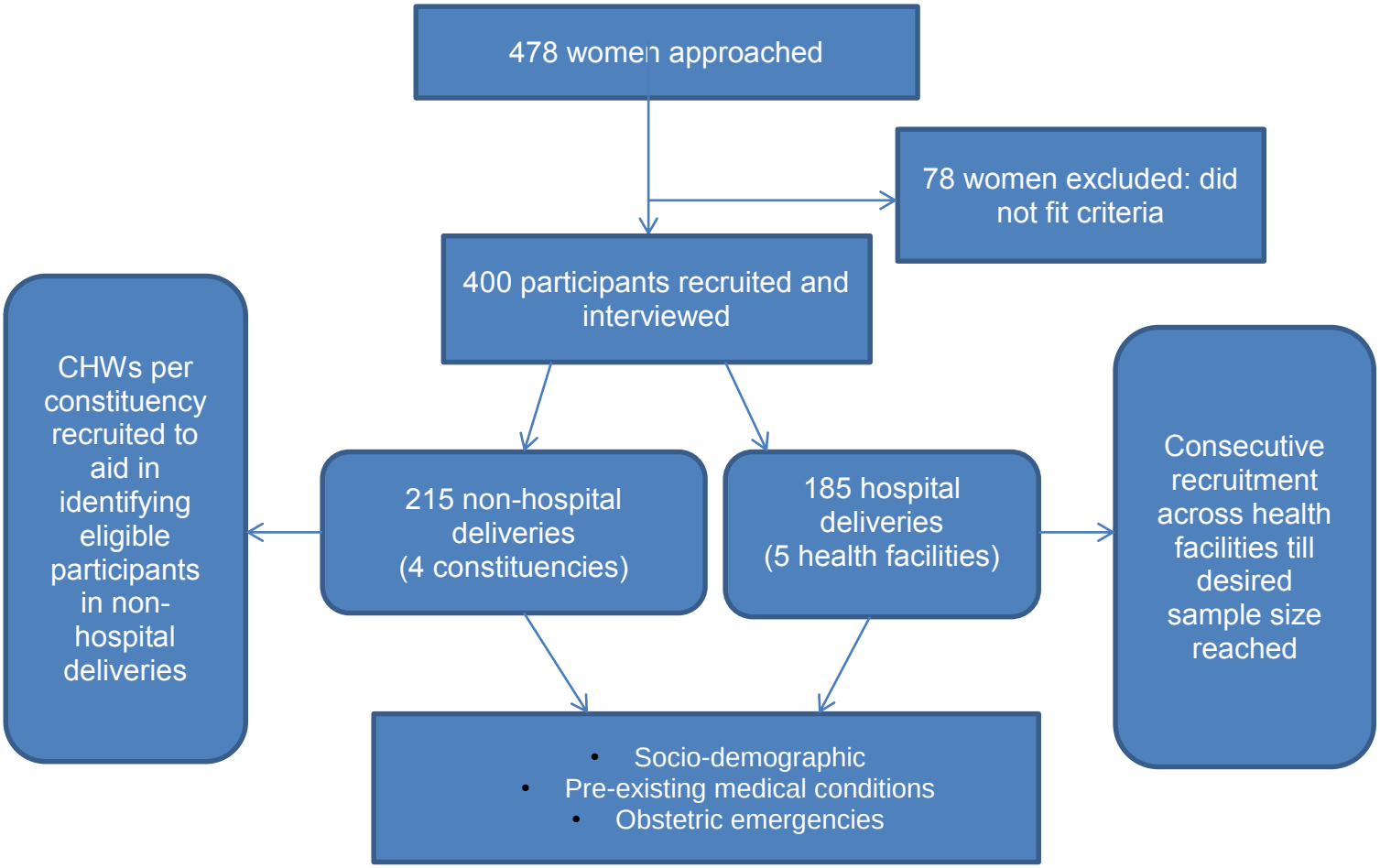
whereas 54% of the deliveries occur at home. At the end of each day research assistants in each health facility communicated to the principle investigator the number of participants recruited in order to keep track on the remaining participants to be recruited.

Community setting (54% of sample size = 215): Data was collected from 4 randomly sampled divisions; 1 in L.E and 3 in L.W based on Lamu County statistics that show that three quarters of the population live in Lamu west. The number of participants to be recruited from each of the four randomly sampled locations was worked out from the population ratios of the four locations based on the Lamu County statistics. Community health units (CHUs) in each location in Lamu County have a list of all the community health workers (CHWs) under them. Each CHW covers twenty households and thus has direct contact with the residents. As such, through their records they were able to link us to any woman within their households of supervision who had a home delivery within a month of data collection. All women who met the inclusion criteria under each CHW were interviewed before randomly selecting another CHW from the list at the CHU in order to recruit more participants until the desired sample size was achieved.

3.7 Study participants' recruitment

Between the months of February to October 2017, a total of 478 women were approached, where 78 were excluded as they did not meet the eligibility criteria. 400 participants were finally interviewed using a standard structured questionnaire. Of these, 215 women were from the community setting following home deliveries i.e. from 4 divisions sampled ramdomly: 1 in Lamu East (Faza) and 3 in Lamu West (Witu, Mpeketoni, Mkunumbi). This was based on population ratios being 1:3 respectively. The remaining 185 women were interviewed consecutively across 5 public health facilities until the desired sample size for hospital deliveries was reached. A greater number of participants were recruited following home deliveries as more than half of the deliveries

in the County occur at home (K.D.H.S 2014). There were two maternal deaths in the hospital setting, of whom their spouses were interviewed.



Study variables:

Box 3 showing objective one data variables

	Independent exposure	Dependent outcome	Source of data
Objective 1	**Socio demographic and economic factors** Age (<19 and >35) Income, Education level, Marital status Residence, religion, History of GBV, Smoking, alcohol and or drug abuse in pregnancy, distance to a health facility with a minimum of basic obstetric care	Health facility Vs Home delivery	Questionnaire

Box 4 showing data variables for objective 2

	Independent exposure	Dependent outcome	Sources of data
Objective 2	**Obstetric emergencies** APH, PPH, Severe pre-eclampsia/Eclampsia, Raptured uterus, Cord prolapse, Shoulder dystocia, Obstructed labour	Still birth, early neonatal death, Preterm births, Early onset neonatal sepsis, Maternal death / MNM i.e. (Adverse pregnancy outcomes)	Questionnaire

Box 5 showing data variables for objective 3

	Independent exposure	Dependent outcome	Sources of data
Objective 3	**Preexisting medical conditions** Chronic hypertension Diabetes, Cardiac disease, Anemia, HIV, Renal disease, Thyroid disease	Maternal death/ maternal near miss (MNM), Stillbirth (macerated or fresh), Preterm labor i.e. (adverse pregnancy outcomes)	Questionnaire

3.8 Definition of the poor outcomes that were assessed

We defined adverse pregnancy outcomes as either one or more of the following: premature deliveries at < 37 completed weeks, macerated or fresh stillbirths, early neonatal sepsis (within 72 hours of delivery), early neonatal death (within one week of delivery), any maternal death (mothers who died while pregnant or within 42 days of termination of pregnancy irrespective of the duration or site of the pregnancy from any cause related to or aggravated by the pregnancy or its management) or a maternal near miss (i.e. referral for dialysis and or intensive care unit (I.C.U), hysterectomy done due to PPH/infection, blood transfusion of two or more units {adjusted as per a study in low resource settings by Ellen et al (43)} and pregnancy related stroke)

3.9 Data processing

Quality control measures were implemented prior to data collection to reduce errors in data analysis. This included training of research assistants on study procedures, interviewing and data recording on the study tools. The questionnaire was also pre tested prior to actual data collection. In addition, data collection manuals were prepared and used to guide data collection. Questionnaires were color coded to differentiate home vs hospital delivery participants. Also, questionnaires from each of the four randomly sampled divisions for home delivery participants were coded as per division. Each questionnaire was inspected for completeness at the end of each day of data collection. Data was entered into databases designed in MS Office Access (2007). The databases were customized using the study questionnaire structure with data stored in numeric coded format, and text for open ended questions. Range and consistency checks were built into the database as a quality assurance measure aimed at reducing data entry errors. Data was transferred from Access databases to SPSS for data cleaning and analysis. Data cleaning involved inspecting each variable in the database to check for invalid entries and inconsistencies. This was done using SPSS procedure for summarizing variables.

3.10 Data analysis

Data analysis was conducted using SPSS (IBM version 20). For the univariable analysis, each individual variable in the dataset was analyzed using descriptive statistics. During this stage continuous variable like age were analyzed by calculating mean and standard deviation for normally distributed variables and median and ranges for skewed variables. Categorical variables were analyzed using frequencies, and relative frequencies or percentages calculated using the relevant denominator values and presentation was done using frequency distributions.

The primary outcome was determined by calculating the percentage of patients with poor obstetric outcomes namely maternal death, referral for ICU care/ dialysis, hysterectomies for PPH, pregnancy related stroke, transfusion of 2 or more units of blood, still births, early neonatal deaths, early onset neonatal sepsis, and preterm deliveries. These outcomes were cross tabulated with risk factors for poor outcomes according to the place of delivery to identify the categorical factors associated with poor maternal and fetal outcomes. Comparison of percentages across levels of categorical independent variables was done using Chi square test or Fisher's exact test. For continuous factors for example age, the mean of patients with and without a risk factor for poor outcome was compared using Student's t-test.

Statistical significance was based on an alpha cut-off level of 0.05. The final stage of analysis was a multivariable analysis conducted using logistic regress for binary outcomes represented by the percentage of patients with poor outcomes as the dependent variable. The independent variables in the logistic regression included all factors showing significant association with quality of care in the bivariate analysis. Odds ratios and 95% confidence intervals was reported from the multivariable analysis.

3.11 Ethical considerations

Ethics approval from the Kenyatta national hospital /University of Nairobi ethics research committee was sought before seeking approval from the Lamu County government. Also, consent was obtained from the participants after informing them about the study objectives and benefits. Patients with obstetric emergencies were not interviewed until they had been stabilized and participants seeking to withdraw from the study were allowed to do so.

3.12 Study limitations

Participants were interviewed within a month of delivery; this might have led to recall bias, a prospective cohort study would help overcome this limitation. Participants' place of delivery was taken as that where delivery occurred rather than on the intended (planned) setting. This latter option may have avoided attributing poor outcomes due to primary or secondary delays to a health facility

3.13 Study strengths

This was the first study on factors associated with adverse pregnancy outcomes in Lamu County thus will help form a baseline study for subsequent studies. It was a countywide study hence more representative of the situation in Lamu. Our study also assessed both non-hospital and hospital deliveries thus not biased towards one of the two compared to prior studies

CHAPTER 4: RESULTS

4.1 Introduction

A total of 400 mothers who were residing in Lamu County and had recently delivered (within a month of the time of data collection) were interviewed. Of these mothers 185 (46.3%) had delivered in a health facility and 215 (53.7%) had delivered outside health facilities. Of the women who delivered outside health facilities, 206 (96%) delivered at home whereas 9 (4%) delivered on route to a health facility as shown in figure 1 below.

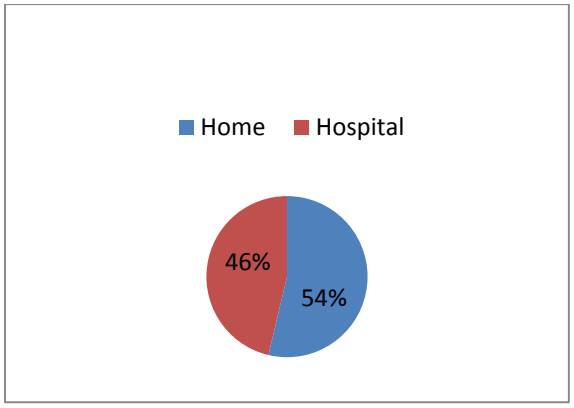


Figure 1: Place of delivery among women in Lamu County

4.2 Pregnancy outcomes following non-hospital and hospital deliveries

Poor pregnancy outcomes were defined as: maternal mortality, hysterectomy, transfusion of two or more units of blood, referral for dialysis or intensive care unit (ICU) for maternal, and early neonatal death (within a week of delivery), stillbirths (fresh or macerated), preterm births and early onset neonatal sepsis (within 72 hours of delivery) for perinatal outcomes. Poor pregnancy outcomes were reported in 63 (15.8%) deliveries overall, and these comprised 30 hospital deliveries (7.5%) and 33 non-hospital deliveries (8.3%).

Of the 63 deliveries with a poor outcome 18 (28.6%) had poor maternal outcome only, 33 (52.4%) poor perinatal outcomes only and in 12 (19%) deliveries resulted in both maternal and perinatal outcomes were poor

Poor perinatal outcomes of study participants following home and health facility deliveries in Lamu County in 2017

Out of the 400 births in Lamu county 45 (11.3%) had poor perinatal outcomes. The most frequent poor perinatal outcome in both in hospital and non-hospital deliveries was preterm birth (11) 7% and (14) 5%. Other outcomes were neonatal mortality [5% (9) compared to 4% (9)], still births [5% (9) versus 2% (4)] and early onset sepsis [2% (3) versus 1% (2)].

Poor maternal outcomes of study participants following home and health facility deliveries in Lamu County in 2017

Of the 400 deliveries, 2 (0.5%) resulted in maternal deaths that presented at home with convulsions and were referred to hospital where they both underwent emergency caesarean section with their fetal outcomes being stillbirths. Separately, there were 3 (0.8%) hysterectomies, I referral for dialysis (0.3%), 1 referral for I.C.U care (0.3%) and 26 mothers (6.5%) were transfused two or more units of blood.

Overall, there was no evidence of a significant association between the occurrence of any adverse pregnancy outcome and place of delivery (OR 1.0 7, 95% CI 0.62-1.83) (table 1) i.e. poor perinatal (OR =1.69, 0.9 – 3.16) (table 2) and maternal outcome (OR 0.65, 0.3 – 1.41); (table 2) below.

Table 1:Association between adverse pregnancy outcomes and place of delivery in Lamu County

	Good outcomes N=337 (n,%)	**Any poor pregnancy outcome N=63 (n,%)**	**OR (95% CI)**	**P value**
Hospital	155(83.8)	30(16.2)	1	
Non-hospital	182(84.7)	33(15.3)	0.94(0.55-1.61)	0.812

Table 2: Association between perinatal and maternal delivery outcomes and place of delivery

	Good perinatal outcomes N=355 n(%)	**Poor perinatal outcomes N=45 n(%)**	**OR (95% CI)**	**P**	**Good maternal outcomes N=370 n(%)**	**Poor maternal outcomes N=30 n(%)**	**OR (95% CI)**	**P value**
Hospital	159(85.9)	26(14.1)	1		174(94.1)	11(5.9)	1	
Non-hospital	196(91.2)	19(8.8)	0.59 (0.32-1.11)	0.102	196(91.2)	19(8.8)	1.53 (0.71-3.31)	0.277

4.3 Socio demographic, economic and cultural factors associated with place of delivery

Table 3 shows the sociodemographic, economic and cultural factors of the study participants with relation to place of delivery. Home deliveries were more common among those aged 30 years and above in comparison to women aged 29 and below (43% vs 28% respectively). Majority of participants professed the Islamic faith, with more delivering at home rather than in the hospital (74% vs 64%, p 0.028). Other socio-demographic factors associated with home delivery were: marital status (i.e. married, and were more likely to deliver in a hospital [96% vs 91%, P 0.028] compared to their single counterparts), low level of education i.e. primary education level or lower 88% vs 80.8%, P 0.001, lower level of income Ksh 7,000 vs 10,000, P <0.001, parity of >1 86% vs 64% P 0.001, and a previous successful vaginal delivery 99% vs 81%, P <0.001.

Table 3: socio demographic, economic and cultural factors associated with choice of place of delivery

Characteristic	Hospital delivery N=185 n (%)	Home delivery N=215 n (%)	P value
Age (Years) (Mean, SD)	25.7 years (6.4)	28.6 (6.6)	**<0.001***
< 20	34(18)	15(7)	
20-29	98(53)	109(50)	**0.006***
30-39	49(27)	80(37)	**<0.001***
≥40	4(2)	11(5)	**0.006***
Age at first birth (years) (Median, IQR)	20 (18 to 22)	19 (18 to 22)	0.422
Religion			
Muslim	118(64)	159(74)	
Christian/other	67(36)	56(26)	**0.028***
Marital status			
Not married	7(4)	20(9)	
Married	178(96)	195(91)	**0.028***
Level of education			
None	40(21)	82(38)	
Primary	109(60)	107(50)	**0.001***
Secondary or higher	36(19)	26(12)	**0.001***
Monthly income (KSh, Median, IQR)	(10000, 7000-16000)	(7000, 6000-10000)	**<0.001***
Monthly income (KSh)			
<5000	10(5.4)	16(7.4)	
5000-14999	73(39.5)	137(63.7)	0.71
15000-24999	28(15.1)	11(5.1)	**0.009***
25000 +	12(6.5)	2(0.9)	0.085
Presence of GBV			
History of GBV	25(13.5)	33(15.3)	0.548
No history of GBV	159(86.5)	182(84.7)	
Substance use			
History of substance abuse	16(8.6)	25(12)	0.315
No history of substance abuse	169(91.4)	190(88)	
Parity			
Primigravidae	66(36)	31(14)	
Parity > 1	119(64)	184(86)	**<0.001***
Normal delivery if parity >1	96(81)	182(99)	**<0.001***

#IQR-Interquartile range, SD^-standard deviation, GBV – Gender based violence, *statistically significant values

4.4 Pre-existing medical conditions, obstetric emergencies and socio-economic factors associated with adverse pregnancy outcomes in home and hospital deliveries

4.41 Pre-existing factors and obstetric emergencies

In total 26 out of 400 mothers had preexisting medical conditions. 11 (6%) mothers delivered in a hospital while 15 (7%) had a non-hospital delivery.

Pre-existing hypertension (OR 12.53, CI 4.12-38.09, P 0.001), other pre-existing medical conditions (OR 11.07, CI 3.57-34.27, P 0.001), PPH/APH (OR 19.94, CI 9.47-41.98, P<0.001) and other obstetric emergencies (OR 71.08, CI 8.99-562.06, P<0.001) were associated with adverse maternal and perinatal outcomes (table 4 below)

Table 4: Pre-existing medical conditions and obstetric emergencies contributing to adverse perinatal and maternal outcomes in home and hospital deliveries in Lamu County

Pre-existing medical condition/ Obstetric emergencies	Poor outcome (n=63) (n, %)	Good outcome (n=337) (n , %)	OR (CI)	p-value
No pre-existing HBP	53(13.8)	332(86.2)		1
Pre-existing HBP	10(66.7)	5(33.3)	12.53(4.12-38.09)	**0.001**
No pre-existing medical condition	54(14)	332(86)		1
Pre-existing medical condition*	9(64.3)	5(35.7)	11.07(3.57-34.27)	**<0.001**
No PPH/APH	35(9.7)	324(90.3)		1
PPH/APH	28(68.3)	13(31.7)	19.94(9.47-41.98)	**<0.001**
No other obstetric emergency	52(13.4)	336(86.6)		1
Other obstetric emergency^	11(91.7)	1(8.3)	71.08(8.99-562.06)	**<0.001**

* Diabetes, hypertension, epilepsy, anemia ^eclampsia, obstructed labor, cord prolapse

4.42 Sociodemographic and economic factors

From table 5 below, Participants' age of 20-29 years compared to <20 years (OR 0.39, CI 0.18-0.89, P 0.024) and being married versus a single status (OR 0.21, CI 0.06-0.68, P 0.01) were shown to reduce the likelihood of an adverse pregnancy outcome. Distance to the nearest health facility of more than 5 kilometers (Km) was associated with adverse pregnancy outcomes: OR 3.63, 95% CI 1.27-10.38, P 0.016

Table 5: Sociodemographic factors contributing to adverse perinatal and maternal outcomes

Socio-demographic/economic characteristics	Poor outcome N=63 n (%)	Good outcome N=337 n (%)	OR (95%CI)	P value
Age				
< 20 years	11(22.4)	38(77.6)		1
20-29 years	21(10.2)	184(89.8)	0.39(0.18-0.89)	**0.024**
30-39 years	27(20.9)	102(79.1)	0.91(0.41-2.02)	0.825
40 years+	4(26.7)	11(73.3)	1.26(0.33-4.73)	0.736
Unmarried	7(25.9)	20(74.1)		1
Married	56(15.0)	317(85.0)	0.21(0.06-0.68)	**0.01**
None	23(19.0)	98(81.0)		1
Primary	29(13.4)	187(86.6)	0.66(0.36-1.20)	0.175
Secondary or higher	11(18.3)	49(81.7)	0.96(0.43-2.12)	0.913
Muslim	48(17.3)	229(82.7)		1
Christian/ Other	15(12.2)	108(87.8)	0.66(0.36-1.24)	0.196
< Ksh 5000	8(30.8)	18(69.2)		1
Ksh 5000-14999	39(18.6)	171(81.4)	0.51(0.21-1.27)	0.147
Ksh 15000-24999	8(20.5)	31(79.5)	0.58(0.19-1.81)	0.35
Ksh 25000 +	2(14.3)	12(85.7)	0.38(0.07-2.08)	0.262
Para 1	16(16.5)	81(83.5)		1
Parity > 1	47(15.5)	256(84.5)	0.93(0.50-1.73)	0.817
Parity <= 3	34(14.5)	201(85.5)		1
Parity > 3	29(17.6)	136(82.4)	1.26(0.73-2.17)	0.402
<5km	5(5.6)	85(94.4)		1
5-9km	16 (17.6)	75(82.4)	3.63(1.27-10.38)	**0.016**
10-19	30(18.1)	136(81.9)	3.75(1.40-10.04)	**0.009**

20-49km	11(25.6)	32(74.4)	5.84(1.88-18.14)	**0.002**

4.5 Comparison of home and hospital deliveries to assess difference in factors among women with adverse pregnancy outcomes

4.51 *sociodemographic, cultural and economic factors*

Table 6 below shows the association between place of delivery and socioeconomic and cultural factors for participants with adverse pregnancy outcomes. Among the women with adverse pregnancy outcomes those aged between 30-39 years were more likely to deliver at home compared to those aged <20 years (OR 0.16, CI 0.03-0.75, p0.021), those with parity less than or equal to 3 were more likely to deliver at a health facility compared to their counterparts that were more likely to deliver at home (OR 9.20, CI 2.88-29.42, P<0.001) and those whose spouses work as casual laborers were more likely to deliver in a health facility compared to their counterparts whose spouses were unemployed (OR 8.00, CI 1.52-42.04, P 0.01)

There was no association between place of delivery and distance to a health facility, intimate partner violence (p = 0.934), cigarette, alcohol or substance abuse during pregnancy (p = 0.885) among women with adverse pregnancy outcomes.

Table 6: Comparison between socio-demographic, economic factors and place of delivery among participants with adverse pregnancy outcomes in Lamu County

Characteristic	Hospital (N = 30) N (%)	Non-hospital (N = 33) N (%)	OR (95% CI)	P value
Age				
< 20 years	8(26.7)	3(9.1)	1.0	
20-29 years	11(36.7)	10(30.3)	0.41(0.09-2.00)	0.272
30-39 years	8(26.7)	19(57.6)	0.16(0.03-0.75)	**0.021**
40 years+	3(10.0)	1(3.0)	1.12(0.08-15.51)	0.93
Marital status				
Unmarried	2(6.7)	5(15.2)	1.0	
Married	28(93.3)	28(84.8)	2.50(0.45-13.98)	0.297
Level of education				
None	12(40.0)	11(33.3)	1.0	
Primary	12(40.0)	17(51.5)	0.65(0.21-1.95)	0.439
Secondary or higher	6(20.0)	5(15.2)	1.10(0.26-4.65)	0.897
Primigravid				
No	16(53.3)	31(93.9)	1.0	
Yes	14(46.7)	2(6.1)	13.56(2.74-67.16)	**0.001**
Parity				
Parity> 3	6(20.0)	23(69.7)	1.0	
Parity ≤3	24(80.0)	10(30.3)	9.20(2.88-29.42)	<**0.001**
Participants occupation				
Unemployed	24(80.0)	22(66.7)	1.0	
Casual	2(6.7)	4(12.1)	0.46(0.08-2.75)	0.394
Self-employed	3(10.0)	6(18.2)	0.46(0.10-2.06)	0.309
Salaried job	1(3.3)	1(3.0)	0.92(0.05-15.56)	0.952
Spouses' occupation				
Unemployed	3(10.0)	12(36.4)	1.0	
Self-employed	13(43.3)	14(42.4)	3.71(0.85-16.21)	0.081
Casual	10(33.3)	5(15.2)	8.00(1.52-42.04)	**0.014**
Salaried job	3(10.0)	2(6.1)	6.00(0.67-53.68)	0.109
Intimate partner violence				
Yes	3(10.0)	3(9.1)	1.0	
No	27(90.0)	29(87.9)	0.93(0.17-5.02)	0.934
Cigarette, alcohol or substance abuse				
Yes	4(13.3)	4(12.1)	1.0	
No	26(86.7)	29(87.9)	0.90(0.20-3.95)	0.885
Distance in Km				
<5	5(100)	0	-	-
5-9	9(56.3)	7(43.7)	1.68(0.49-5.72)	0.405
10-19	13(43.3)	17(56.7)	1.0	
20-49	2(18.2)	9(81.1)	0.29(0.05-1.58)	0.153

≥50	1(100)	-	-	-

4.52 Pre-existing medical conditions and obstetric emergencies

There was no statistically significant difference between place of delivery in women who had adverse pregnancy outcomes, with an underlying pre-existing medical condition or obstetric emergency except for severe PPH being twice more common following a home delivery (54.5 vs 23.3%, P 0.014) (table 6 and 7 below).

Table 7: Association between preexisting medical conditions and place of delivery among women with adverse pregnancy outcomes in Lamu County

Medical condition	**Hospital (N = 30) N (%)**	**Non-hospital (N = 33) N (%)**	**OR(95% CI)**	**P value**
Preexisting diabetes				
No diabetes	29(96.7)	31(93.9)	1.0	
Diabetes	1(3.3)	2(6.1)	0.53(0.05-6.21)	0.617
Preexisting hypertension				
No HBP	26(86.7)	27(81.8)	1.0	
High blood pressure	4(13.3)	6(18.2)	0.69(0.18-2.74)	0.6
Any other preexisting medical condition				
No condition	28(93.3)	29(87.9)	1.0	
Other medical condition	2(6.7)	4(12.1)	0.52(0.09-3.06)	0.467

Table 8: Association between place of delivery and occurrence of an obstetric emmergency in index pregnancy among participants with adverse pregnancy outcomes in Lamu County

	Hospital (N = 30) N(%)	**Non-hospital (N = 33) N(%)**	**P value**
Type of emergency			
Excessive bleeding after delivery (PPH)	7(23.3)	18(54.5)	**0.014**
Bleeding before delivery (APH)	4(13.3)	1(3.0)	0.165
Convulsions	5(16.7)	2(6.1)	0.198
Obstructed labor	0	0	NA

However, on multivariate regression analysis (table 8 below) comparing place of delivery among participants with adverse pregnancy outcomes; only parity of 3 or below was associated with a hospital delivery (OR 21.02, CI 2.97-149.07, P=0.002)

Table 9: Multivariable logistic regression analysis among participants with adverse pregnancy outcome

	Hospital (N=30) N (%)	**Non-hospital (N=33) N (%)**	**OR (95% CI)**	**P value**
Age				
< 20 years	8(26.7)	3(9.1)		
20-29 years	11(36.7)	10(30.3)	1.15(0.12-10.67)	0.904
30-39 years	8(26.7)	19(57.6)	0.15(0.01-1.98)	0.151
40 years+	3(10.0)	1(3.0)	7.03(0.09-526.05)	0.376
Income				
< Ksh 5000	2(6.7)	6(18.2)		
Ksh 5000-14999	15(50.0)	24(72.7)	0.92(0.1-8.55)	0.943
Ksh 15000-24999	6(20.0)	2(6.1)	9.37(0.49-178.86)	0.137
Not reported	5(16.7)	1(3.0)	25.33(0.7-914.37)	0.077
Marital status				
Unmarried	2(6.7)	5(15.2)		
Married	28(93.3)	28(84.8)	0.73(0.03-18.93)	0.849
Education level				
None	12(40.0)	11(33.3)		
Primary	12(40.0)	17(51.5)	0.94(0.16-5.39)	0.943
Secondary or higher	6(20.0)	5(15.2)	0.19(0.01-3.09)	0.242
Parity				
Parity > 3	6(20.0)	23(69.7)		
Parity <= 3	24(80.0)	10(30.3)	21.02(2.97-149.07)	**0.002**
Medical condition				
No preexisting medical condition	27(90.0)	27(81.8)		
Preexisting medical condition	3(10.0)	6(18.2)	0.26(0.03-2.19)	0.213
Emergencies in pregnancy				
No PPH/ APH	21(70.0)	14(42.4)		
PPH/ APH	9(30.0)	19(57.6)	0.32(0.06-1.78)	0.193

4.6 Discussion

In this first countywide study on factors contributing to adverse pregnancy outcomes following home and health facility deliveries in Lamu County, generally, women that are more likely to deliver at home regardless of the obstetric outcome (good or poor) were shown to be: older i.e 30years of age or more, who had a prior normal vaginal delivery, multiparous (more than three prior deliveries), with a low level of education and a low level of income. This could be due to older women generally having had a prior birth experience and a previous un eventful delivery tends to be reassuring of the outcome of subsequent pregnancies. These results are similar to a study done in Malawi that showed that; lack of a formal education, higher birth order pregnancy with a good birth outcome in the previous pregnancy and low level of income were associated with a home delivery. In addition, a rural residence and single marital status were also associated with a home delivery(44)

With regard to factors associated with adverse pregnacy outcomes, our study demonstrated that: obstetric emergencies, pre-existing medical conditions like hypertension, diabetes, anemia and epilepsy, social characteristics like teenage pregnancies, single parenthood, distance to the nearest health facility of >5Km ; are associated with adverse maternal and perinatal outcomes. These results are comparable to a study done in Keiyo district following deliveries in public hospitals in the region; where single parenthood, preexisting medical conditions and experience of obstetric emergencies were associated with adverse pregnancy outcomes.However in addition: caesarean, vacuum deliveries, poor staffing and poor staff attitudes, low education level and un employment were associated with adverse maternal and perinatal outcomes (45)

Similar to our study, a systematic review of 142 studies in low and middle income countries showed that maternal age (<20years/ >35years) and parity (<1/>5) were associated with adverse

pregnancy outcomes. However in addition lack of education and poverty were correlated with adverse pregnancy outcomes (2) The reasons for the above disparities could be due to a generally low level of education (60% primary and below), a higher level of poverty Countywide (38% earning under a dollar a day) (KDHS 2014)

Post partum hemorrhage was the most frequent adverse maternal oucome with an overall prevalence rate of 11% of which 6.5% was severe PPH. Preterm birth was the most common adverse perinatal outcome accounting for 7% of hospital and 5% of home deliveries. Two maternal deaths Occurred in hospital whereas none occurred at home. This correllates to a meta annalysis in Sub saharan Africa whereby two out of three studies showed a higher maternal mortality rate following a hospital delivery compared to a home delivery. The speculation given to address this was due to the fact that when complications arise, one would then report to a hospital, thus more complicated presentations and more likelyhood of higher adverse outcomes in a hospital aspecially in the setting of late refferals (9) The overall prevalence of adverse maternal and perinatal outcomes was 15.8% i.e. 7.5% following health facility deliveries and 8.25% following home deliveries. This was not statistically different with regard to occurrence of adverse outcomes according to place of delivery. This could be due to patients presenting late to a health facilty thus attributing adverse outcomes related to first or second delays to a health facilty as seen in cases of obstructed labour in our study, lack of fetal movements most of which had bad outcomes. A better way of addressing this might have been recruiting patients on the basis of intetion of place of delivery irrespective of the eventual place of delivery or assessing for first and second delays.

In comparison to the perinatal outcomes of the meta annalysis mentioned above comparing adverse outcomes of home vs hospital in Subsaharan Africa two studies showed home deliveries to have better outcomes (North Eastern Tanzania and rural Congo), one found no significant difference

(rural Burkina Faso) and three found hospital deliveries to have better outcomes (rural Tanzania, Burkina Faso nad Malawi) (9)

Factors that were associated with place of delivery in Lamu County among women who had adverse pregnancy outcomes were: PPH twice more common following a home delivery (54.5% Vs 23.3% P 0.014) [These results are comparable to a study in Karachi Pakistan, which demonstrated that PPH was the main adverse event following a home delivery i.e. 50.6% followed by retained placenta (7)], older women aged between 30-39 years were more likely to deliver at home compared to those aged <20 years, those with parity ≤3 were more likely to deliver at a health facility and those whose spouses work as casual laborers were more likely to deliver in a health facility compared to their counterparts whose spouses were unemployed. There was no statistically significant difference with place of delivery in patients with pre-existing medical conditions.

These results are similar to the results of our study on the overall participants' choice on place of delivery discussed above, thus making an inference that women that develop adverse pregnancy outcomes do not differ in the sociodemographic and cultural characteristics that make them chose either a home or hospital delivery

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

In Lamu County, home delivery was more common among women with the following characteristics: older (≥30yrs), who had a prior normal vaginal delivery, multiparous (>3), with a low level of education and a low level of income. Contributors to adverse outcomes were: obstetric emergencies, pre-existing medical conditions like hypertension, diabetes, anemia and epilepsy, social characteristics like teenage pregnancies, single parent-hood and distance to the nearest health facility of >5kms. Among patients with adverse pregnancy outcomes those that developed severe PPH requiring transfusion of ≥2 units of blood were associated with a home delivery. Interventions to reduce adverse outcomes should focus on: patient education on need for hospital delivery, upgrading of health centers to being able to provide comprehensive obstetric care as well as working with traditional birth attendants to act as ambassadors in referring patients in labor to deliver in a hospital setting.

5.2 Recommendations

- To raise awareness in the community on need for a hospital delivery despite a prior good obstetric history with emphasis on high risk patients or those with preexisting medical conditions.

- Upgrading of health centers to be able to provide comprehensive obstetric care so that in the event of need for these services, women do not have to traverse long a distance a thus loosing on an opportunity of good pregnancy outcomes.

- In the meantime, maternity waiting homes in close proximity to health facilities providing comprehensive obstetric care to help curb limitations with the terrain.

- Regular drills for PPH as well as training on emergency obstetric and neonatal care and mobile rescue teams equipped with essential drugs and equipment to provide first aid and resuscitative measures.

- Working with traditional birth attendants and making them ambassadors for early referral of patients in order to deliver under skilled birth attendance in a hospital setting.

- A follow up study to look at the three model delay in seeking health care.

5.3 Conflict of interest

No conflict of interest declared

5.4 Funding

This research received no specific grant from any funding agency in the public, commercial, or non profitable sectors.

Timelines

	5/16	/9/16	01/17	01/17	1/17	02/17	11/17	7/18	8/18	8/18
Proposal development	■									
Presentation		■								
ERC approval			■							
Training of staff				■						
Pretest questionnaires					■					
Data collection						■				
Data analysis							■			
Presentation of results								■		
Completion of dissertation									■	
Manuscript writing										■

Budget

Item	Approximate cost
Stationary(pens, paper)	10,000
Printing costs (400 questionnaires, proposal, report)	30,000
Travel expenses/ accomodation	70,000
Research assistants	160,000
Statistician	30,000
Total	300,000

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APPENDICES

APPENDIX I:

PARTICIPANT CONSENT FORM FOR ENROLLMENT IN THE STUDY

Tittle of the study: Factors contributing to adverse pregnancy outcomes in health facility and home deliveries in Lamu County, Kenya.

Principal investigator/ Institutional affiliation: Dr Hind .A. Maawiya, MMed Obsgyn student; The University of Nairobi, school of medicine.

Introduction:

I would like to tell you about a study being conducted by the above listed researcher. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in this study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research:

i) Your decision to participate is entirely voluntary
ii) ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal
iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and

Research Committee protocol no. P737/10/2016

What is this study about?

The researchers are interviewing individuals who are residents of Lamu County and had either a home or hospital delivery within a month of data collection. The purpose of the interview is to find out factors which are contributing to adverse pregnancy outcomes in this County. Participants in this research study will be asked questions about incidences surrounding their recent delivery process. There will be approximately 400 participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

What will happen if you decide to be in this research study?

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

- You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 20 minutes. The interview will cover topics such as the delivery process and events surrounding it.
- After the interview has finished we will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include: cases whereby we might need clarification on the answers provided or in the event that a referral for further care needs to be given.

Are there any risks, harms discomforts associated with this study?

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

Are there any benefits being in this study?

The information you provide will help us better understand some of the key loopholes in maternal and neonatal access and provision of health care in the County. This information is a contribution to science and a step towards better understanding of the health care system and hopefully an insight on the changes that need to be made.

Will being in this study cost you anything?

No.

What if you have questions in future?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page. For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke. The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

What are your other choices?

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

APPENDIX II:

Consent form (statement of consent)

Participant's statement:

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential. By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: **Yes** **No**

I agree to provide contact information for follow-up: **Yes** **No**

Participant's name: _____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement:

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

Researcher's Name: _____ Date: __ _____

Signature _____

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

For more information contact Hind.A.Maawiya at 0712896754

APPENDIX III:

QUESTIONNAIRE

Code No._____

Study setting_____

SOCIO - DEMOGRAPHIC DATA

1. Age ----------

2. Parity----------

3. Gestation at birth----------

4. Marital status

a) Married b) single c) separated d) widowed e) Others (Specify) ----------

5. Age at first birth ---------- years.

6. Residence as per location

---

7. Education

a) None b) Primary c) Secondary d) College/University

8. Religion

a) Christian b) Muslim c) Hindu d) Other (Specify) ----------

9. Occupation

a) Unemployed b) Casual job c) Self- employed d) Salaried job

10. Husband/partner‘s occupation

a) Unemployed b) Self- employed c) Casual job d) Salaried job

11. Type of housing

a) Temporary b) Semi-permanent c) Permanent

12. Ownership of house

a) Own home b) Rental c) Others (Specify)

13. Total monthly family income ----------

14. History of gender based violence

a) Yes b) No

If yes specify the frequency in a month ----------

15. Is there a history of smoking (active or passive), alcohol consumption or drug abuse in index pregnancy? a) Yes b) No

If yes specify type and frequency of substance abuse in a day ----------

ANTENATAL CARE

16. Did you attend ANC during your recent or current delivery? a) Yes b) No

If yes, which facility did you attend?

a) Public facility b) Private facility c) TBA d) Others (Specify) ----------

If no, specify reason why ----------

17. Who decided on where you will attend ANC?

a) Self b) Husband/partner c) Friend d) Others (Specify)

18. When did you start attending ANC?

a) First trimester b) Second trimester c) Third trimester

19. Were the ANC profile investigations done? a) Yes b) No

If Yes, Which ones were done? (Check in ANC card and indicate the parameters)

a) Hemoglobin level ----- b) Blood group ------- c) VDRL ----------

d) Serology ------- e) Urinalysis ----------

20. What other parameters were observed during your ANC visits?

a) Blood pressure b) Weight c) Height d) Others (Specify)

21. Did you receive tetanus toxoid injection? a) Yes b) No

If Yes, When? _____

If No, Why? a) Not available b) Allergic c) Others (Specify)

22. How many times did you receive tetanus toxoid? _____

23. Have you ever had a pregnancy that miscarried, aborted or stillbirth?

a) YES b) NO

If yes specify

a) Miscarried b) Aborted c) Stillbirth d) Premature e) Neonatal mortality

DELIVERY

24. What was the mode of recent delivery?

a) Normal Vaginal delivery b) Vacuum delivery c) Caesarean Section

25. Where did you deliver your baby?

a) Hospital b) Health center c) Home d) Others (Specify)

If at home, explain why ----------

If home, did you have to be taken to a health facility following delivery? a) Yes b) No

If yes specify reason why ----------

26. Who assisted you during delivery?

a) Nurse/Midwife b) doctor c) TBA d) Alone e) Others (Specify)

If alone, explain why ----------

27. was there any complication following delivery? a) Yes b) No

If yes, what was the nature of the complication?

a) Obstructed labor b) APH c) PPH d) Preterm birth e) convulsions f) retained placenta g) neonatal sepsis within 72hrs of delivery h) neonatal death within a week of delivery I) others (Specify) ----------

28. What intervention was done? ---------- If transfused specify how many units, if you had surgery following the birth complication specify which one ----------

29. What was the outcome of your last delivery?

a) Preterm birth b) Live birth

c) Stillbirth d) Neonatal death within a week of delivery e) others (Specify) ----------

30. What was the weight of the baby at birth? ----------

PRE – EXISTING CONDITIONS

31. Did you have any pre-existing medical conditions before pregnancy? a) Yes b) No

If Yes, which ones?

a) Diabetes mellitus b) Hypertension c) Cardiac disease

d) HIV/AIDS e) thyroid disease f) renal disease g) others (Specify) ----------

32. Were you on treatment? a) Yes b) No

If yes, for how long----------

33. Did the pregnancy worsen the condition? a) Yes b) No

If yes, did the pregnancy have to be terminated? a) Yes b) No

34. Have you had any other illnesses during the recent pregnancy? a) Yes b) No

If Yes, which ones?

a) Malaria b) Anemia c) Hypertensive disease in pregnancy d) Others (Specify)

35. Have you ever used any Family Planning methods? a) Yes b) No

If Yes, which ones?

a) Pills b) Injectable c) Implants d) IUCD e) Others (Specify)

If No, why?

a) Cultural factors b) Lack of partner‘s consent c) fear d) Side effects

e) Unavailable f) Others (Specify)

OBSTETRIC EMERGENCIES

36. Are you aware of any obstetric emergencies? a) Yes b) No

If yes, which ones?

a) APH b) PPH c) Eclampsia

d) Cord prolapse e) No fetal movements f) Obstructed labor g) others (specify) ----------

HEALTH FACILITY FACTORS

37. What type of health Facility did you attend?

a) District hospital b) Sub-district hospital c) Health center

38. What services were you going for?

a) ANC b) Delivery c) others (specify) ----------

39. Did you receive all the services you were looking for? a) Yes b) No

If No, why? a) Unavailable b) Lack of staff c) Lack of equipment d) others (specify) ----------
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40. What is the distance from your home to the heath facility? ----------

41. What do you think of the health facility staff?

a) Extremely good b) Good c) Fair d) Bad e) Extremely bad

42. How long did it take for you to be attended to at the health facility?

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Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/19

23rd January 2017

Dr. Hindu A Maawiya
Reg. No.H58/75090/2014
Dept. of Obs/Gynae
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Maawiya

REVISED RESEARCH PROPOSAL: "FACTORS CONTRIBUTING TO ADVERSE PREGNANCY OUTCOMES IN HOME AND HEALTH FACILITY DELIVERIES IN LAMU COUNTY, KENYA: A CROSS SECTIONAL STUDY (P737/10/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above revised proposal. The approval period is from 23rd January 2017 – 22nd January 2018.

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) 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*).
f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
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.

Kindly arrange to submit a copy of registration by Pharmacy and Poisons Board and approval when ready..

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 Deputy Director, CS, KNH
The Assistant Director, Health Information, KNH
The Chair, KNH- UoN ERC
The Dean,School of Medicine, UoN
The Chair, Dept. of Obs/Gynae, UoN
Supervisors: Prof. Omondi Ogutu, Dr. Alfred Osoti

COUNTY GOVERNMENT OF LAMU
Department of Health, Sanitation and Environment
Office of the County Director of Health Services

Tel:0773870537
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LAMU COUNTY HOSPITAL
P.O. BOX 45-80500
LAMU

When replying please quote;
Reference No.
LMU/COUNTY/G.C/VOL.1/149

Date: 4th may,2017

Dr. Hindu A Maawiya
Reg. No. H58/75090/2014
Dept. Obs/gynae
College of Health Science
University of Nairobi

Dear Madam,

RE: REVISED RESEARCH PROPOSAL: FACTORS CONTRIBUTING TO ADVERSE PREGNANCY OUTCOMES IN HOME AND HEALTH FACILITY DELIVERIES IN LAMU COUNTY.

Reference is made to your letter Ref. No. KNH-ERC/A/19 dated 23rd January,2017.

This office has no obligation of you doing research in any of our facility in Lamu county.

Yours .

Amina Bunu
FOR: COUNTY DIRECTOR-HEALTH SERVICES
LAMU COUNTY