

**QUALITY OF ANTENATAL CARE SERVICES AND PREGNANCY OUTCOMES  
AMONG PATIENTS WITH PRE-ECLAMPSIA WITH SEVERE FEATURES MANAGED  
AT KENYATTA NATIONAL HOSPITAL**


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DEGREE OF MASTER OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY  
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**OCTOBER 2021**

## DECLARATION

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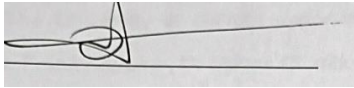
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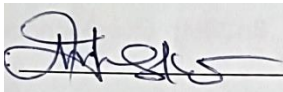


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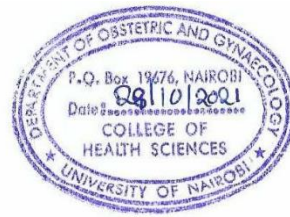
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## **DEDICATION**

Prof. Shanyisa Khasiani, the best mother anyone could ask for. We did it!!

## **LIST OF ABBREVIATIONS**

AKI	Acute Kidney Injury
ANC	Antenatal Care
APGAR	Appearance, Pulse, Grimace, Activity, Respiration
CS	Caesarean Section
DBP	Diastolic Blood Pressure
EMONC	Emergency Obstetric and Neonatal Care
FANC	Focused Antenatal Care
GXM	Grouping and Cross Matching
HBsAg	Hepatitis B Surface Antigen
Hb	Hemoglobin
HDP	Hypertensive Diseases in Pregnancy
HELLP	Hemolysis, Elevated Liver Enzymes and reduced Platelets
HIV	Human Immunodeficiency Virus
ICU	Intensive Care Unit
JASA	Junior Aspirin
KNH	Kenyatta National Hospital
MCH	Maternal and Child Health
MgSO <sub>4</sub>	Magnesium Sulphate
MOH-K	Ministry of Health Kenya
NBU	New Born Unit
PE	Pre- eclampsia
PES	Pre-eclampsia with severe features
PMH	Pumwani Maternity Hospital
PNC	Post Natal Care
QOC	Quality of Care
RBS	Random Blood Sugar
SBP	Systolic Blood Pressure
SCBU	Special Care Baby Unit
SS	Sample Size
STI	Sexually Transmitted Infection

TBA	Traditional Birth Attendant
UoN	The University of Nairobi
VDRL	Venereal Disease Research Laboratory Test
WHO	World Health Organization

## OPERATIONAL DEFINITION OF TERMS

**Antenatal care:** Care provided by skilled healthcare professionals to pregnant women and adolescent girls in order to ensure the best health conditions for both mother and baby.

**Quality of care:** The degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

**Preeclampsia:** A disease in pregnancy characterized by the presence of a systolic blood pressure greater than or equal to 140 mm Hg or a diastolic blood pressure greater than or equal to 90 mm Hg or higher, on two occasions at least 4 hours apart in a previously normotensive patient.

**Preeclampsia with severe features:** Is a disorder of pregnancy characterized by high blood pressure and significant proteinuria after 20 weeks gestation. Preeclampsia with severe features is defined as the presence of one of the following symptoms or signs in the presence of preeclampsia: Systolic Blood Pressure of 160 mm Hg or higher or Diastolic Blood Pressure of 110 mm Hg or higher, on two occasions at least 4 hours apart while the patient is on bed rest (unless antihypertensive therapy has previously been initiated); impaired hepatic function as indicated by abnormally elevated blood concentrations of liver enzymes (to double the normal concentration), severe persistent upper quadrant or epigastric pain that does not respond to pharmacotherapy and is not accounted for by alternative diagnoses, or both; progressive renal insufficiency (serum creatinine concentration  $>1.1$  mg/dL or a doubling of the serum creatinine concentration in the absence of other renal disease);

new onset cerebral or visual disturbances; pulmonary edema; thrombocytopenia (platelet count  $<100,000/\mu\text{L}$ ).

**Pregnancy Outcome:** The results of conception and ensuing pregnancy. It can be further classified as good maternal, fetal and neonatal outcomes and poor maternal, fetal and neonatal outcome based on the ensuing pregnancy.

**Gestational hypertension:** Blood pressure of more than 140/90 mm Hg or a rise in systolic pressure of at least 30 mm Hg, or a rise in diastolic pressure of at least 15 mm Hg over the previously known blood pressure for the first time in pregnancy after 20 weeks, without proteinuria.

**Superimposed pre-eclampsia:** Includes “new-onset proteinuria” in a woman with hypertension before 20 weeks of gestation, a sudden increase in proteinuria if already present in early gestation, a sudden increase in hypertension, or the development of HELLP syndrome. Women with chronic hypertension who develop headache, scotomata or epigastric pain also may have superimposed pre-eclampsia.

**Eclampsia:** The presence of new-onset grand mal seizures not attributable to any other causes in a woman with pre-eclampsia. The seizures may occur before, during or after delivery. Antepartum eclampsia accounts for about 75% of all cases while the rest occur in labour or within 48hrs of delivery. Late postpartum eclampsia occurs more than 48 hours after delivery but less than 4 weeks postpartum.

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## ABSTRACT

### QUALITY OF ANTENATAL CARE SERVICES AND PREGNANCY OUTCOMES AMONG PATIENTS WITH PRE-ECLAMPSIA WITH SEVERE FEATURES MANAGED AT KENYATTA NATIONAL HOSPITAL

**Introduction.** Hypertensive disorders in pregnancy are the second most common cause of maternal mortality after obstetric hemorrhage and occur in 6-8% of all pregnancies. Pre-eclampsia with severe features (PES) still remains a major medical and public health concern. High quality of antenatal care (ANC) is associated with improved maternal, fetal and neonatal outcomes. Globally although 86% of pregnant women access ANC with skilled health personnel at least once, only 3 in 5 (62%) receive  $\geq 4$  ANC visits (UNICEF, 2016). In Kenya, 60% of pregnant women had  $\geq 4$  ANC visits (KDHS 2014)

**Objective:** The primary objectives were to determine the association between the quality of ANC services, pregnancy outcomes, the types of health facilities and the patients' perception of ANC services among patients with PES managed at Kenyatta National Hospital.

**Methodology** This was a descriptive cross-sectional study in which postpartum patients who were diagnosed with PES at a gestation period of 28 weeks or higher and who had delivered within the first 72 hrs were consecutively sampled. The study was conducted at the Post Natal Wards (GFA, GFB, 1A) of Kenyatta National Hospital. Quality of care was defined as presence of all parameters of the 2016 ANC World Health Organization (WHO) recommendations and Ministry of Health guidelines which were; appropriate ANC visits by gestation, prescription of prenatal vitamins, a complete antenatal profile (HIV/VDRL/HB/Urinalysis/Blood Group/Blood sugar/), discussion of a delivery plan, weight measurement, counseling on fetal movements, assessment of uterine fundal height and fetal heart rate, nutritional counseling and information on progress of antecedent pregnancy. Hypertension related parameters that were assessed during ANC included: blood pressure, administration of antihypertensive drugs, counseling on danger signs, and administration of MgSO<sub>4</sub>. These parameters were assessed using the patients file, ANC booklet, and interviewer questionnaires. Pregnancy outcomes were adverse or good maternal, fetal and neonatal outcomes. Data was entered into and analyzed using SPSS<sup>®</sup> version 21. Categorical data was analyzed and presented as frequencies and proportions; continuous data was summarized and presented as means and standard deviations and compared using the chi-square test. Continuous variables were calculated using mean and SD or median and inter-quartile range and compared using Independent t- test. Chi square test was used to assess factors associated with adverse outcomes.

**Results:** Between April and July 2019, 240 postpartum women with PES were screened and 161 (67%) who were eligible enrolled. About one third (n=56, 35%) of study participants received good quality of ANC. The most performed general ANC parameter was prescription of prenatal vitamins (70.2%) while the least performed was discussion of a delivery plan during ANC (55.3%). The most performed hypertension related ANC parameter was weight measurement during ANC (68.3%) while the least was administration of MgSO<sub>4</sub>(38.5%) There were more adverse maternal and neonatal

outcomes in women who had poor (61%) compared to those who had good (31%) quality of ANC, however this was not statistically significant ( $p=0.085$ ). Majority (61%) of patients who had poor quality of care, received ANC from government health facilities. Patients who received poor quality of ANC ranked their care at 75% compared to those who received good quality ANC who ranked their care at 85%

**Conclusion:** Overall poor quality of ANC services was offered to patients with PES. Poor quality of ANC services was associated with adverse outcomes (maternal/fetal/neonatal). Patients with PES were more likely to receive poor quality of ANC services in a government facility as compared to a non-government facility. There was no difference between perceived and received quality of care.

**Recommendation:** Antenatal clinics especially those at government facilities should improve the quality of care overall and for patients with preeclampsia. Patients with PES who attend ANC should be given prenatal vitamins, have a complete antenatal profile, be counseled on fetal movements, undergo fetal surveillance (detection of fetal heart), be informed on the progress of their ongoing pregnancy, have nutritional counseling and have discussed and agreed on a delivery plan. Under hypertension related parameters all patients with PES should have their blood pressures monitored, be given the necessary antihypertensives, be counseled on danger signs in pregnancy and be given MgSO<sub>4</sub>. ANC clients should be educated and encouraged to demand better quality of ANC services offered to them by healthcare workers.

**Key words:** Antenatal Care Services, Quality of Care, Pre-eclampsia with Severe Features, Pregnancy Outcomes.



## **CHAPTER ONE: INTRODUCTION**

### **1.1 BACKGROUND**

The global maternal mortality rate is 211 per 100,000 live births (1). The maternal mortality rate in Kenya is estimated to be at 362 per 100,000 live births (2). At Kenyatta National Hospital (KNH) maternal mortality rate was reported be at 639 per 100,000 live births (3).

Hypertensive disorders in pregnancy, are one of the most common causes of maternal and perinatal mortality (4). Pre-eclampsia with severe features (PES) still remains a major medical and public health concern and a leading cause of maternal adverse long and short-term morbidities including acute kidney injury, ICU admission, and infant mortality and morbidity such as cerebral palsy, vision and hearing impairment, and learning disabilities (5). Pregnant women with PES usually develop poor maternal, fetal and neonatal outcomes and is associated with 50,000–100,000 maternal deaths world-wide (6). Regionally the incidence of pre-eclampsia/eclampsia in Tanzania was found to be 1.7% (7). There was paucity of data from Kenya on the magnitude of the morbidity burden of preeclampsia with severe features.

Antenatal care (ANC) is the intervention given to gravid women before delivery and helps in ensuring that both mother and fetus and neonate have good outcomes. It is essential in both reducing maternal, fetal and neonatal morbidity and mortality. For antenatal care services to be effective, they must be available, have effective referral systems and have essential obstetric care (8).

Quality of antenatal care can be measured by effectiveness, utilization, compliance and continuity of care (9). The satisfaction of pregnant women who attend ANC has been associated with quality of ANC services rendered (10). Good quality of ANC ensures that pregnant women are offered high quality emergency obstetric care and skilled delivery. It can subsequently determine pregnancy outcomes (11). High-quality ANC is usually associated with higher client's satisfaction and subsequently leads to improved maternal, fetal and neonatal outcomes (12).

At Kenyatta National Hospital (KNH), no study has been conducted that assesses the quality of ANC services offered to patients with PES and their subsequent pregnancy outcomes. Limited studies have been done locally and regionally on quality of ANC and how it contributes to adverse pregnancy outcomes in this setting. The findings of this study can inform policy on quality of ANC services offered and create mechanisms for appropriate levels of care for patients with PES.

## **CHAPTER TWO: LITERATURE REVIEW**

### **2.1 Global Burden of Disease in Pregnancy**

Hypertensive disorders of pregnancy (HDP) ranks second in causes of maternal mortality. They constitute of five conditions; pre-eclampsia, chronic hypertension, gestational hypertension and pre-eclampsia superimposed on chronic hypertension and pre-eclampsia with severe features (PES)-eclampsia. PES and eclampsia are the most severe form of hypertensive disorders of pregnancy and are associated with compelling maternal and perinatal morbidity and mortality (13-14).

### **2.2 Recommended Management**

Patients with PES need to be closely monitored, have appropriate investigations and timely intervention. In Kenya, the Ministry of Health in 2012 launched guidelines to administer to patients with PES. They recommended hospital admission; nursing in a quiet semi- dark room, monitoring of vital signs; administration of magnesium sulphate, fluid input/ output monitoring; laboratory tests (full blood count, liver enzymes, serum creatinine), antihypertensives, and planning delivery (time and mode) (15).

### **2.3 Recommended Quality of ANC services**

ANC care serves to reduce morbidity and mortality by promoting good maternal, fetal, neonatal outcomes. This ensures all gravid women at danger of established complications during labor and delivery process are subsequently identified and are given timely referral to an appropriate point of care. It is also used to detect and treat complications associated with pregnancy. The WHO Focused Antenatal Care (FANC)

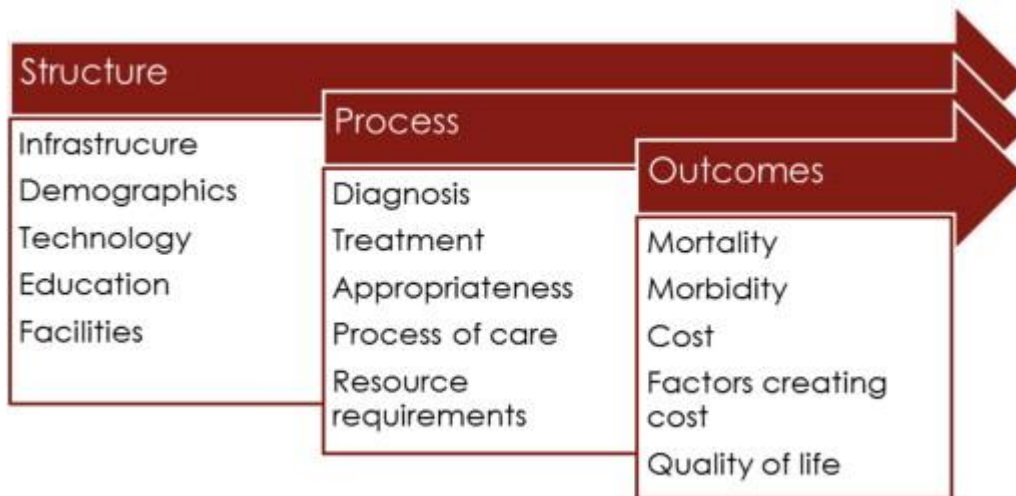
model developed in 2012 recommended 4 antenatal visits carried out at four critical times, 1st visit at 8-12 weeks of gestation, 2<sup>nd</sup> visit at 24-26 weeks of gestation, 3<sup>rd</sup> visit at 32 weeks of gestation, and 4<sup>th</sup> visit at 36-38 weeks of gestation. However, the new guidelines from 2016 increased the ANC visits to a minimum of eight visits due to increased perinatal mortalities. According to WHO, good quality ANC services results in pregnant woman attaining a positive pregnancy experience. This is defined as ensuring pregnant women are able to get as near normal physical and socio-cultural normality. This aims to ensure a healthy pregnancy for mother and baby (by minimizing risks, treating any pregnancy related ailment and preventing death). Following this period, it allows the pregnant woman to progress to a safe labor and delivery and postpartum period. By doing this they ensure that women achieve positive motherhood (where the pregnant women are encouraged to have high self-esteem during and after pregnancy, have autonomy over her own care and be offered high quality ANC). WHO advocates for quality ANC care and insists that it should encompass all of the following parameters:

- Nutritional intervention and counseling.
- Maternal assessment, a complete antenatal profile (ANP) –assessment of HIV, VDRL, RBS, Urinalysis, Rhesus and Blood Group, Hepatitis B Surface Antigen.
- Fetal Assessment (at least one obstetric ultrasound before 24 weeks)
- Preventing and treating common physiological symptoms and signs of pregnancy (nausea and vomiting, epigastric pain, constipation, lower back pain and leg edema).

- Health systems interventions to improve the quality and utilization of care (up to date and duly completed woman hand held notes, scheduled ANC visits – a minimum of 8 visits) (16).

## 2.4 Assessing Quality of Care

According to the Donabedian Model, quality of care can be assessed by looking at the following categories: “structure,” “process,” and “outcomes. Structure studies how healthcare is delivered, including the infrastructure e.g. hospital buildings, personnel, healthcare financing, and equipment in the facility. Process examines the relationships between patients and their health providers. Finally, outcomes examine the residual effects of healthcare on the patients and their surrounding populace (17).



**Figure 1: Donabedian Model**

[https://www.researchgate.net/figure/The-Donabedian-model\\_fig1\\_274097282](https://www.researchgate.net/figure/The-Donabedian-model_fig1_274097282)

Donald E. Lighter

## **2.5 Quality of ANC services among patients with Pre-eclampsia with Severe Features**

Management of PES in Kenya faces many challenges. Sub-standard care and delays (in seeking care, reaching the health facility and delay in provision of care) all contribute to these challenges. In 2013, the University of Nairobi (UoN), Kenya Medical Research Institute (KEMRI) Wellcome Trust conducted a clinical audit to evaluate service delivery in public hospitals that provide comprehensive obstetric care. Quality of care provided to women with PES and Eclampsia was one of the indicators measured. They used WHO quality assessment tools. The indicators used were; blood pressure charting, pulse rate charting, fetal surveillance, magnesium sulphate loading dose; magnesium sulphate maintenance dose; fluid input/output chart, full blood count (FBC) serum urea/creatinine/electrolytes (UECs), liver function tests (LFT), and tendon reflexes. The survey demonstrated that the level of care provided to women with PES in Kenya was subpar. Most of the selected indicators performed poorly. Blood pressure was charted in 90% of pregnant women, 76% of the ANC clients had a form of fetal surveillance done. Magnesium sulphate was not given to all patients with PES; Fluid input/output charting was only done in 51% of clients. FBC, UECs, LFTS were only done in 17%, 12% and 5% of patients respectively. They concluded that the guidelines were not being followed despite them being available in many public facilities (18).

Findings from a National Health Facility Survey by Kagema F et al done in 2011 revealed that most expectant women had their first ANC contact at 20 weeks of gestation. Majority of the pregnant women attending were multigravidas. They also noted that only 35% of

healthcare workers enquired about pregnancy induced hypertension and less than 20% of them enquired about pregnancy related convulsion or eclampsia. 80% of health facilities had Magnesium Sulphate and 24% of health facilities had hydralazine but not all patients with PES were given. They also showed that 83% of healthcare workers correctly could diagnose PES/E but only 1% knew the correct steps in managing the condition (19).

## **2.6 Association between quality of antenatal care and pregnancy outcomes**

In Nepal a prospective descriptive study looking at the impact of antenatal care on maternal and perinatal outcomes revealed that most of the study participants had their first ANC contact after the first trimester (75.8%). Gestational hypertension and anemia occurred more in women who did not attend ANC. The percentage of pre-term and low birth weight babies was demonstrated to be higher in gravid women who did not attend any ANC. New Born Unit admission was higher among them and some of the indications for admission were neonatal jaundice, birth asphyxia and neonatal sepsis. Peri-natal mortality was 16 times more in women who had less than 4 ANC contacts compared to those that had more than 4 visits. Neonatal and maternal outcomes were better in those who had frequent and scheduled ANC visits. They concluded that the quality of ANC services needed to be improved to improve maternal, fetal and neonatal outcomes. (20).

A cross-sectional study done by Ekane H et al looking at quality of antenatal care and outcome of pregnancy that involved 300 immediate post-partum women in three hospitals in Fako Division, Cameroon showed that 99% of participants had at least one ANC contact, and 15.5% of the participants started ANC early. 67% of them received

optimal care during their ANC. The study showed that those who started their ANC at a later gestation had a higher chance of receiving inadequate care as compared to those who started their ANC at an earlier gestation. Inadequate care was found among teenagers and those who were single. It was associated with poor pregnant outcomes such as pre-term deliveries, post-term babies, increased numbers of labor induction, labor augmentation, stillbirths, low birth weights, and poor Apgar scores. They concluded that adverse pregnancy outcomes were associated with poor quality ANC (21).

Locally in 2015, Kinuthia C et al looked at ANC practices and pregnancy outcomes among referred and booked patients with pre-eclampsia at PMH (Pumwani Maternity Hospital). It was a retrospective cohort study, looking at ANC attendance at PMH. It revealed that ANC services at PMH had better screening, investigations, diagnosis and management as compared to its referral facilities. ANC attendees with pre-eclampsia resulted in better maternal outcomes. Despite this there were some gaps in ANC provision at PMH. Both groups had delays in timely diagnosis of patients and subsequent management of patients resulting in development of PES.

A cohort survey of 1,562 perinatal outcomes during 2004–2005 local study done by Brown CA et al on antenatal care and perinatal outcomes in Kwale County, Kenya, revealed that 32% of participants had attended at least one ANC. Women who visited their ANC providers at least once were twice as likely to have a live birth in comparison to a stillbirth using multivariate models (23).



Nisar N et al conducted a community-based cross-sectional survey on a sample of 323 women in Pakistan looking at factors affecting utilization of antenatal care among reproductive age group women (15-49 years) in an urban squatter settlement of Karachi. They discovered that 33% of their study population had ANC services from an untrained care provider. The percentage of women who sought their ANC services from a government health facility (14.5%) was reduced as compared to those seeking theirs from a private facility (57.9%). 26.7% of expectant women opted to receive care at home. They recommended the need to evaluate government health facilities in Karachi so as to find out the reason of poor utilization of their ANC services (24).

### **2.7 Patients' perception of quality of ANC services**

In Nigeria a cross-sectional study aimed at assessing antenatal care service attendees' perception of quality of maternal healthcare (MHC) services in Anambra State, done was done by Onyeonoro U et al in 2007. It looked at a total of 310 women of reproductive age with a previous history of gestation attending ANC services between September, 2007 and August, 2008. The study showed that utilization of ANC/PNC services was quite high. Majority of the women who sought MHC services were satisfied (89.7%) especially with the staff attitude (85.1%), and waiting time (84.1%) (25).

### **2.8 Study Justification**

Hypertensive disorders complicate 6-8% of all pregnancies (26). PES still remains a major medical and public health concern. It is a leading cause of maternal adverse long and short-term morbidities which include ICU admission, acute kidney injury, infant mortality and morbidity (5).

Antenatal care (ANC) is the care given to gravid women before delivery and helps in ensuring that both mother and fetus and neonate have good outcomes. It is essential in both reducing maternal, fetal and neonatal morbidity and mortality. For antenatal care services to be effective, they must be available, have effective referral systems and have essential obstetric care (8).

In 2013, a clinical audit carried out by the MOH, UoN and KEMRI revealed that the management of patients with PES was generally poor (7). Approximately 58% of women in Kenya had more than 4 ANC visits. Of these majority (42%) of the women had their first ANC between 6-7months of pregnancy (18).

At Kenyatta National Hospital (KNH), no study has been conducted that assesses the quality of ANC services offered to patients with PES and their subsequent pregnancy outcomes. Limited studies have been done locally and regionally on quality of ANC and how it contributes to adverse pregnancy outcomes in this setting. The findings of this study can inform policy on quality of ANC services offered and create mechanisms for appropriate levels of care for patients with PES.

## **2.9 Research Question**

Is there an association between quality of ANC services and pregnancy outcome among patients with pre- eclampsia with severe features at Kenyatta National Hospital between April 2019 and July 2019?

## **2.10 Study Objectives**

### **2.10.1 Broad Objective**

To determine the association between the quality of ANC services, pregnancy outcomes, the types of health facilities and the patients' perception of ANC services among patients with pre- eclampsia with severe features managed at Kenyatta National Hospital.

### **2.10.2 Specific Objectives**

Among women with **PES** and within **72 hours post- partum**:

1. To determine the association between quality of ANC services and pregnancy outcomes.
2. To determine the association between types of health facilities and quality of ANC services offered.
3. To determine the association between the patients' perception of quality of ANC services received versus the actual quality of ANC services delivered.

## **2.11 Conceptual Framework**

### **2.11.1 Narrative**

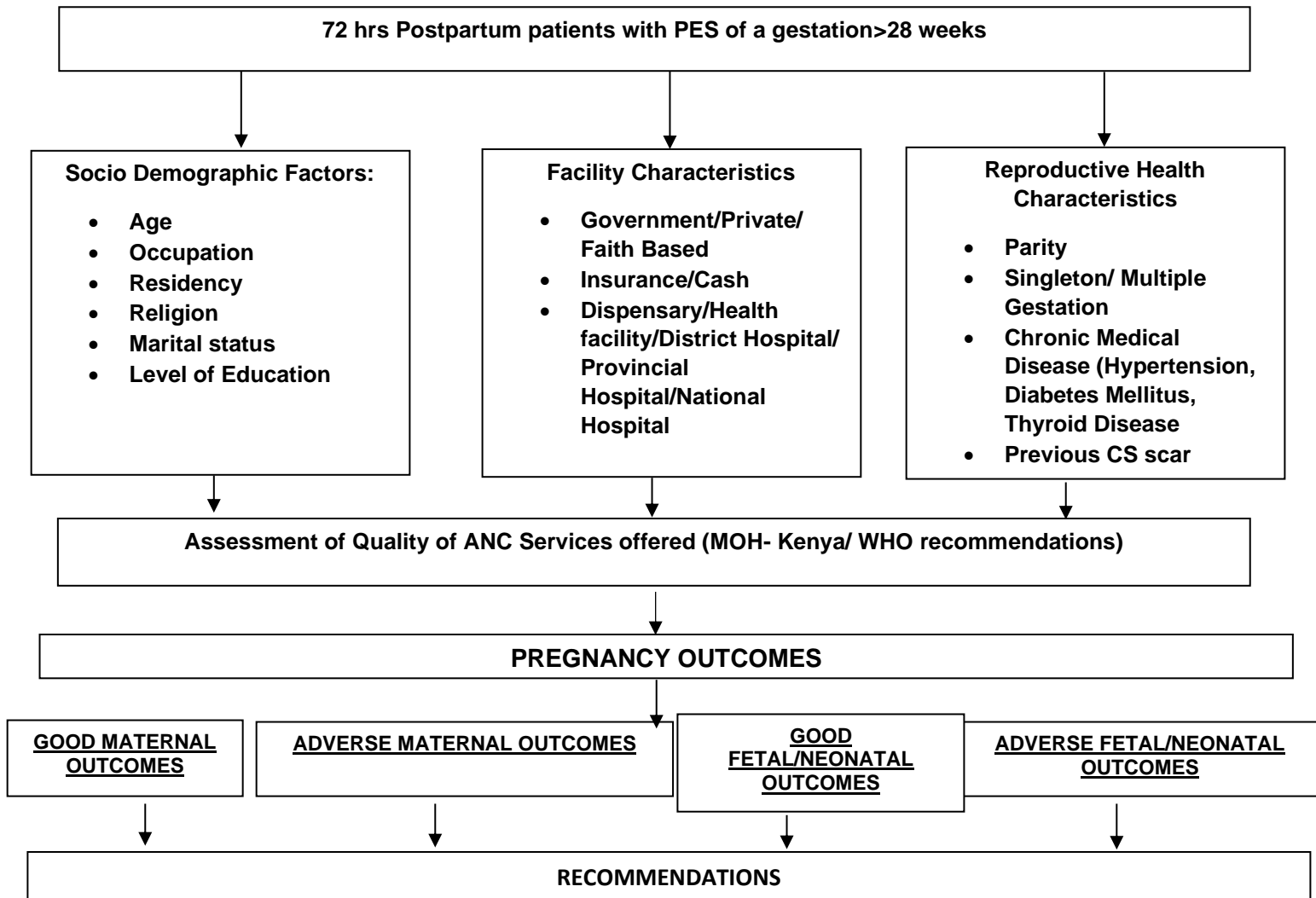
PES is associated with increased maternal, fetal and neonatal morbidity and mortality. WHO recommended quality of ANC services involves maternal and fetal monitoring, nutritional counseling, treating common physiological symptoms of pregnancy and encouraging health systems interventions to improve the quality and utilization of care. All of these parameters have to be met to be considered as optimal quality of ANC services offered. These factors can influence quality of ANC services offered. These aspects of care can directly affect maternal and fetal outcome especially in women with PES.

The study sought to assess if there was an association between quality of care and pregnancy outcomes among patients with PES at KNH. Selected process and outcome indicators were used to measure quality of ANC. Process indicators were divided in 2 main categories: General ANC indicators and hypertensive related indicators. General ANC indicators were further subdivided into appropriate number of ANC visits by gestation; prescription of prenatal vitamins; complete ANC profile; delivery plan during ANC; weight measurement during ANC; counseling on fetal movements; assessment of uterine fundal height and fetal heart rate assessment; information about antecedent pregnancy and nutritional counseling during antecedent pregnancy. Hypertensive related indicators included blood pressure monitoring during ANC; administration of anti-hypertensive drugs during ANC; counseling of danger signs of PES and administration of MgSO<sub>4</sub>. All the process indicators had to have been met for quality of ANC to be

considered good. If one or more of the indicators was not offered during ANC, it was deemed as poor quality of ANC.

Outcome indicators were divided into maternal, fetal and neonatal. The primary independent variables were socio-demographic factors, reproductive health characteristics, and facility characteristics of postpartum women with PES who had attained at least at 28 weeks of gestation at delivery. Dependent variables were selected processes and outcome indicators of quality of ANC as per WHO recommendations for care provided to patients with PES.

**FIG 2: CONCEPTUAL FRAMEWORK**



## CHAPTER THREE: METHODOLOGY

### 3.1 Study Design

This study was a hospital a descriptive cross-sectional study.

### 3.2 Study Area

This study was conducted at the department of Obstetrics and Gynaecology, Kenyatta National Hospital (KNH). It is located in located in Nairobi County, Kibra Sub-County and is the largest referral and teaching hospital in Kenya. It has a bed capacity of approximately 2000 beds. This hospital has a robust labour ward that on average, conducts 20 – 50 deliveries per day. The Obstetrics and Gynaecology department consists of one labour ward, an acute gynaecology ward, 3 antenatal and post-natal wards, and two maternity theatres. It has antenatal care clinics which run from Monday to Friday. The unit works in tandem with other units such as New Born Unit, Intensive Care Unit and Renal Unit. The unit also works closely with the Laboratory Department and Radiology Department in the hospital.

Antenatal care services are offered at the ANC clinics that run daily from Monday to Thursday. Postnatal clinics are conducted every Monday. These clinics are run by a team of midwives, residents and consultants in the Obstetrics and Gynaecology department. At Accident and Emergency there is an Obstetrics and Gynaecology consultation room where patients are seen and reviewed and acute emergencies can be stabilized and admitted as per need on a 24hour basis. Approximately 40 mothers are seen every Monday which is the booking clinic day for ANC. There are three dedicated Obstetrics

and Gynecology (Obs/Gyn) firms and each of these are allocated one ANC per week. On average a total of 11,500 mothers are seen in the ANC clinics per year.

Patients with PES are initially admitted and managed at the KNH labour ward. On average, a total of 10 patients are admitted and managed for PES per day. After stabilization, all patients are immediately delivered. The mother and neonate are assessed post-delivery and their vitals are monitored. After delivery if the mother and neonate are stable, they are discharged to the post-natal wards (GFA, GFB, 1A). If any patient (mother or neonate) is not stable they are monitored further in labour ward and referred to the appropriate point of care (Intensive Care Unit, Renal Unit, New Born Unit).

### **3.3 Study Population**

Postpartum women, who had attained a gestation of 28 weeks or more with a diagnosis of PES, delivered at KNH or referred to the KNH after delivery and who were willing and able to give consent.

### **3.4 Inclusion Criteria**

All patients diagnosed with PES who had delivered within the first 72 hrs and were at Labor ward or Postnatal wards at the KNH.

### **3.5 Exclusion Criteria**

Patients who are unable to communicate, impeded Glasgow Coma Scale (GCS) less than 15 and those who had no proxy of information from other sources (ANC booklet/ Referral note/ Patient Guardian)



### 3.7 Sample Size Determination

Sample size was calculated using the Fisher's formula;

$$n = \frac{Z^2 x P(1 - P)}{d^2}$$

Where,

$n$  = Desired sample size

$Z$  = value from standard normal distribution corresponding to desired confidence level  
( $Z=1.96$  for 95% CI)

$P$  = expected true proportion (estimated at 9.2%, from a cross-sectional study conducted by Mona R. et al (2017) at Assiut Women's Hospital, Egypt between October 2015 and September 2016; looking at effects of irregular antenatal care attendance, found 9.2% of those that didn't attend ANC.

$d$  = desired precision (0.05)

$$n_0 = \frac{1.96^2 x 0.092(1 - 0.092)}{0.05^2} = 147$$

A Sample size of 130 patients will be required for the study. 10% will be added for missing data.

A total of **161** patients will be required for the study.

### 3.8 Sampling Procedure

Consecutive sampling of all postpartum patients with PES was done. Patients were identified and selected for the study by the Principal Investigator. Every patient meeting the eligibility criteria was sampled until the sample size was met.

### **3.9 Recruitment and Consent**

Potential study participants were recruited by the attending nurse in labour ward and the post-natal wards (GFA, GFB, 1A). The subjects were identified and chosen for the study if they met the eligible criteria. Recruitment and enrolment were carried out by the research assistants, attending nurse or principal investigator who were all part of the study team. The consent form was read out to the potential clients from the patient's bed side after being screened off from the rest of the patients for privacy. Patients who opted to join the study signed a consent form and were subjected to the study questionnaire (annex) by either the principal investigator or the research assistant.

### **3.10 Ethical Considerations**

**Ethical approval:** Approval was obtained from the joint University of Nairobi and Kenyatta National Hospital Ethical Review committee before the study was initiated. Subsequent institutional approval was sought from the KNH Scientific and Research department and the Department of Obstetrics and Gynecology to register the study.

**Informed consent:** The study participants gave informed consent. The informed consent form was sought by the principal investigator and study assistants, both of whom were highly trained nurses and medical doctors who had undergone training in ethics and medical research. Persons who declined to provide informed consent were excluded from the study. Study participants who choose to withdraw from the study were allowed to do so and subsequently removed.

**Benefits of the study:** This aim of the study was to find out if there was an association between the quality of antenatal services and pregnancy outcomes in postpartum women with PES. This was intended to benefit providers of ANC services, to closely monitor the standards of practice and also help design or improve those services for better outcomes and beneficial to patients of such cases.

There were no potential risks to the patients during the course of the study, as no invasive procedures were performed on them. Confidentiality was maintained throughout the study.

### **3.11 Data Collection**

The patients who opted to participate in the study were required to sign the consent form, which was counter-signed by the investigator. Records were kept regarding reasons for non-participation of eligible participants. The investigator or research assistant then countersigned the consent form. The participant was then given a copy of the signed consent form.

### **3.12 Study Procedure**

The study involved a face-to-face interview with the patient and also involved extraction of other relevant data from patient's medical records (ANC booklet and file).

### **3.13 Data Management and Statistical Analysis**

Prior to data collection ethical approval was sought, thereafter recruitment of research assistants was carried out to help in data collection. The research assistants were subsequently trained in data collection methods which involved interviewing techniques, confidentiality, information retrieval, questionnaire filling and subsequent storage of collected data. To maintain confidentiality, all questionnaires did not have identifying features such as names of the patients but had a pre-assigned serial number. The questionnaires were checked for completeness prior to storing them in a locked drawer that was only accessible to the PI and the research assistants.

Data was entered and analyzed by the use of SPSS version 21.

For the specific objective: **To determine the association between quality of ANC services and pregnancy outcomes-** data was analyzed using Chi square measure of association and presented as tables. Quality of ANC services was analyzed using MOH- Kenya 2012 Guidelines on management of PES and the 2016 WHO ANC Recommended Guidelines. Utilization of all the parameters equated to good quality of ANC services. If one or more of the parameters in the guidelines was not offered this was considered poor quality of care. Pregnancy outcomes were further classified as maternal, fetal and neonatal outcomes. Maternal outcomes were classified as non-complicated or complicated as a single entity. Fetal/ neonatal outcomes were assessed as non-complicated or complicated where each was represented as a single entity. Relative risk ratio was used to measure the association between quality of ANC and pregnancy outcomes. A p value of  $<0.05$  was taken as being significant statistically.

For the specific objective: **To determine the association between type of health facility and quality of ANC services offered-** categorical data on type of health care facility and quality of ANC services were analyzed using Chi- square measure of associations and presented as tables. Relative risk ratio was used to measure the association between quality of ANC and pregnancy outcomes. A p value of  $<0.05$  was taken as being significant statistically.

For the specific objective: **To determine the association between the patients' perception of quality ANC services received and actual quality of ANC services delivered-** we used a Likert scale with a scale of 1-5, where 1 being "strongly agree"

and 5 being “strongly disagree”. The association between perception of quality ANC services and ANC services was assessed using Mann- Whitney U test. A p value of <0.05 was taken as being significant statistically

Categorical data was analyzed and presented as frequencies and proportions, continuous data was summarized and presented and summarized as means and standard deviations, where applicable median and inter-quartile range will be reported. Bi-variate and multivariate analysis which included use of Chi-square. P-values, Odds ratio, and 95% confidence intervals (CIs) were calculated and reported where applicable. A P value <0.05 was considered being statistically significant.

### **3.14 Study Limitations**

It was anticipated that some patients may have declined in participating in the study or have pulled out after recruitment. Some of the pregnancy outcomes that occurred after the 72hr window period may not have been captured in the study. There was incomplete data in some of the recruited participants ANC booklets and medical files. Recall bias was factored in while assessing their perception of ANC services offered.

### **3.15. How to overcome the limitations:**

The sample size was increased by 10% to take care of opt outs. Missing data from ANC booklets was corroborated with the patient’s medical records and participants ‘antenatal history. The study followed up recruited patients for up to a week to ensure that accurate pregnancy outcomes were captured. A structured pretested Likert questionnaire was

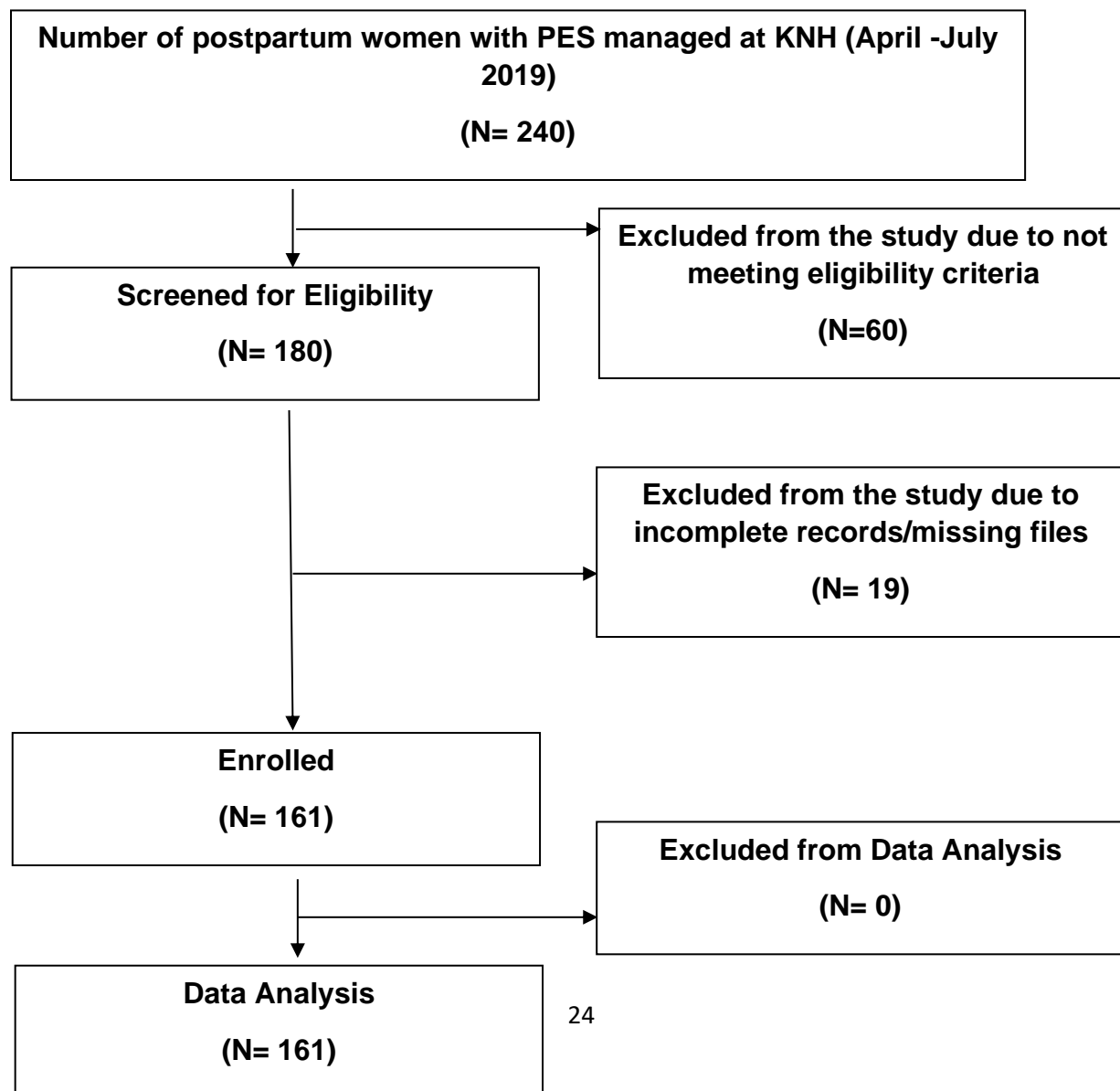
used and patients were asked to rank their responses from “Strongly Agree” to “Strongly Disagree”.

## CHAPTER FOUR: RESULTS

### 4.1 INTRODUCTION

A total of 180 of postpartum women who had attained a gestation of at least 28 weeks at delivery and had a diagnosis of preeclampsia with severe features being managed at Kenyatta National Hospital (KNH) were screened for the study and 161 enrolled during the data collection period from April 2019 till July 2019.

### 4.2 STUDY FLOW CHART





### **Fig 3: Study Flow Chart**

Between April and July 2019, 240 postpartum women with PES were managed at KNH. 180 of them met the eligibility criteria for the study. Of the patients meeting the inclusion criteria 19 of them were excluded due to incomplete records and missing files. 161 of the patients with PES who were eligible were subsequently enrolled and none were excluded from data analysis.

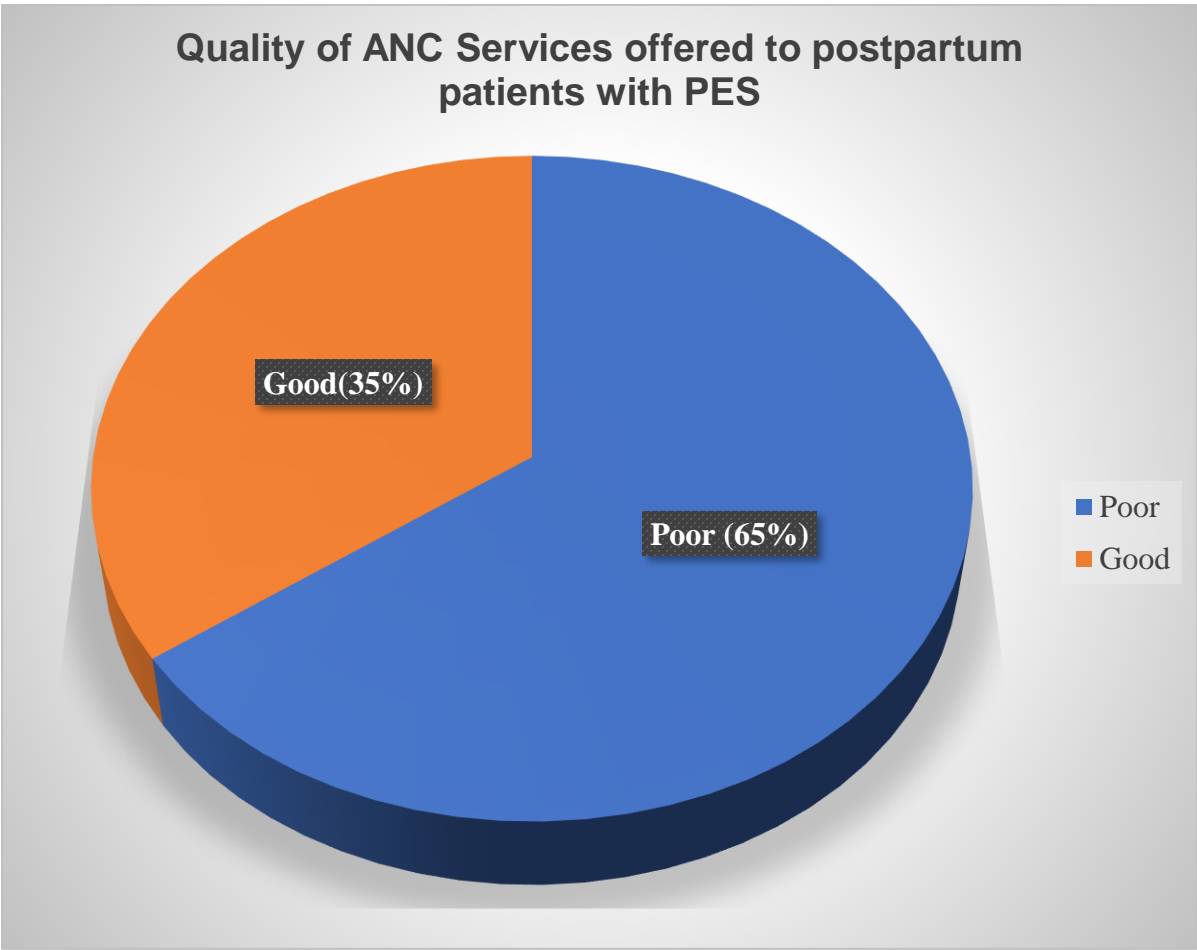
### 4.3 QUALITY OF ANC SERVICES

We defined QOC from the parameters listed in table 1 below. They were divided into general ANC related parameters and hypertension related parameters. Women who had good QOC were offered all the following parameters. If any parameter was not offered in their ANC it was termed as poor quality of ANC services.

**Table 1: Definition of Quality of ANC Services**

<b>Good Quality of ANC services</b>	<b>Poor Quality of ANC services</b>
<b>General ANC</b>	<b>General ANC</b>
Appropriate ANC visits as per gestation	Lack of appropriate ANC visits as per gestation
Prescription Pre-natal Vitamins	No prescription Pre-natal Vitamins
Complete ANC profile (HIV/VDRL/HB/Urinalysis/Blood Group / Blood sugar/UECs/LFTS/FBC)	Incomplete ANC profile (HIV/VDRL/HB/Urinalysis/Blood Group / Blood sugar/UECs/LFTS/FBC)
Delivery Plan During ANC	No delivery Plan During ANC
Weight Measurement during ANC	No weight Measurement during ANC
Counseling on Fetal Movements	No Counseling on Fetal Movements
Assessment of Uterine Fundal Height and FHR	No Assessment of Uterine Fundal Height and FHR
Informed on the progress of the antecedent pregnancy	No information on the progress of the antecedent pregnancy
Nutritional counseling during antecedent pregnancy	No Nutritional counseling during antecedent pregnancy
<b>Hypertension Related</b>	<b>Hypertension Related</b>
BP monitoring during ANC	No BP monitoring during ANC
Administration of antihypertensive drugs during ANC	No administration of antihypertensive drugs during ANC
Counseled on danger signs	No counseling on danger signs
Administration of MgSO <sub>4</sub>	No administration of MgSO <sub>4</sub>

**4.4 QUALITY OF ANC SERVICES, MATERNAL AND FETAL OUTCOMES**



**Fig 4: Quality of ANC services offered to patients with postpartum patients with**

As indicated in Fig 4, 65% of study participants received poor quality of ANC services where as 35% of study participants received good quality ANC services.

## 4.5 Participants' Characteristics

This section describes the participant characteristics who were recruited for the study from the post-natal wards at Kenyatta National Hospital.

**Table 2: Socio-demographic and obstetric characteristics of patients by quality of care**

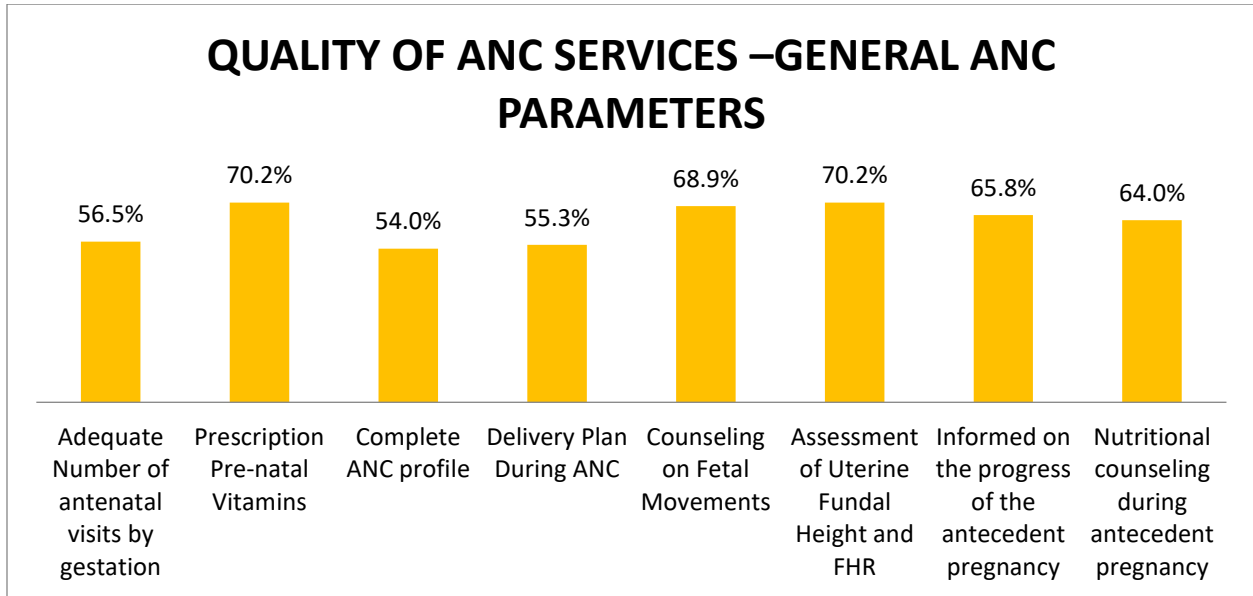
Characteristics	Good Quality of ANC (N=56)	Poor Quality of ANC (N=105)	P value
Maternal Age (Mean)	30.8 ± 5.9	28.7 ± 5.9	0.039
Gestation Age at Delivery (Mean)	36.3 ± 3.8	35.3 ± 3.8	0.116
<b>Parity</b>			
Para 1+0	18 (32.1)	36 (34.3)	0.784
>Para 1+0	38 (67.9)	69 (65.7)	
<b>Religion</b>			
Catholic	18 (32.1)	29 (27.6)	Ref
Protestant	37 (66.0)	72 (68.6)	0.602
Muslim	1 (1.8)	2 (1.9)	0.864
Others	0 (0.0)	2 (1.9)	0.271
<b>Education</b>			
Primary	6 (15.8)	32 (30.5)	Ref
Secondary	22 (39.2)	17 (16.2)	0.001
Tertiary	28 (50)	56 (53.3)	0.045
<b>Prior Obstetric Outcome</b>			
Live births (Term)	27 (48.3)	51 (48.6)	Ref
Live births (Pre-term)	1 (1.8)	9 (8.6)	0.116
Still births	12 (21.4)	12 (11.4)	0.175
First pregnancy	13 (23.2)	28 (26.7)	0.750
Abortion	3 (5.4)	5 (4.8)	0.870
<b>Medical Comorbidities</b>			
Asthma	3 (5.3)	2 (1.9)	0.624
Chronic Hypertension	8 (14.2)	9 (8.6)	0.705
Diabetes Mellitus	1 (1.8)	4 (3.8)	0.355
Hyperthyroidism	0 (0.0)	1 (0.95)	1.000
No Comorbidities	44 (78.6)	89 (84.8)	Ref
<b>Mode of Delivery in Antecedent Pregnancy</b>			
CS	29 (51.2)	58 (55.2)	0.675
SVD	27 (48.2)	47 (44.8)	
<b>Ultrasound Done Before 24 weeks of gestation</b>			
Yes	13 (23.2)	13 (12.4)	0.075
No	43 (76.8)	92 (87.7)	

The mean maternal age of the patients who received good QOC was significantly higher (30.8 ± 5.9 years) compared to those who received poor QOC (28.7 ± 5.9 years), (p=0.039).

Women who had good QOC (39.2%) were significantly more likely to have secondary education compare to those who had poor QOC (16%).(p=0.002), Other characteristics including religion, prior obstetric outcome, medical comorbidities, mode of delivery in prior pregnancy and ultrasound done before 24 weeks were similar between the two categories of QOC.

## 4.6 QUALITY OF ANC SERVICES

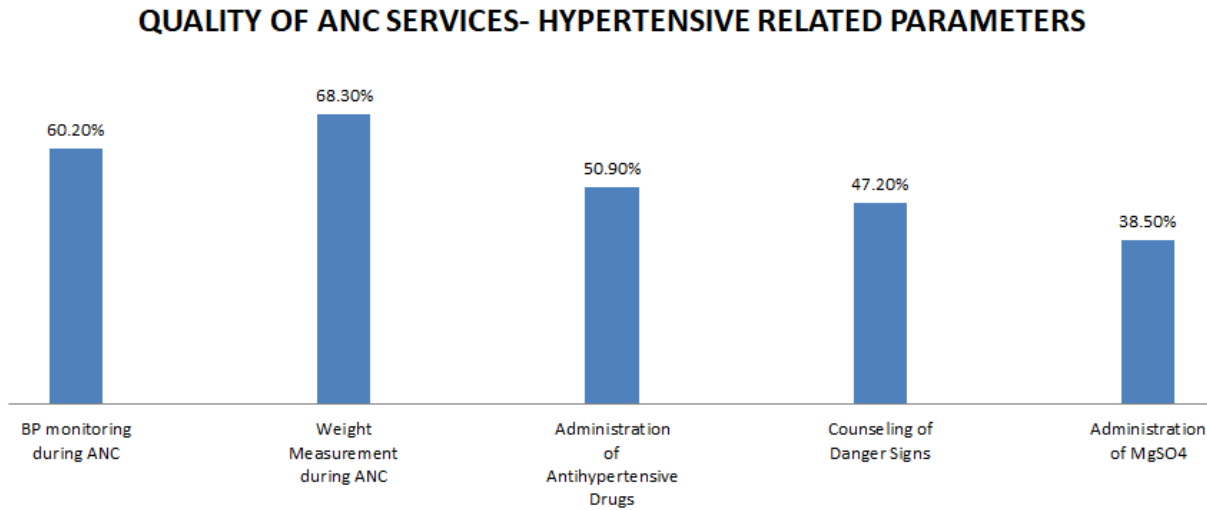
### General ANC Parameters



**Fig 5: Quality of ANC services: General ANC parameters of patients with PES managed at KNH**

Following the definition of QOC, more than half of each variable was performed. According to Fig 5, the least practiced general ANC related parameter was providing a complete ANC profile (54%). The most practiced general ANC related parameter was prescription of pre-natal vitamins and assessment of uterine fundal height and fetal heart rate (70%). All patients PES were not offered all the general ANC parameters.

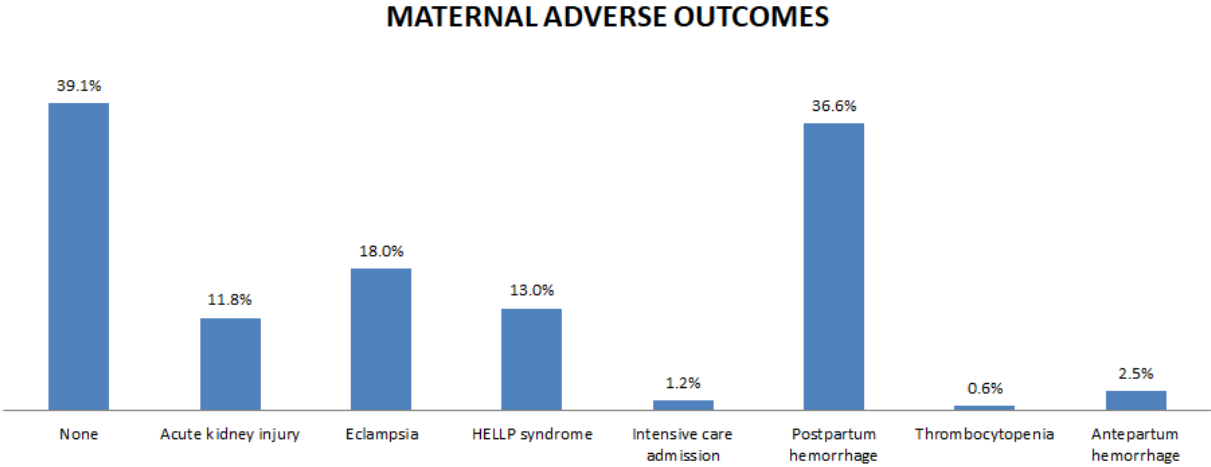
## HYPERTENSIVE RELATED PARAMETERS



**Fig 6: Quality of ANC services: Hypertensive related parameters of patients with PES managed at KNH**

As shown in Fig 6, under hypertension related ANC parameters, more than half of each parameter was performed apart from administration of MgSO<sub>4</sub> (38.5%) The most practiced parameter related parameter was weight measurement (68.5%). All of the patients with PES were not offered all the hypertensive related ANC parameters.

# MATERNAL OUTCOMES



**Fig 7: Maternal adverse outcomes among patients who were managed for PES at Kenyatta National Hospital**

As referenced by Fig 7, the most common adverse maternal outcome was PPH (36.6%). Lowest adverse maternal outcome was thrombocytopenia (1%). 39% of the study participants had no adverse maternal outcomes.



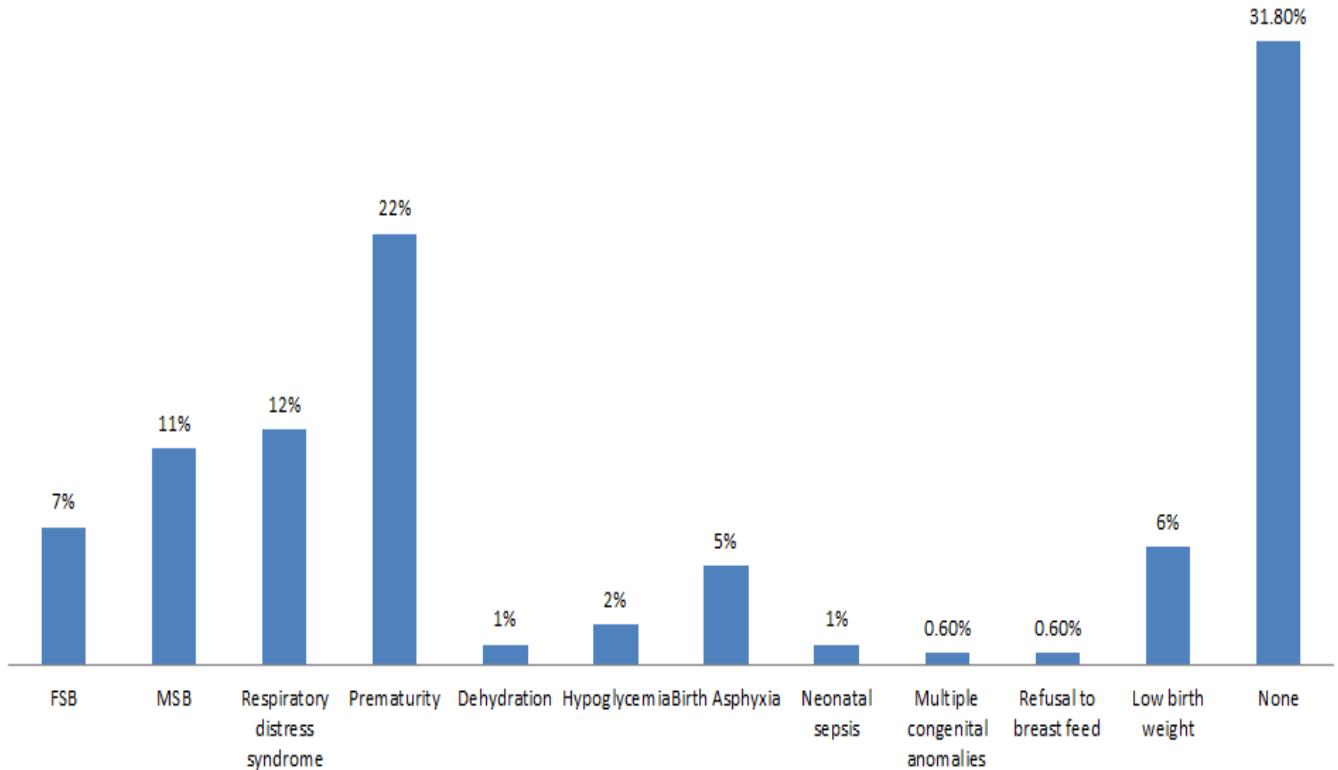
**Table 3: Quality of ANC services and maternal outcomes of patients with PES managed at KNH**

	Adverse Maternal Outcomes (N=98)	Good Maternal Outcomes (N=63)	RR	p value
Poor Quality of ANC	69 (70)	36 (57.7)	1.27	0.085
Good Quality of ANC	29 (30)	27 (42.3)	0.78	
Total	98	63		

According to Table 3, 61 % of the patients had adverse maternal outcomes. Of those who had adverse maternal outcomes 70% of them received poor quality of ANC services. The patients who were offered poor quality of ANC services were 1.27 times likely to have adverse maternal outcomes however the difference was not statistically significant.

## NEONATAL OUTCOMES

### ADVERSE NEONATAL OUTCOMES



**Fig 8: Adverse Neonatal Outcomes among patients who were managed for PES at Kenyatta National Hospital**

According to Fig 8, Majority of the neonates (68.2%) of patients had no adverse neonatal outcomes. The most common neonatal complication was prematurity (22%). The least common neonatal complication was neonatal sepsis and dehydration (1% each).

**Table 4: Quality of ANC services and neonatal outcomes of patients with PES managed at KNH**

	Adverse Neonatal Outcomes (N=104)	Good Neonatal Outcomes (N=57)	RR	p value
Poor Quality of ANC	70 (67.3)	35 (61.4)	1.1	0.085
Good Quality of ANC	34 (32.7)	22 (38.6)	0.91	
Total	104	57		

Table 4 shows 65 % of the patients had adverse neonatal outcomes. Of those who had adverse neonatal outcomes 67% of them received poor quality of ANC services. The patients who were offered poor quality of ANC services were 1.1 times likely to have adverse neonatal outcomes however it was not statistically significant.

#### 4.7 QUALITY OF ANC SERVICES AND TYPE OF HEALTH FACILITIES

**Table 5: Quality of ANC services and type of health facility**

	Poor Quality of ANC (N=105)	Good Quality of ANC (N=56)	RR	p value
Government Facility (N= 130)	86 (66)	44 (79)	1.07	0.61
Non-Government Facility	19 (61)	12 (21)	0.93	
Total	105	56		

**\*Government Facilities included Dispensaries, District Hospitals and National Teaching and Referral Hospitals,**

**\*Non-Government Facilities included Faith Based Hospitals and Private Hospitals**

65% of health facilities offered poor quality of ANC services. Of the facilities offering poor quality of ANC services 66% of them were government facilities. Patients with PES who went to Government health facilities were 1.07 times more likely to receive poor quality ANC services.

#### 4.8 PERCEIVED QUALITY OF ANC SERVICES

**TABLE 6: Perceived quality of ANC services received versus ANC services delivered.**

<b>INFORMATION EXCHANGE</b>	<b>Mean Rank</b>		<b>p-value</b>
	<b>Good</b>	<b>Poor</b>	
I was informed about the various antenatal tests and procedures.	82.5	80.2	0.736
My questions were answered truthfully.	84.8	79.0	0.347
The ANC team managing me was constantly updated especially on critical information regarding me.	90.1	76.1	0.045
My ANC provider(s) ran all the test necessary for my pregnancy to ensue safely	84.0	79.4	0.506
My results were explained to me in way I understood	84.8	79.0	0.402
My ANC provider(s) answered my questions honestly	83.5	79.6	0.558
My ANC provider(s) gave me adequate information and involved me in every aspect of decision making regarding my care.	86.6	78.0	0.225
My ANC provider(s) ensured that my medical information was confidential	85.0	78.9	0.358
My ANC provider(s) fully explained to me the reasons for all my blood work and other tests during my ANC	84.0	79.4	0.463
<b>ANTICIPATORY GUIDANCE</b>	<b>Mean Rank</b>		<b>p-value</b>
	<b>Good</b>	<b>Poor</b>	
My ANC provider(s) gave me various options and subsequently allowed me to choose my birth experience.	88.5	77.0	0.072
I was assessed and fully informed about the importance of breastfeeding	87.1	77.7	0.195
My ANC provider(s) took me through my pregnancy and prepared me adequately for my birth experience.	89.0	76.7	0.073
My antenatal care provider(s) allowed me to voice my concerns regarding my expectations during the labor and delivery process.	82.5	80.2	0.735
I was fully informed about the importance of exercise during my pregnancy.	82.4	80.2	0.762
I was counseled on the importance of a balanced diet during my pregnancy.	85.5	78.6	0.305
My ANC provider(s) evaluated how my pregnancy was affecting my day to day activities.	87.4	77.6	0.142
My ANC provider(s) was able to help me find community programmes that were beneficial.	84.7	79.0	0.403

I was counseled about alcohol consumption during my pregnancy.	80.2	81.4	0.872
I was screened for depression and for postpartum depression pre- and post-delivery.	78.6	82.3	0.617
My ANC provider(s) ensured that they tackled every aspect my pregnancy that seemed important to me.	86.7	78.0	0.207
<b>SUFFICIENT TIME</b>	<b>Mean Rank</b>		<b>p-value</b>
	<b>Good</b>	<b>Poor</b>	
During my ANC my ANC care provider(s) took as much time as I required.	89.3	76.6	0.044
My ANC services were always rushed	91.9	75.2	0.017
During my ANC my ANC provider(s) took time and subsequently ensured that they answered all my questions.	84.9	78.9	0.342
My ANC provider(s) were patient with me and allowed me to voice my concerns	89.0	76.7	0.069
During my ANC my ANC provider(s) took time to listen to my concerns	85.2	78.8	0.317
<b>APPROACHABILITY</b>	<b>Mean Rank</b>		<b>p-value</b>
	<b>Good</b>	<b>Poor</b>	
My ANC providers were abrupt with me	81.9	80.5	0.851
I felt rushed during my ANC	79.7	81.7	0.765
My ANC providers made me feel like my questions were not valid	80.1	81.5	0.836
My ANC providers made me feel afraid to ask important questions	84.1	79.4	0.511
<b>AVAILABILITY</b>	<b>Mean Rank</b>		<b>p-value</b>
	<b>Good</b>	<b>Poor</b>	
I was able to easily access my ANC providers	83.7	79.6	0.545
If I could get in-touch with my ANC providers they would always return my phone calls	91.6	75.3	0.022
My ANC provider(s) could easily be reached if I had any question or concern.	93.8	74.2	0.005
I could readily access my ANC provider(s) if I needed something urgently	86.6	78.0	0.221
I could always access my ANC provider(s) by phone when necessary	94.4	73.8	0.005
<b>SUPPORT AND RESPECT</b>	<b>Mean Rank</b>		<b>p-value</b>
	<b>Good</b>	<b>Poor</b>	
My ANC provider(s) always treated me with respect	87.7	77.4	0.111
My ANC provider(s) always supported my input, in my ANC	88.9	76.8	0.057
My decisions regarding my care was always taken into consideration and respected by my ANC provider(s)	86.1	78.3	0.225
My ANC provider(s) were always patient with me	85.2	78.8	0.315

My ANC provider(s) always supported my decisions that felt right by me	90.1	76.1	0.036
My ANC provider(s) always supported me throughout my pregnancy	90.1	76.1	0.033
My ANC provider(s) was always response and attentive when I was talking	90.2	76.1	0.041
All concerns were taken seriously during my pregnancy by my ANC provider(s)	91.8	75.3	0.012
I felt in control and owned all the decisions being made about my antenatal care	84.5	79.1	0.458
My ANC provider(s) supported all my decisions regarding my antenatal care	86.4	78.1	0.222
I felt comfortable with my ANC provider(s)	89.8	76.3	0.038
My belief system, morality and set values was supported and upheld by ANC provider(s)	86.1	78.3	0.254

As indicated by Table 9, the mean rank score of perceived quality of care was calculated from a Likert scale using the Mann- Whitney U Test. Generally, study participants perceived that they received good quality of ANC services. Patients with PES who received good quality of ANC services perception of ANC services was ranked at 85% compared to 75% in those who received poor quality of ANC services.

There was no major difference in perception of ANC care in those who received good quality of ANC compared to those who received poor quality of ANC under information exchange, anticipatory guidance and sufficient time. There was however a noticeable difference in perception of availability of the healthcare provider in those who received good quality ANC services compared to those who received poor quality ANC services.

## CHAPTER FIVE: DISCUSSION

The main objective of this study was to assess the quality of ANC services and pregnancy outcomes among patients with PES managed at KNH.

On the association between quality of ANC services and pregnancy outcomes we found that poor quality of ANC services was associated with increased risk of adverse outcomes (maternal/fetal/neonatal). This outcome was consistent with a retrospective cohort study done by Barbosa et al in 2015 that included all women with hypertensive disorders of pregnancy (HDP) admitted to a tertiary hospital in a 4-year period. The study looked at maternal, fetal and neonatal outcomes in women with HDP and the impact of ANC services found that pregnant women who did not attend ANC or subsequently had inconsistent ANC services had higher mortality rates. Approximately 67% of maternal, fetal or neonatal deaths occurred in women with inconsistent ANC care (27). This was consistent with our study which showed that majority of patients who had adverse maternal outcomes (61%) and adverse neonatal outcomes (65%) received poor quality of ANC services. This was also consistent with Tuladhar H et al who looked at the impact of antenatal care on maternal and perinatal outcome showed that pregnancy induced hypertension and anemia was seen more in women who didn't attend any ANC. Their study showed that the women who had inconsistent ANC care (inadequate or no ANC care) had higher rates of preterm and low birth weight babies. (20).

In a retrospective study done by Essiben et al which looked at 247 cases of eclamptic women managed at Yaounde Gynaeco-Obstetric and Paediatric Hospital from 2017-2018 revealed that majority of women who had eclampsia as a complication (51.7%) did not



meet the recommended number of ANC as per the national guidelines (21). This was consistent with our study.

On the association between type of health facility and quality of ANC services offered, 82% of Government health facilities offered poor quality of ANC services as compared to 18% of private facilities that offered poor quality of ANC services. Patients with PES who went to Government health facilities were 1.07 times likely to receive poor quality of ANC services. This was consistent with the SIRCLE Facility Survey conducted by MOH-Kenya in 2013 where quality of ANC provided to women with Pre-eclampsia with severe features and Eclampsia in public hospitals in Kenya was poor. Average care ranked at 50%. Blood pressure monitoring was the highest ANC parameter at 90% while the lowest ANC parameter was checking tendon reflexes (0%) (19). In our study the most common ANC parameter done was prescription of prenatal vitamins while administration of MgSO<sub>4</sub> was the lowest ANC parameter performed (38.5%). Our study showed similar findings to the study done by Kagema et al which revealed that the most common ANC parameter performed in patients with severe preeclampsia/eclampsia was blood pressure monitoring at (71%) while the least was urine testing for presence of proteins (12%). It differed with our study as it went on to assess the healthcare workers' knowledge in diagnosis and management of PES where it showed it was 83% and 77% respectively.

In determining the association between the patients' perception of quality of ANC services received versus actual quality of care received it was found that majority of the study participants' perception of quality of ANC services offered was good. This was consistent with Onyeonoro U et al who looked at maternal healthcare (MHC) services in Anambra State. They found that 89.7% of patients were satisfied with ANC/PNC services as

compared with our study which found that patients with PES who received good quality ANC services ranked their ANC services at 85%. Those who received poor quality of ANC services ranked their ANC services at 75.%. Most of them were satisfied with the staff attitude (85.1%), waiting time (84.1%) (25). In our study those who received good quality of care ranked highest the availability of healthcare provider (96%) while those who received poor quality of ANC services ranked approachability of the health worker highest (80%).

The difference was the study population where we solely looked at patients with PES and Onyeonoro U et al looked at all postpartum women who had attended MHC in Anambra state.

To the best of our knowledge we could not find specific studies that compared patients' perception of quality of ANC services versus the actual care received in patients with PES.

## **5.1 CONCLUSION**

Overall poor quality of ANC services was offered to patients with PES. Poor quality of ANC services was associated with increased risk of adverse outcomes (maternal/fetal/neonatal). Patients with PES were more likely to receive poor quality of ANC services in a government facility as compared to a non-government facility. There was no major difference between perceived quality of care in those who received good quality of ANC services and poor quality of ANC services.

## **5.2 RECOMMENDATIONS**

1. Antenatal clinics especially those at government facilities should improve the quality of care overall and for patients with preeclampsia.
2. Patients with PES in the ANC should be given prenatal vitamins, have a complete antenatal profile, be counseled on fetal movements, undergo fetal surveillance (detection of fetal heart), be informed on the progress of their ongoing pregnancy, have nutritional counseling and have discussed and agreed on a delivery plan. Under hypertension related parameters all patients with PES should have their blood pressures monitored, be given the necessary antihypertensives, be counseled on danger signs in pregnancy and be given MgSO<sub>4</sub>.
3. ANC clients should be educated and encouraged to demand better quality of ANC services offered to them by healthcare workers.

### **5.3 STRENGTHS AND LIMITATIONS**

Our study has several strengths. To the best of our knowledge this is the first study that attempted to determine the association between quality of ANC services and pregnancy outcomes among patients with PES. The study also used comprehensive ANC parameters to assess quality of care received among patients with PES. The study also had a qualitative arm where we attempted to assess perception of ANC services among patients with PES.

Our study has several limitations. The study design was a hospital based cross section study so it was not possible to infer causation. Also, collection of some of the information was retrospective, thus running the risk of recall bias.

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## CHAPTER 6: ANNEXES

### Annex 1: Letter to ERC

Dr Kohe Alexandre (MBChB)

H58/87615/2016

The Chairperson,  
Ethics, Research and Standards Committee,  
Kenyatta National Hospital and University of Nairobi,  
P.O. Box 20723,  
NAIROBI

Dear Sir/Madam,

**RE: SUBMISSION OF MASTERS 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 Gynecology at the University of Nairobi, College of Health Sciences.

Yours Sincerely,

Dr. Kohe Alexandre,  
Senior House Officer,  
Department of Obstetrics and Gynecology,  
College of Health Sciences  
University of Nairobi

**ANNEX 2: QUESTIONNAIRE**

**DATE:**

**SERIAL NO.**

**SECTION 1: INTERVIEW PROCESS. ENGLISH VERSION (TO BE FILLED WITH THE ASSISTANCE OF THE PRINCIPAL INVESTIGATOR IN CASES WHERE AN EXPLANATION IS REQUIRED): TICK IN THE BOX PROVIDED**

**SECTION A: SOCIODEMOGRAPHIC DATA**

1. Age (Years): \_\_\_\_\_

2. Education background:

a) Primary

c) Secondary

b) Thirdly

d) None

3. Religion

a) Catholic

c) Muslim

b) Protestant

d) Others: \_\_\_\_\_

4. Employment history:

a) Employed

c) Self-employed

b) Unemployed

5. Marital status:

a) Married (monogamous)

c) Separated

b) Married (polygamous)

d) Widowed

c) Divorced

e) Single

6. Do you currently smoke cigarettes' or use traditional tobacco? Yes  No

If the answer to question above is yes, indicate:

Number of sticks per day and total: \_\_\_\_\_

Number of years since you started smoking: \_\_\_\_\_

7. Do you currently drink alcohol? Yes  No

If the answer to question above is yes, indicate:

Type of drink: \_\_\_\_\_

Quantity: \_\_\_\_\_

Specify how often you drink: \_\_\_\_\_

**SECTION B: PAST OBSTETRIC HISTORY**

8. What was the outcome of the last pregnancy?

Livebirths (Term):  Livebirths (Preterm):

Stillbirths:

9. Which year was your last delivery? \_\_\_\_\_

10. Were there any complications during your last delivery?? Yes  No

11. If Yes (Please tick as applies from the list below)

- a) Bleeding  d) Hypertension   
b) Preterm birth  e) Others (specify  \_\_\_\_\_  
c) Infection (specify  \_\_\_\_\_

12. Have you delivered via Caesarean section? Yes  No

13. If yes to question 11 above, what was the indication?

- a) Bleeding in pregnancy  c) Previous Caesarean delivery   
b) Fetal distress  d) Failed induction

### **SECTION C: ANTENATAL HISTORY**

14. Did you ever attend Antenatal Clinics during your pregnancy? Yes  No

15. At what gestation did you attend your first ANC \_\_\_\_\_

16. If the answer to question 15 is yes, specify where:

- a) Dispensary  c) District hospital   
b) Provincial hospital  d) National hospital   
e) Faith Based Hospital  f) Private Hospital

17. How many ANC did you attend? \_\_\_\_\_

18. At what gestation in weeks were these Antenatal profile tests done? (Indicate gestation in weeks when each test was done):

	Test	Result	Not tested	Gestation in weeks done

a)	HIV test result			
b)	HepBSAg Result			
c)	VDRL			
e)	UECs			
f)	LFTs			
g)	Hemoglobin level:			
h)	Urinalysis			
i)	Blood group:			
j)	Blood sugar			

19. Was an ultrasound done before 24 weeks? Yes  No

20. Was Junior Aspirin initiated during your Antenatal Clinic? Yes  No

21. you had any chronic illness prior to this pregnancy? Yes  No

If yes to above, specify which illness: \_\_\_\_\_

22. Were you given antihypertensive drugs during your Antenatal Clinic? Yes  No

23. Were given a delivery plan during your Antenatal Clinic? Yes  No

24. Was your uterine fundal height palpated and corroborated with dates? Yes  No

25. Was your blood pressure being measured during your antenatal clinic? Yes   
No

26. Was your weight taken during your Antenatal Clinic? Yes  No

**COUNSELING ON DANGER SIGN DURING ANTENATAL CLINIC**

27.

		Yes	No
a)	Were you told to return if there was reduced or absence of fetal movements?		

b)	Were you told to return if you have severe headache/ blurred vision?		
c)	Were you told to return if you have swollen hands/feet?		
d)	Were you told to return if you have vaginal bleeding?		
e)	Did the health care provider inform you about the progress of your pregnancy?		

## **SECTION D – INTRAPARTUM CARE**

### **INITIAL ASSESMENT OF LABOR**

28.

		<b>Yes</b>	<b>No</b>
a)	Was a vaginal exam done?		
b)	Was the fetal heart rate monitored?		
c)	Was the fundal height, presentation and lie checked?		
d)	Was a general exam done?		
e)	Was urine output measured?		
f)	Was pulse taken?		
g)	Was temperature taken?		
h)	Were you asked about danger signs of pregnancy?		
i)	Was Magnesium Sulphate Administered?		
j)	Was your blood pressure monitored?		

### **FETAL OUTCOMES**

29. Fetal complications (Tick any box the applies)

a)	Fresh Still Birth	
b)	Macerated Still Birth	
c)	None	

30. Mode of delivery (tick one of the options below)

Spontaneous Vertex Delivery	
Vacuum Delivery	
Forceps Delivery	
Caesarean Section	

## NEONATAL OUTCOMES

31. Apgar score: \_\_\_\_\_

32. Birth weight: \_\_\_\_\_

33. Fetal admission to new born unit: Yes  No

34. Indication for admission: (Tick any box the applies)

a)	Birth Asphyxia	
b)	Neonatal Sepsis	
c)	Respiratory Distress Syndrome	
d)	Prematurity	
e)	Low birth weight	
f)	Other	

## MATERNAL OUTCOMES

35. Maternal outcomes

a)	None	
b)	Eclampsia	
c)	Postpartum hemorrhage	
d)	Intensive Care Admission	
e)	Acute Kidney Injury	
f)	HELLP syndrome	
g)	Antepartum Hemorrhage	
h)	Post-Partum Hemorrhage	
i)	Postpartum Cardiomyopathy	
j)	None	

## PERCIEVED QUALITY OF CARE

“Strongly Disagree” (1), “Disagree” (2), “Neither Agree Nor Disagree” (3), “Agree” (4) and “Strongly Agree” (5).

**INFORMATION EXCHANGE**

36.

		1	2	3	4	5
a)	I was informed about the various antenatal tests and procedures.					
b)	My questions were answered truthfully.					
c)	The ANC team managing me was constantly updated especially on critical information regarding me.					
d)	My ANC provider(s) ran all the test necessary for my pregnancy to ensue safely					
e)	My results were explained to me in way I understood					
f)	My ANC provider(s) answered my questions honestly					
g)	My ANC provider(s) gave me adequate information and involved me in every aspect of decision making regarding my care.					
h)	My ANC provider(s) ensured that my medical information was confidential					
i)	My ANC provider(s) fully explained to me the reasons for all my blood work and other tests during my ANC					

**ANTICIPATORY GUIDANCE**

37.

		1	2	3	4	5
a)	My ANC provider(s) gave me various options and subsequently allowed me to choose my birth experience.					
b)	I was assessed and fully informed about the importance of breastfeeding					
c)	My ANC provider(s) took me through my pregnancy and prepared me adequately for my birth experience.					
d)	My antenatal care provider(s) allowed me to voice my concerns regarding my expectations during the labor and delivery process.					
e)	I was fully informed about the importance of exercise during my pregnancy.					
f)	I was counseled on the importance of a balanced diet during my pregnancy.					
g)	My ANC provider(s) evaluated how my pregnancy was affecting my day to day activities.					

h)	My ANC provider(s) was able to help me find community programmes that were beneficial.					
i)	I was counseled about alcohol consumption during my pregnancy.					
j)	I was screened for depression and for postpartum depression pre- and post-delivery.					
k)	My ANC provider(s) ensured that they tackled every aspect my pregnancy that seemed important to me.					

### SUFFICIENT TIME

38.

		1	2	3	4	5
a)	During my ANC my ANC care provider(s) took as much time as I required.					
b)	My ANC services were always rushed					
c)	During my ANC my ANC provider(s) took time and subsequently ensured that they answered all my questions.					
d)	My ANC provider(s) were patient with me and allowed me to voice my concerns					
e)	During my ANC my ANC provider(s) took time to listen to my concerns					

### APPROACHABILITY

39.

		1	2	3	4	5
a)	My ANC providers were abrupt with me					
b)	I felt rushed during my ANC					
c)	My ANC providers made me feel like my questions were not valid					
d)	My ANC providers made me feel afraid to ask important questions					

### AVAILABILITY

40.

		1	2	3	4	5
a)	I was able to easily access my ANC providers					
b)	If I could get in-touch with my ANC providers they would always return my phone calls					



c)	My ANC provider(s) could easily be reached if I had any question or concern.					
d)	I could readily access my ANC provider(s) if I needed something urgently					
e)	I could always access my ANC provider(s) by phone when necessary					

## SUPPORT AND RESPECT

40.

		1	2	3	4	5
a)	My ANC provider(s) always treated me with respect					
b)	My ANC provider(s) always respected my input, knowledge and experience					
c)	My decisions were always respected by my ANC provider(s)					
d)	My ANC provider(s) were always patient with me					
e)	My ANC provider(s) always supported my decisions that felt right by me					
f)	My ANC provider(s) always supported me throughout my pregnancy					
g)	My ANC provider(s) always paid close attention when I was talking					
h)	All concerns were taken seriously during my pregnancy by my ANC provider(s)					
i)	I felt in control and owned all the decisions being made about my antenatal care					
j)	My ANC provider(s) supported all my decisions regarding my antenatal care					
k)	I felt at ease with my ANC provider(s)					
l)	My values, morals and beliefs were respected by ANC provider(s)					

## **ANNEX 3: CONSENT INFORMATION**

### **STUDY TITLE: INFLUENCE OF QUALITY OF ANTENATAL CARE ON PREGNANCY OUTCOMES AMONG PATIENTS WITH PRE-ECLAMPSIA WITH SEVERE FEATURES AT KENYATTA NATIONAL HOSPITAL**

#### Investigator

I, DR. KOHE D. ALEXANDRE, am a postgraduate student at the University of Nairobi Obstetrics and Gynaecology department. I am conducting the study, as part fulfilment for the award of the degree of Master of Medicine in Obstetrics and Gynaecology by the University of Nairobi. **Contacts: 0716947483 resident in Obstetrics and Gynaecology** at the University of Nairobi, **email [kohe.dukakis@gmail.com](mailto:kohe.dukakis@gmail.com)**, **postal address P.O.BOX 3002 – 00506, Nairobi.**

#### Supervisors:

1. DR. ALFRED OSOTI, Senior Lecturer of the Department of Obstetrics and Gynaecology, University of Nairobi. **Contacts: 0733886664. Email: [alfosoti@gmail.com](mailto:alfosoti@gmail.com) . Postal address, University of Nairobi College of health Sciences P.O.BOX 19676 code 00202.**
2. DR. GEORGE GWAKO, Lecturer, of the Department of Obstetrics and Gynaecology, University of Nairobi. **Contacts: 0722992268 Email: [gngwako@gmail.com](mailto:gngwako@gmail.com) Postal address, University of Nairobi College of Health Sciences P.O.BOX 19676 code 00202.**
3. PROF. MOSES OBIMBO, Associate Professor and Chairman of the Department of Human Anatomy, University of Nairobi. **Contacts: 0721585906. Email: [obimbomad@gmail.com](mailto:obimbomad@gmail.com) . Postal address, University of Nairobi College of health Sciences P.O.BOX 19676 code 00202.**
4. DR. FRANCIS KAGEMA Honorary Lecturer of the Department of Obstetrics and Gynaecology, University of Nairobi. **Contacts: 0722712186 Email: [kagemafrank@gmail.com](mailto:kagemafrank@gmail.com) Postal address, University of Nairobi College of Health Sciences P.O.BOX 19676 code 00202.**

## PURPOSE OF THE STUDY

To evaluate the association between quality of ANC and pregnancy outcomes among patients with PES managed at Kenyatta National Hospital.

## STUDY PROCEDURE:

You will be asked questions about your age, number of children, details of antenatal clinic attendance, whether you smoke, if you are currently on any medication or recently taken, any other illness you have had during the current pregnancy, duration and any other symptoms associated i.e. fever, pain. We will then look at your ANC clinic card and delivery records to see if there is quality of ANC that you received may have predisposed you to developing pre-eclampsia with severe features. We will also look at your pregnancy outcomes within 72 hrs. post-delivery.

## BENEFITS:

As a potential study participant, you may not directly benefit from the study, but the findings of the study will be used to provide guidelines and policy documents on treatment and standard of care that will benefit women with the same conditions in future.

## RECRUITMENT AND CONSENT

Study personnel will explain the research procedures to you in either English or Kiswahili language, subsequently ensure that you provide written information where necessary and must obtain written informed consent, before commencement of any study procedures.

## POTENTIAL RISKS

The study procedures do not pose any danger to you. The study staff are highly trained medical doctors and nurses. We take into consideration that answering some personal questions may be quite stressful. There will be no extra cost to you for participating in the study.

There will be no direct cash benefits to any participant in this study however treatment, intervention or prompt referral will be carried out if deemed appropriate.

## CONFIDENTIALITY

We will not use any identifier like your name or initials on the questionnaires. The information you give us will not be used for any other purpose other than from the study.

## MINORS

Pregnant women aged 14 years and above will be allowed to participate in the study. In Kenya, Pregnant women between 14 – 18 years are legally allowed to give consent. (Emancipated minors are pregnant women below the age of 18 years who got pregnant out of will.)

## VOLUNTARINESS OF PARTICIPATION AND WITHDRAWAL FROM THE STUDY

Participation is voluntary and you are free to decline the study or to withdraw from the study at any time. Declining to give consent or withdraw from participation will not influence your management in any way.

## FOLLOW UP

No follow up is required after participation in the study. However routine check-ups at the postnatal clinics is highly recommended.

## ETHICAL APPROVAL

This study has been reviewed and approved by the UON/KNH Ethics and Research Committee. If you need any further clarification regarding this study please contact the principal researcher:

**Dr. Kohe Alexandre** on **0716947483**, a resident in **Obstetrics and Gynaecology** at the University of Nairobi, email [kohe.dukakis@gmail.com](mailto:kohe.dukakis@gmail.com), postal address **P.O.BOX 3002 – 00506, Nairobi**. Or, the lead supervisor of the study **Dr. Alfred Oso**ti, Senior Lecturer at the University of Nairobi, department of Obstetrics and Gynaecology, on **0733886664**. Email: [alfosoti@gmail.com](mailto:alfosoti@gmail.com) . Postal address, **University of Nairobi College of health sciences P.O.BOX 19676 code 00202**.

**Or**

**The Secretary, UON/KNH-ERC**

**Tel, 020-2726300 ext. 44102. Email: [uonknh\\_erc@uonbi.ac.ke](mailto:uonknh_erc@uonbi.ac.ke)**

**Consent Form.**

I affirm that I have explained the study to the participant and sought voluntary informed consent from her.

Signature research assistant/principle investigator.....

Initials.....Date.....

The study has been fully explained to me and I duly accept to participate. I have not been coerced or cajoled in any way.

Initials of participant.....

Participant's .....signature/Thumb  
print.....Date.....

Witness initials.....Date.....

## **STUDY TITLE: INFLUENCE OF QUALITY OF ANTENATAL CARE SERVICES AND PREGNANCY OUTCOMES IN PATIENTS WITH PREECLAMPSIA WITH SEVERE FEATURES**

### **APPENDIX B: KISWAHILI CONSENT INFORMATION (Nakala ya itikio)**

Utaulizwa maswali juu ya umri wako, idadi ya watoto, maelezo ya mahudhurio ya kliniki ya wajawazito, ikiwa unavuta sigara, ikiwa unatumia dawa yoyote au umechukua hivi karibuni, ugonjwa mwingine wowote ambao umekuwa nao wakati wa ujauzito wa sasa, muda na dalili zingine zozote zinazohusiana yaani homa, maumivu. Halafu tutaangalia kadi yako ya kliniki ya ANC na rekodi za kujifungua ili kuona ikiwa kuna ubora wa ANC uliyopokea unaweza kuwa umekusudia kukuza pre-eclampsia na sifa kali. Tutaangalia pia matokeo yako ya ujauzito ndani ya masaa 72 baada ya kujifungua

### **LENGO LA UTAFITI:**

Tunakusudia kutambua ubora wa ANC wa akina mama walio na shinikizo la damu kali na jinsi ya kuhakikisha wanapata huduma nzuri.

### **KUSHIRIKI KWAKO NI KWA HIARI:**

Taratibu za utafiti hazina hatari kwako. Wafanyakazi wa utafiti ni madaktari na wauguzi waliofundishwa sana. Tunazingatia kuwa kujibu maswali kadhaa ya kibinafsi kunaweza kuwa ya kusumbua sana. Hakutakuwa na gharama ya ziada kwako kushiriki katika utafiti. Hakutakuwa na faida ya moja kwa moja ya pesa kwa mshiriki yeyote katika utafiti huu hata hivyo matibabu, kuingilia kati au rufaa ya haraka itafanywa ikiwa itaonekana inafaa

### **MATEMBEZI YA UTAFITI NA TARATIBU ZA UTAFITI**

Utaulizwa maswali juu ya umri wako, idadi ya watoto, maelezo ya mahudhurio ya kliniki ya wajawazito, ikiwa unavuta sigara, ikiwa unatumia dawa yoyote au umechukua hivi karibuni, ugonjwa mwingine wowote ambao umekuwa nao wakati wa ujauzito wa sasa, muda na dalili zingine zozote zinazohusiana yaani homa, maumivu. Halafu tutaangalia kadi yako ya kliniki ya ANC na rekodi za kujifungua ili kuona ikiwa kuna ubora wa ANC uliyopokea unaweza kuwa umekusudia kukuza pre-eclampsia na sifa kali. Tutaangalia pia matokeo yako ya ujauzito ndani ya masaa 72 baada ya kujifungua.

## TATIZO NA/AU KUKOSA STAREHE

Taratibu za utafiti hazina hatari kwako. Wafanyakazi wa utafiti ni madaktari na wauguzi waliofundishwa sana. Tunazingatia kuwa kujibu maswali kadhaa ya kibinafsi kunaweza kuwa ya kusumbua sana.

## FAIDA

Kama mshiriki anayeweza kushiriki katika utafiti hauwezi kufaidika moja kwa moja na utafiti, lakini matokeo ya utafiti yatatumika kutoa miongozo na hati za sera juu ya matibabu na kiwango cha utunzaji ambacho kitawanufaisha wanawake walio na hali kama hizo hapo baadaye.

## GHARAMA KWAKO

Hakutakuwa na gharama ya ziada kwako kushiriki katika utafiti. Hakutakuwa na faida ya moja kwa moja ya pesa kwa mshiriki yeyote katika utafiti huu hata hivyo matibabu, kuingilia kati au rufaa ya haraka itafanywa ikiwa itaonekana inafaa

## USIRI:

Hatutumia kitambulisho chochote kama jina lako au herufi za kwanza kwenye dodoso. Habari unayotupatia haitatumika kwa madhumuni mengine yoyote isipokuwa ya utafiti..

Utafiti huu umepitiwa na kupitishwa na Kamati ya Maadili na Utafiti ya UON / KNH. Ikiwa unahitaji ufafanuzi wowote zaidi kuhusu utafiti huu tafadhali wasiliana na mtafiti mkuu:

**Shida au maswali:** Ikiwa una maswali kuhusu haki zako kama mshiriki wa utafiti, yafaa uwasiliane na mtafiti mkuu **Dr.Kohe Alexandre** kwa nambari ya simu **0716947483**, barua pepe:**kohe.dukakis@gmail.com**, sanduku la posta **3002- 00506, Nairobi. Au msamizi mkuu Dr. Alfred Osoti** nambari ya simu **0733886664**, barua pepe:**alfosoti@gmail.com**, sanduku la posta, **University of Nairobi college of health sciences P.O.BOX 19676 code 00202.**

Au**Karani** wa kamati ya maadili ya utafiti ya **Hospitali ya Kitaifa ya Kenyatta na Chuo Kikuu cha Nairobi** Sanduku la Posta **19676-00202, Nairobi**, Nambari ya simu: **0202-272-6300 Ext 44355**; barua pepe:[uonknh\\_erc@uonbi.ac.ke](mailto:uonknh_erc@uonbi.ac.ke)

**Consent form (Kiswahili version)**



**Kauli ya itikio na sahihi:** Ninathibitisha kuwa nimeelezea utafiti kwa mshiriki na nimetafuta idhini ya hiari kutoka kwake. Utafiti umeelezewa kikamilifu kwangu na ninakubali kushiriki. Sijashurutishwa au kubanwa kwa njia yoyote.

_____	_____	_____
Jina la mshiriki (chapa)	Sahihi ya mshiriki/kidole gumba	Tarehe
_____	_____	_____
Mfanyikazi wa utafiti anaye Endeleza itikio (chapa)	Sahihi ya mfanyikazi wa utafiti	Tarehe
_____	_____	_____
Jina la shahidi	Sahihi ya shahidi	Tarehe

#### ANNEX 4: STUDY TIMELINES

<b>Activity</b>	<b>Feb 2019</b>	<b>Mar 2019</b>	<b>Apr 2019</b>	<b>May 2019</b>	<b>Jun 2019</b>	<b>Jul 2019</b>	<b>Aug 2019</b>
Proposal development	■						
Ethical approval		■					
Data collection			■	■			
Data analysis					■		
Final write up of results						■	
Presentation of results							■

## ANNEX 5: STUDY BUDGET

Item	Description	Amount in Ksh
Personnel	4 research assistants' allowances @Ksh 1000x 30 days	Ksh 120,000
	Data clerk/statistician@ 30,000Ksh	Ksh 30,000
Supplies	Draft proposals printing:70pages, 3 copies @Ksh 5shs per page	Ksh 1050
	Final proposal printing: 70 pages, 3 copies @5Kshs per page	Ksh 1050
	Questionnaires printing ,9 pages, @5 Ksh per page	Ksh 45
	Questionnaires photocopying, 9 pages, 150 copies @ 3 Ksh per page	Ksh 4050
	Airtime @ Ksh.1000 x 4 research assistant	Ksh 4000
Transport costs	4 research assistants x 1000	Ksh 4000
KNH/UON ERC	Submission to ERC (twice)	Ksh.2,000
Contingencies	-	Ksh, 5000
<b>Subtotal</b>		<b>162,195</b>
<b>Total</b>		<b>Ksh. 167,060</b>

### BUDGET NOTES

1. 4 Research Assistants will be enrolled into the study. 1 research assistants will recruit and interview participants in the postnatal wards (GFA, GFB and 1A) and 1 will enroll and interview participants in labor ward. They will be working daily for 10 hrs.
2. All the research assistants will be given Ksh.1000 airtime for communication with the principle investigator and themselves.
3. Contingency has been reviewed to 3% of the total budget.
4. Each research assistant will be paid Ksh. 1000 for transport. This is to cater for the transport of questionnaires to the principle investigator and statistician.
5. The statistician will be paid as per UON/KNH rates.

## **ANNEX 6: FUNDING AGENCY**

The study was self-funded upon approval by the KNH/UON Ethics Research Committee

Protocol No (859/12/2018)



UNIVERSITY OF NAIROBI  
COLLEGE OF HEALTH SCIENCES  
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**KNH-UoN ERC**

Email: [uonknh\\_erc@uonbi.ac.ke](mailto:uonknh_erc@uonbi.ac.ke)  
Website: <http://www.erc.uonbi.ac.ke>  
Facebook: <https://www.facebook.com/uonknh.erc>  
Twitter: @UONKNH\_ERC [https://twitter.com/UONKNH\\_ERC](https://twitter.com/UONKNH_ERC)

Ref: KNH-ERC/A/165

6<sup>th</sup> May, 2019

Dr. Kohe Alexandre  
Reg. No. H58/87615/2016  
Dept.of Obstetrics and Gynaecology  
School of Medicine  
College of Health Sciences  
University of Nairobi



Dear Dr. Kohe

**RESEARCH PROPOSAL: QUALITY OF ANTENATAL CARE SERVICES AND PREGNANCY OUTCOMES AMONG PATIENTS WITH PRE-ECLAMPSIA WITH SEVERE FEATURES MANAGED AT KENYATTA NATIONAL HOSPITAL (P859/12/2018)**

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 6<sup>th</sup> May 2019 – 6<sup>th</sup> May 2020.

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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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 Director, CS, KNH  
The Chairperson, KNH- UoN ERC  
The Assistant Director, Health Information, KNH  
The Dean, School of Medicine, UON  
The Chair, Dept. of Obstetrics and Gynaecology, UON  
Supervisors: Dr. Alfred Osoi, Dr. Frank Kagema, Dr. George Gwako, Dr. Moses M. Obimbo

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