

**PREDICTORS OF ADMISSIONS AMONG OBSTETRIC  
PATIENTS AT THE CRITICAL CARE UNIT,  
KENYATTA NATIONAL HOSPITAL**



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I hereby declare that this document does not contain any material that has been previously submitted for a degree or diploma in any university. It also does not contain any material that has been previously published unless where referencing has been used.

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## **LIST OF ABBREVIATIONS:**

- AMA: Advanced Maternal Age
- ARDS= Acute Respiratory Distress Syndrome
- ART: Assisted Reproductive Technology
- CCF= Congestive Cardiac Failure
- CCU: Critical Care Unit
- GCS: Glasgow Coma Scale
- HDP : Hypertensive Disorder of Pregnancy
- HDP: Hypertensive Disease of Pregnancy
- HELLP= Hemolysis, Elevated Liver Enzymes, Low platelets.
- HIC: High Income Countries
- IHD= Ischemic Heart Disease
- IVF : In Vitro Fertilization
- KDHS: Kenya Demographic Health Survey
- KNH: Kenyatta National Hospital
- LMICs : Low and middle income countries
- MI= Myocardial Infarction
- MMR: Maternal Mortality Rate
- PACU: Post Anaesthesia Care Unit
- PEC: Pre-eclampsia
- PPH: Postpartum hemorrhage
- SAMM: Severe Acute Maternal Morbidity
- SPO2: Peripheral Capillary Oxygen Saturation
- WHO: World Health Organization

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## ABSTRACT

**Background:** World Health Organization (WHO) describes severe maternal morbidity as near death (near miss) but survival from complications which occurred during pregnancy, childbirth or within 42 days of termination of pregnancy(1). Maternal morbidity and mortality is tragic, since pregnant women are generally young and healthy patients. Pregnancy, delivery and puerperium can be complicated by maternal morbidity therefore necessitating admission to a Critical Care Unit (CCU). Transfer to the CCU is usually one of the indicators of maternal morbidity(2).

Pregnancy is associated with significant physiological changes which may complicate the management of a critically ill patient. It is, therefore, necessary for both the patient and the care giver to understand these changes(3). Various factors could lead to delayed diagnosis and treatment of a complication such as; delay in access to fully equipped facility, poor ante-natal screening, low socio-economic status and lack of education(4) .

**Objective:** To determine the predictive factors leading to admissions of critically ill obstetric patients after delivery from 24 weeks gestation to 6 weeks post-partum into the CCU.

**Methods:** This was a prospective case-control study among obstetric patients from 24 weeks gestation to 6 weeks post-partum admitted in the Critical Care Unit (CCU) after delivery. Cases were recruited in the CCU and the controls were obstetric patients after delivery admitted in the labour ward. Controls were unmatched with the cases and were chosen after the indexed case. The presence of risk factors is rare in the general population of obstetric patients in the labour ward. Data was extracted from the patient files and additional information obtained from the patients. Statistical analysis was done in SPSS version 21.0 and the risk factors associated with CCU admission determined using odds ratios with p values at 5% level of significance. We used logistic regression to analyze the predictors of CCU admission. The study findings are hereby presented using figures, tables, pie-charts and bar-graphs.

**Results:** The study showed that an increase in pre-pregnancy Body Mass Index was a contributing risk factor for admission into the CCU. An increase in gestational age was protective, hence reducing the chance of being admitted into the CCU. The two commonest indications for admission were severe eclampsia and obstetric hemorrhage.



# 1.0 CHAPTER ONE

## INTRODUCTION

Every day, approximately 830 women die from preventable causes related to pregnancy and childbirth(5). 99% of all maternal deaths occur in Low and middle income countries (LMICs). Maternal mortality is higher in women living in rural areas and among poorer communities in these countries (6). The vulnerable group includes the adolescents who face a high risk of complications and death as a result of pregnancy. Understanding the basic physiology in pregnancy will help in the management of the obstetric patient. Maternal morbidity and mortality is an indicator of quality of obstetric care(7). It also calls for a multidisciplinary approach to the management of patients.

Pregnancy is associated with many maternal physiological and organ changes. These changes are primarily due to production of progesterone by the corpus luteum in early pregnancy and the placenta from ten weeks. It is associated with progressive enlargement of the uterus with increasing complexity and needs of the developing fetus. There are various changes that occur in organ systems, which return to normal after delivery.

In the cardiovascular system, there is an increase in the cardiac output by 30-50%. This increase is very sensitive to position because of compression of the inferior vena cava by the gravid uterus. During labor the cardiac output increases by another 30%. The heart rate and stroke volume also increase. These changes are due mainly to demands of the utero-placental circulation; they should, therefore, not be mistaken for cardiac dysfunction(8).

In the respiratory system, the lung function changes occur due to increase in progesterone levels and the enlarging uterus which interferes with lung expansion. The oxygen consumption rate increases due to increased metabolic demands by the fetus, placenta and maternal organs. The functional residual capacity is reduced, therefore, when the respiratory system is affected by illness, supplementary oxygen and mechanical/assisted ventilation may be employed to mitigate the decline in respiratory function(8).

Increase in the blood volume affects the distribution of drugs; therefore, drug dose adjustment should be considered.

In the Renal system, the creatinine clearance and glomerular filtration rate of drugs are increased; therefore, for drugs that are renally excreted, their dosing regimen should be adjusted to maintain therapeutic levels. Hydronephrosis could occur due to marked dilation of the ureters caused by the increased levels of progesterone and by back flow due to pressure from the enlarged uterus on the ureters(8).

## **1.1 Literature review**

### **1.1.1 Maternal mortality/ morbidity:**

According to World Health Organization “There is a story behind every maternal death and life-threatening complication; and understanding the lessons behind them can help to prevent bad outcomes”(9). Maternal mortality is higher in women living in rural areas and among poorer communities(1). Young adolescents face a high risk of complications and death as a result of pregnancy (1,10). However, the obstetric population is changing globally; clinicians are being presented with older mothers who have pre-existing disorders and advanced chronic medical conditions.

The fifth millennium development goal (MDG) aimed at improving health with a target of reducing the maternal mortality ratio by 75% between 1990 and 2015. Globally the maternal deaths declined from 523,000 in 1990 to 289,000 in 2013. In Africa the lifetime risk of dying during pregnancy and childbirth is 1 in 40. This, therefore, makes sub-Saharan Africa the most dangerous place for a woman to have a baby. The MMR in Kenya is 362 per 100,000 live births and it has not achieved significant improvement in the reduction of maternal deaths. It is, therefore, classified by WHO as making ‘insufficient progress’ towards achievement of the MDG since the average annual decline in maternal mortality has been less than 2%(11).

According to the Kenya Demographic Health Survey (KDHS) 2014, these maternal deaths account for 14% of all deaths to women aged 15- 49 years. In this survey, the maternal mortality ratio was 362 maternal deaths per 100,000 live births for the seven-year period preceding the survey. When comparing the estimate of an MMR of 362 with the MMR estimated in the previous KDHS (2008-09 KDHS estimate of 520 maternal deaths per 100,000 live births), the

differential was not large enough to conclude whether or not there had been any change over time between the two surveys. These numbers have, however, been decreasing over time. In 1990 the maternal mortality per 100,000 was 670, 590 in 1998 and 414 in 2003(12). Between 1990 and 2015, maternal mortality worldwide dropped by about 44%. Between 2016 and 2030, as part of the Sustainable Development Agenda, the target is to reduce the global maternal mortality ratio to less than 70 per 100 000 live births(12)

### **1.1.2 Physiological changes in pregnancy**

Pregnancy and labour are considered as physiological processes; the potential for catastrophic complications is constant and may develop in a matter of minutes. These changes may mimic a medical condition. The pregnant woman is usually young and in good health before some become critically ill during this period. This may arise from a previously undiagnosed condition, unmasked during pregnancy or just of sudden onset such as HDP (hypertensive disorder of pregnancy); hence, her prognosis will be better if she receives timely critical care intervention. This is now changing with many women at advanced maternal age (AMA) getting pregnant through ART/IVF. A deep insight and complete understanding of the physiological needs of both the mother and foetus pose a big challenge during critical illness situations.

Critically ill obstetric patients pose a challenge in treatment to the intensivist because of the physiological changes that are associated with pregnancy(13).

Similarly, advances in medical care have led to increasing numbers of complex, high risk obstetric patients. Having sound knowledge of the normal physiology is essential to optimize outcomes.

### **1.1.3 Severe Obstetric Morbidity**

Obstetric patients requiring critical care unit (CCU) admission may reflect near-miss maternal mortality or Severe Acute Maternal Morbidity (SAMM)(14). The global prevalence of SAMM is about 0.015%-8.23%. A maternal near-miss case is defined as “a woman who nearly died but survived a complication that occurred during pregnancy, childbirth, or within 42 days of termination of pregnancy(14,15)”. Near miss events are strongly correlated with death and may

provide relevant insight into the impact of maternal factors and quality of obstetric care and outcomes(16).

Most pregnancy-related critical care illnesses occur during the postpartum period (12). During the antenatal period, the patient is likely to be admitted with diseases non-specific to pregnancy such as pneumonia. Pregnancy-specific diseases resulting in CCU admission include obstetric hemorrhage, pre-eclampsia/eclampsia, HELLP (Hemolysis, Elevated Liver enzymes, and Low Platelet count) syndrome, acute fatty liver of pregnancy, amniotic fluid embolism and peripartum cardiomyopathy. Critical illness could also result from pregnancy-induced worsening of pre-existing diseases; kidney disease and valvular heart disease. Pregnant women are also predisposed to diseases seen in non-pregnant women; asthma, acute respiratory distress syndrome, pyelonephritis or pulmonary embolism. The pregnant woman can develop conditions co-incidental in pregnancy, e.g. trauma, intestinal obstruction or appendicitis(17).

According to the Confidential Enquiry into Maternal Deaths in Kenya (CEMD) conducted between June 2015 and July 2016, 486 deaths were assessed. The causes of maternal death were obstetric hemorrhage 192 (39.9%), non-obstetric complications/indirect maternal deaths 96 (19.8%) and hypertensive disorders associated with pregnancy 74 (15.2%). Out of these deaths 49.8% were referrals from other hospitals; mostly the sub-county hospitals(18).

### ***1. Obstetrical Hemorrhage(19):***

The incidence of obstetric hemorrhage in the high income countries is gradually decreasing. According to the Confidential Enquiry into Maternal Deaths (CEMD - 2014) in the United Kingdom, direct causes of maternal morbidity and mortality have declined hence more cases of indirect causes are causing maternal mortality such as genital tract sepsis, amniotic fluid embolism, thromboembolism, and anaesthesia related causes(20).

Obstetrical haemorrhage may occur antepartum, intra-partum or postpartum. It is the leading cause of maternal mortality worldwide, though higher in the LMICs.

Postpartum hemorrhage is defined as; blood loss >1000mls (14). In 60-70% of patients, postpartum hemorrhage is due to uterine atony following delivery. Placental retention is seen in 20-30%. In some of these cases it is due to abnormally implanted placenta (AIP). Aggressive coordinated multidisciplinary approach between obstetricians, midwives and the anesthesiologists is required(17). Each delivery unit is expected to have a protocol for the management of PPH and this will save lives.

## **2. *Pre-eclampsia*(19):**

This is a multisystem disease characterized by impaired organ perfusion resulting in vasospasm and activation of the coagulation system.

Pre-eclampsia is defined as hypertension and proteinuria occurring after 20<sup>th</sup> week of gestation and resolves 6-12 weeks after delivery. However, it is now known that the process of pre-eclampsia may be starting much earlier in pregnancy from 16 weeks or even earlier.

Pre-eclampsia with severe features is defined as one of the following:

- Severe hypertension; systolic blood pressure above 160mmHg or diastolic blood pressure above 110mmHg.
- Oliguria; less than 400ml/24hrs
- Cerebral irritability
- Proteinuria >5g/24hrs
- Epigastric or right upper quadrant pain
- Pulmonary edema

## **3. *Eclampsia*(19):**

Eclampsia is a complication of pre-eclampsia. It is defined as; occurrence of seizures in the absence of other neurological disorders in a pregnant woman with hypertension. Convulsions may occur during pregnancy or in the first 10 days postpartum together with at least two of the following features within 24 hours after the convulsions:

- Hypertension ( $>170/110$ mmHg), though patients may still convulse even with blood pressures lower than this.
- Proteinuria ( $>+$  on dipstick)
- Thrombocytopenia( $<100 \times 10^9/l$ )
- Elevated liver enzymes especially aspartate aminotransferase( $>42U/l$ )

#### 4. *HELLP Syndrome*(19):

Majority of patients with HDP may present with this syndrome at any gestation.

This syndrome is a constellation of findings that include:

- Hemolysis with a microangiopathic hemolytic anaemia
- Elevated liver enzymes
- Thrombocytopenia( $<100 \times 10^9/l$ )

#### 5. *Sepsis*:

Sepsis is a systemic response to infection manifested by two or more of (14):

- Temperature  $>38$  degrees Celsius
- Heart rate  $>100$  beats/minute
- Respiratory rate  $>20$  breaths/minute

- White cell count  $>17 \times 10^9/l$
- Bacteremia; positive blood culture
- Elevated CRP

Severe sepsis is associated with one of the following(19):

- Tissue hypo-perfusion; leading to lactic acidosis, oliguria
- Organ dysfunction; acute renal failure, liver failure
- Altered mental state
- Hypotension; systolic blood pressure  $<90\text{mmHg}$  or drop of  $>40\text{mmHg}$  in the absence of other causes of hypotension

Pregnancy exposes women to specific infections, e.g. pyelonephritis (colonization of the kidney with Gram-negative bacteria), chorioamnionitis, endometritis and pneumonia. The most common source of infections leading to chorioamnionitis is oral infections in pregnancy. Therefore, oral care is of paramount importance in pregnancy.

The most recent maternal mortality report in the UK revealed that sepsis was the leading cause of death(20)

#### Predictors of admissions in LMICs:

Admissions of critically ill patients in the LMICs vary from those in the HICs (High Income Countries). The profile of mortality rates in the HICs are between 0%-9.4%, whereas in the LMICs, they range from 33%-52%(7). This wide gap between the two groups is due to a combination of factors: poverty, illiteracy, lack of awareness about health complications, social and behavioral factors and paucity of research in obstetric critical care. In the HIC (High income countries) they

have quality obstetric care, well equipped labour wards, functioning obstetric post anaesthesia care units (PACU), evidence based practice and financial adequacy.

Data from Africa; Nigeria and Kenya has shown high maternal morbidity and mortality with obstetric hemorrhage and complications of Severe Pre-eclampsia and eclampsia. In a study in Kenya by Githae on: “Course and outcome of Obstetric patients admitted to a University Hospital Intensive care”; forty two patients were admitted in the CCU from November 2003 to November 2010. Indications for admission were hemorrhage 44%, sepsis 26%, HELLP syndrome 12%, and thromboembolism 6%(21).

Another study from Nigeria by Okafor et al on: “Risk factors for maternal deaths in unplanned obstetric admissions into the intensive care unit in Nigeria” from January 1997 to December 2006 revealed that there were 25 unplanned obstetric admissions. Indications for these admissions were pre-eclampsia/eclampsia 41.1%, hemorrhage 37.5%, and respiratory distress 12.5%. There were 12 deaths (48%). The risk factors associated with mortality were organ dysfunction on admission, massive blood loss (>1000mls) and late presentation. The high mortality in the study was due to limited supply of blood products and inadequate prenatal care resulting in increased disease severity(22).

A study done in Nigeria by A.S. Adeniran et al measuring “Predictors of maternal mortality among the Critically ill Obstetric patients 2013” showed that the mean age of subjects and controls was  $28.92 \pm 5.09$  versus  $29.44 \pm 5.74$  ( $p = 0.736$ ), the level of education was higher among controls ( $p = 0.048$ ) while more of the cases were of low social class ( $p = 0.321$ ), did not have antenatal care ( $p = 0.131$ ) and had partners with lower level of education ( $p = 0.156$ ) compared to controls. The two leading indications for admission among cases and controls were massive postpartum haemorrhage (>1000mls) and severe pre-eclampsia. The mean duration of admission was higher among controls ( $3.32 \pm 2.46$  versus  $3.00 \pm 2.58$ );  $p = 0.656$ ) while the mean cost of CCU care was higher among the cases ( $p = 0.472$ ). The statistically significant predictors of maternal deaths were the patient’s level of education, low Glasgow Coma Scale (GCS) score on admission, low oxygen saturation, multiple organ failure at CCU admission and the need for mechanical ventilation or inotropic drugs after admission. They, therefore, concluded that early recognition of the need for CCU care, adequate pre-CCU admission supportive care and prompt transfer would improve outcome(4).



Poverty remains one of the major barriers to human development in Kenya. A study published in 2015 on “Reasonable Goals for Reducing Poverty in Africa - Targets For Post 2015 MDGs And Agenda 2063” ranked Kenya sixth among top 10 countries in Sub-Saharan Africa with large populations living in extreme poverty. A study by Lanre-Abass BA et al from Nigeria on “Poverty and maternal mortality in Nigeria” concluded that poverty is a major barrier to human development. It is a contributor to maternal morbidity and mortality as the mothers are unable to access adequate care. This, therefore, hinders the number of ante-natal visits(23).

According to the latest data by UNICEF on maternal health( May 2016); Globally 85% of pregnant women access antenatal care with skilled health personnel at least once, only six in ten receive at least four antenatal visits. In sub-Saharan Africa and South Asia fewer women receive at least four antenatal visits; 42-49%. This is because of poverty and low level of education (24). In Kenya with the introduction of free maternal care in June 2013, up to 63% of women now have skilled attendance at birth compared to 46% previously. Nearly 90% have at least one ANC attendance during the pregnancy(25).

Lack of adequate maternal healthcare is also a contributor to severe maternal morbidity and mortality. The goal to improving care is improving poverty levels and empowering women. A study done by Lucie MT Byrne Davis et al (2015) on “Understanding implementation of maternal acute illness management by measuring capability, opportunity and motivation” concluded that a major cause of maternal death in low income countries is lack of adequate healthcare (26).

#### **1.1.4 Predictors of maternal admissions in developed countries**

In the west, the obstetric population is changing, increasingly presenting clinicians with older mothers who have pre-existing disorders and advanced chronic medical illnesses like essential hypertension, diabetes(27). It is, therefore, essential to adopt an early multidisciplinary approach in their management.

In the HICs, Obstetric hemorrhage and pre-eclampsia are no longer the leading causes of severe maternal morbidity since they are recognized early and managed. Sepsis is the current leading cause of maternal mortality(17)

A study done in Greece by Al-Zirgi et al on “Prevalence and risk factors of severe obstetric hemorrhage” showed that pregnant women above the age of 30 are at a high risk of hemorrhage hence a higher risk of being admitted to the critical care unit (28).

If severe obstetric morbidity is a tip of the iceberg, having maternal units with independent Critical Care Units is essential to improving maternal care. In the High Income Countries they have modern fully equipped labour wards, quality obstetric care, maternal critical care units and evidence based practice .A study done by G. Kostopanagioutou in Greece over a four-year period to identify the effects of using PACU for high risk obstetric patients showed that it was successfully used as an intermediate facility to treat high risk patients, thus avoiding unnecessary CCU admissions(29).

**Table 1: Critical care admission criteria:**

The admission criterion is based on the critical nature of the underlying disease process. The criterion is almost similar to the triage principle as per the guidelines of the Joint Commission. Admission should be within the following guidelines.

<i>Organ System</i>	<i>Clinical Indications</i>
General/ Obstetric	Sepsis, severe pre-eclampsia, Eclampsia, HELLP syndrome, Amniotic fluid embolism, PPH
Pulmonary	Severe asthma, severe pneumonia, ARDS, respiratory failure, pulmonary oedema, pulmonary embolism
Cardiac	Valvular heart disease, rheumatic heart disease, CCF, severe hypertension, IHD, MI, peripartum cardiomyopathy, dysrhythmias

Renal	Acute pyelonephritis, renal failure
Endocrine	Diabetic ketoacidosis, thyrotoxicosis, pancreatitis
Gastrointestinal	Hepatic failure, HELLP Syndrome
Hematological	Coagulation disorders, Anaemia
Surgical/ anaesthetic complications	Anaesthetic complications during surgery for caesarian section, surgical complication on table

Goals in management of critically ill obstetric patients involve intensive monitoring and physiologic support for patients with life-threatening but potentially reversible conditions. Multidisciplinary approach is essential in the management of critically ill obstetric patients. Understanding the physiological changes of pregnancy and the course of the diseases that complicate pregnancy is essential to provide optimal quality care (30)

## **2.0 CHAPTER TWO**

### **STUDY JUSTIFICATION**

Severe maternal morbidity is an important measure of quality assurance. Pregnancy is a physiological state that needs to be thoroughly understood. Majority of our pregnant women are young and should carry the pregnancy and deliver safely. Management of obstetric patients in the labour ward and the Critical Care Unit (CCU), requires vigilance and having adequate knowledge. This study was, therefore, expected to improve the quality of care.

Since the introduction of free maternity care in June 2013 by the Government of Kenya, Kenyatta National Hospital has had more pregnancy related admissions leading to increased admissions of mothers into the Critical Care Unit (CCU). This study, therefore, intended to identify any preventable and unpredictable factors that lead to admission into the CCU.

Admission of a critically ill obstetric patient is largely unpredictable but preventable. Improved maternal outcomes have a great socio-economic impact because the newborn babies experience maternal care and reduced cost of medical bills associated with prolonged hospital stay. Being in the critical care unit is nearly always an unforeseen and frightening experience for women and their families.

Early recognition and prompt management will reduce the financial burden on the patient and her relatives and also reduce the cost of health care. It will ensure that relatives don't have to experience the psycho-social stress involved when one is admitted to the critical care unit. It will also ensure that the newborns receive immediate maternal care.

No local data exists in determining the predictors of CCU admissions for obstetric patients. This study will form a basis for improvement in analyzing and carefully managing pregnant mothers. The study highlights predictive factors that are associated with CCU admissions of critically ill obstetric patients.

The findings of this study will help in assessing the execution of Article 43 of the Kenya Constitution, 2010 which states that: "every person has a right to the highest attainable standard of health care services, including reproductive health care". Recommendations will be put in place

by designing pathways at local levels which will ensure that a critically ill patient accesses equitable care irrespective of location

### **3.0 CHAPTER THREE**

#### **STUDY QUESTION**

What are the predictive factors leading to admissions of obstetric patients in the Critical Care Unit in KNH, from 24 weeks of gestation to 6 weeks postpartum; from October 2017 to February 2018?

#### **3.1 Broad Objective:**

To determine the predictive factors leading to admissions amongst critically ill obstetric patients post-delivery from 24 weeks gestation up to 6 weeks post-partum admitted at the CCU.

#### **3.2 Specific Objectives:**

1. To determine the socio-demographic characteristics of obstetric patients admitted in the CCU.
2. To establish the indications for admissions into the CCU.
3. To evaluate pre-CCU admission interventions offered to the obstetric patients
4. To identify the predictive factors for admission into the CCU

## **4.0 CHAPTER FOUR**

### **RESEARCH METHODOLOGY**

#### **4.1 Study design**

This study utilized un-matched case-control design to determine risk factors that predicted admission of obstetric patients post-delivery from 24 weeks gestation to 6 weeks post-partum in the CCU.

#### **4.2 Study site**

This research was carried out at the Kenyatta National Hospital. KNH is the largest referral and teaching hospital in Kenya. The clientele of the Kenyatta national hospital is national in outlook with both rural and urban population.

The bed capacity in the hospital is approximately 1,800; it has 50 wards, 20 outpatient clinics, 24 operating theatres and accident and emergency department. The maternity unit has three wards and a labor ward.

The study took place in the Critical care unit (CCU), satellite CCUs and labour ward. The use of these satellite CCUs is because of limited bed capacity in the main CCU. The CCU at Kenyatta National Hospital is well-equipped with 21 beds. Other auxiliary CCUs include: Acute Room, Cardiothoracic CCU, Neurointensive CCU, NICU, PICU and Medical Ward CCU. The units are mainly manned by consultant Anesthesiologists and Anesthesia registrars (SHOs) with the help of other physicians. Labour ward is manned by consultant obstetricians and Obstetrics registrars (SHOs).

#### **4.3 Study Population**

**Cases:** All obstetric patients admitted to the Critical Care Unit after delivery from 24weeks gestation to 6 weeks post-partum

**Controls:** Unmatched random sample of post-partum mothers who deliver normally in KNH on the same day without following CCU admission

#### **4.4 Inclusion/ exclusion criteria:**

##### **4.4.1 Inclusion criteria**

The consent was sort from either the patient or next of kin.

- All consenting obstetric patients after delivery from 24 weeks gestation to 6 weeks post-partum admitted to the CCU for the cases.
- All consenting obstetric patients after delivery from 24 weeks gestation to 6 weeks post-partum admitted to the CCU due to non-obstetric cause
- All consenting mothers who deliver from other facilities and are referred to KNH for CCU care
- All consenting mothers who need CCU care and are awaiting admission to the unit
- For the controls, all obstetric patients who deliver normally in labour ward on the same day without morbidity

##### **4.4.2 Exclusion criteria**

- Delivery before 24 weeks gestation
- ICU admission after 6 weeks post-partum
- Patients in whom consent was declined or unobtainable

#### **OPERATIONAL DEFINITION:**

Severe maternal morbidity will be defined as; any woman with any clinical condition compatible with criteria established by Mantel et al(31) defining it during gestation, delivery or in the first 42 days of peuperium.

Criteria:

1. Admission to the CCU for whatever reason
2. Hypovolemia requiring 2 or more units of packed red blood cells
3. Pulmonary edema
4. Sepsis
5. Intubation and ventilation for more than 60 minutes except for general anesthesia



6. Diabetic ketoacidosis
7. Coma for more than 12 hours
8. Cardio-respiratory arrest
9. Peripheral oxygen saturation <90% for more than 60 minutes
10. Severe pre-eclampsia
11. Sub-arachnoid or intra-parenchymal hemorrhage
12. Anaesthetic accident: Severe hypotension due to regional anaesthesia
13. Thyrotoxic crisis

#### 4.5 Sample size estimation

This study compared risk factors associated with ICU admission among obstetric patients. Previous studies have reported various factors associated with this condition and for the purpose of sample size estimation pre-eclampsia, with high prevalence among ICU patients (Mungai et al, 2014), will be used. Sample size was calculated using a formula for comparing 2 proportions as follows:

$$n = \frac{2(Z_{1-\alpha/2} + Z_{1-\beta})^2 P_{av}(1-P_{av})}{(P_0 - P_1)^2}$$

N is the sample size required in each group

$Z_{1-\alpha/2}$  refers to the level of significance or confidence interval = 1.96 for 95% CI

$Z_{1-\beta}$  refers to the power of obtaining difference between the two groups = 0.84 for 80% power

$P_0$  – Proportion of pregnant women with pre-eclampsia in the control group = 2% (Abalos et al, 2013)

$P_1$  – Proportion of ICU admitted obstetric patients with pre-eclampsia = 34% (Mungai et al, 2014)

$P_{av}$  – Average proportion of pre-eclampsia in the two groups = 18%

Substituting into the formula:

A minimum sample size (n) of **20** women in the case group and **40** in the control group was required to establish the risk factors of ICU admission in obstetric patients.

An attrition of 10% was allowed to cater for any missing data or patient drop out after recruitment.

## **4.6 Sampling procedure**

### **4.6.1 Selection of cases**

The cases were identified using convenient sampling procedure where the investigator reviewed the CCU admission register daily to identify all obstetric patients who had delivered after 24 weeks gestation and up to 6 weeks post-partum admitted in the CCU. The admissions that were eligible for this study were approached and those meeting the inclusion criteria were enrolled consecutively into the study.

### **4.6.2 Selection of controls**

The controls of this study were selected from all maternal cases who delivered in labour ward without any complications. Controls were unmatched with the cases and were chosen after the indexed case. The presence of the risk factors was anticipated to be rare in the general population of obstetric patients in the labour ward. The controls were randomly selected from labour ward using simple random sampling procedure. Selection was done by generating a sampling frame from the admission register in the labour ward. A list of random numbers was also generated in Microsoft Excel and then used to randomly select the study participants from the sampling frame. This was done until the total number required for the controls was achieved.

## **4.7 Recruitment and consenting process**

The patients who were eligible for the study were approached and given information about the study. The consenting process involved providing information on the study procedures, the benefits, risks, confidentiality, and the fact that any patient who volunteered to participate and opted not to be recruited did not compromise the level of care given. The patients who consented

to participate were asked to sign a consent form. Consent from the relatives or caregiver was sought for those patients who were too sick to consent.

#### **4.8 Data collection**

Data collection in the CCU for the cases was done only by the principal investigator. A research assistant with clinical background was recruited and trained to collect data for the controls in the maternity/ labour ward. Data was collected both from the patient directly and also abstracted from the patient files. The social demographic information and clinical history were obtained from the patient or caregiver. The information related to the current admission in CCU and maternity was abstracted from the files. All the information was entered in a structured data collection tool. The main variables that were incorporated into the tool included:

- Socio-demographic factors: Age, parity, social class, booking status, level of education, smoking/drug use, Alcohol intake history
- Pre- pregnancy Body Mass Index(BMI)
- Indication for admission
- Admission Parameters: GCS, SPO2, Respiratory rate, Pulse rate, Blood pressure, multiple-organ complication
- Gestation at delivery
- Previous obstetric history of PPH, PET.
- Associated comorbidities
- Mode of Delivery
- Obstetric care Team
- Source of patient: KNH patient or referral
- Treatment/interventions before CCU admission
- Preadmission laboratory and imaging findings

##### **4.8.1 Data quality assurance**

The principal investigator ensured the data was of high quality by putting in place controls at every stage of sampling and data collection. The investigator ensured all the data collection tools were completely and coherently filled. In addition, the investigator and the research assistant routinely

checked through the tools at the end of each interview and any inconsistency was resolved immediately before the study participant was released.

#### **4.8.2 Data management and analysis**

Data was entered and managed in pre-coded Microsoft Excel data entry sheet as data collection progressed. At the end of data entry and cleaning, data was exported to SPSS version 21.0 software for statistical analysis.

The study population was described using demographic and clinical characteristics by summarizing categorical data into percentages and continuous data into means or medians. Indications for CCU admissions were summarized and presented as proportions. CCU parameters were presented as means and percentages as appropriate.

Cases and controls were compared using Chi square test of associations for categorical data, independent t test for comparing means and Mann Whitney U test for comparing non-normally distributed continuous data.

The risk factors for CCU admission were determined and presented based on odds ratios as estimates of relative risk of admission associated with the exposure variable of interest. Multiple logistic regression analysis was performed to determine the independent factors predicting CCU admission among obstetric patients. Statistical test was interpreted at 5% level of significance.

#### **4.8.3 Data Storage, Privacy/security and Archival**

All data collected shall be kept locked and confidential at all times and only accessible to the investigator and data manager.

Electronic forms of data shall be protected with confidential passwords at all times.

Data will be preserved until analysis, presentation and archival are done.

## 5.0 CHAPTER FIVE

### **Ethical considerations:**

1. No names of patients were used in this study
2. The study did not have harmful effects on subjects, not entailing any invasive procedures, drug administration or omission nor present any hazard whatsoever.
3. No extra cost was incurred by the study subjects
4. Study subjects who declined inclusion in the study were able to leave the study at any point without victimization or compromise to their clinical management.
5. The study findings will be shared with the University of Nairobi and Kenyatta National Hospital administration to facilitate improvement of patient care and development of SOPs
6. Permission was sought from Kenyatta National Hospital- University of Nairobi Ethics and Research Committee before undertaking the study after the departmental approval.
7. Institutional clearance for this study was sought and obtained from the Kenyatta National Hospital administration
8. None of the patients that declined consent were denied access to appropriate care.

## **6.0 CHAPETR SIX**

### **RESULTS**

#### **6.1 Study period**

All eligible participants were recruited from October 2017 to February 2018 at the Kenyatta National Hospital Critical Care Unit and Maternity Wards.

#### **6.2 Dataset**

The data consists of measurements obtained from a total of 71 subjects from both the cases and control groups. Two sets of questionnaires were used for the two groups. There were a total of 12 variables in the data set. The response variable was to assess predictive factors that would lead to CCU admission of the obstetric patient.

#### **6.3 Study Sample Characteristics**

A total of seventy one patients were recruited to the study. Fifty subjects were selected into the control group and twenty one into the cases group. All were females identified from the maternity wards and the CCU. In the control group, the youngest and oldest subjects were aged 15 and 43 years respectively whereas in the cases group the youngest and oldest were 18 and 39 years respectively. From Table1 the mean ages in the two groups were (28.3+/-6.4 versus 28.1+/- 6.4; P value 0.944) and mean parities (2.5+/-1.4 versus 2.0+/-1.0; P value 0.204) were similar.

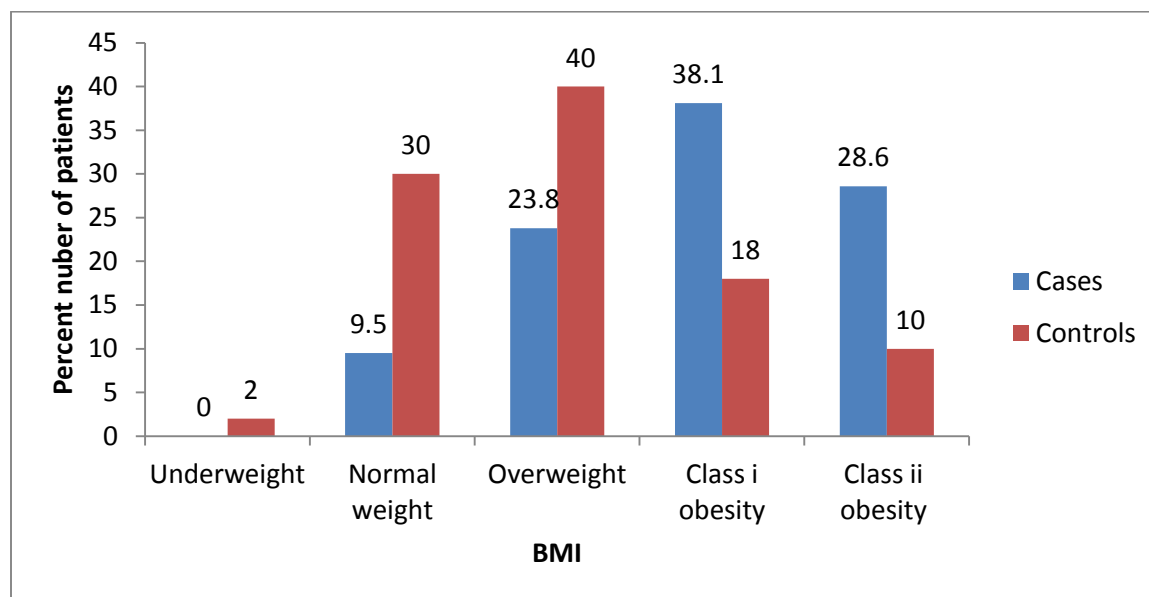
The level of education in the two groups was almost evenly distributed in the two groups (Cases: 50% lower, 50% upper; Controls: lower 42.9%, upper 57.1%). Multiparity was noted in the two groups.

Analysis of the body mass index in the two groups was conducted. The mean Standard deviation in the cases and control was 33.7+/- 8.2 and 27.8+/- 7.0 respectively. One subject in the control group was underweight (2%). For normal weight category; cases 2 (9.5%) and controls 15 (30%). The overweight category; cases 5(23.8%) and controls 20 (40%). Class I overweight category; cases: 8(38.1%) and controls: 9(18%). For class II overweight; cases 6 (28.6%) and controls 5(10%). The p value was 0.003 hence this parameter was statistically significant.

The number of antenatal clinic visits was statistically significant with the mean being; cases: 3.0+/-1.0 and controls: 4.3+/-1.8 with a p value 0.004. The gestation by age was also statistically significant with averages of 35.7+/-4.4(cases) versus 38.8+/-1.3(controls); p value <0.001.

Amongst the seventy one subjects only one took recreational drugs. This subject reported to have been taking marijuana occasionally.

It was noted that four subjects took alcohol in the cases group; other subjects did not have a history of alcohol intake. This was statistically significant; p value 0.006.



**Figure 1: Body mass Index**

In figure 1, it shows that the majority of cases were in class I and II obesity compared to controls.

#### 6.4 Admission History

In Table 2 the two commonest reasons for admission into the CCU were severe eclampsia and obstetric hemorrhage with a frequency of 40% and 20% respectively. Other indications for CCU admission included respiratory distress (5%), post cardiac arrest (5%), poor reversal from General Anaesthesia (10%), rheumatic heart disease (5%), and intra-abdominal sepsis (5%). The mode of admission into the critical care unit involved either referral from another facility (81%), transfer from the ward in the hospital (14.2%) or transfer from theatre (4.8%).

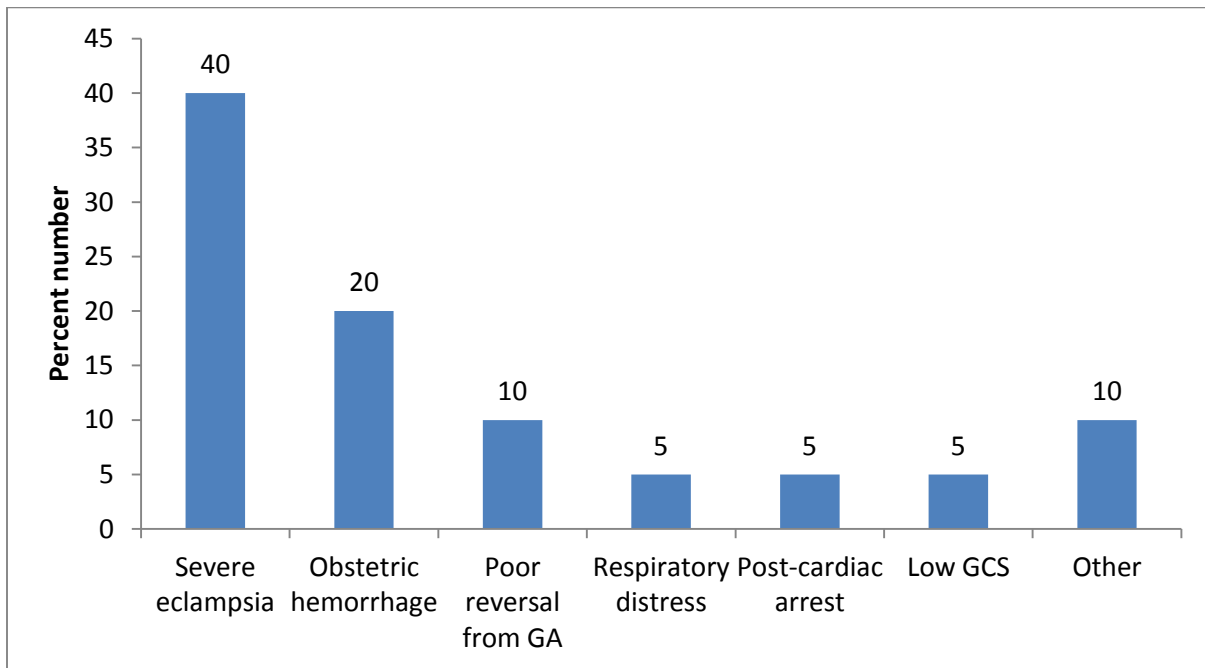
Before admission into the CCU, the cases were managed mostly by the obstetric consultant (71.4%), the obstetric registrar (71.4%) and the midwife (81%).

Various treatment interventions had been offered to the subjects before admission including transfusion of blood and blood products (57.1%), oxygen supplementation awaiting CCU admission (90.5%), hemodialysis (4.8%) and cardiopulmonary resuscitation (19.0%).

The vital signs before admission were an average pulse rate of 110.8 (SD 20.4), respiratory rate of 25 breaths/min (IQR 18.5-31.0), systolic blood pressure of 138 (SD 34.7) and SpO<sub>2</sub> of 95% (SD 3.5).

Most (76.2%) of the cases that were admitted into the CCU had low Glasgow Coma Scale (< 8T).

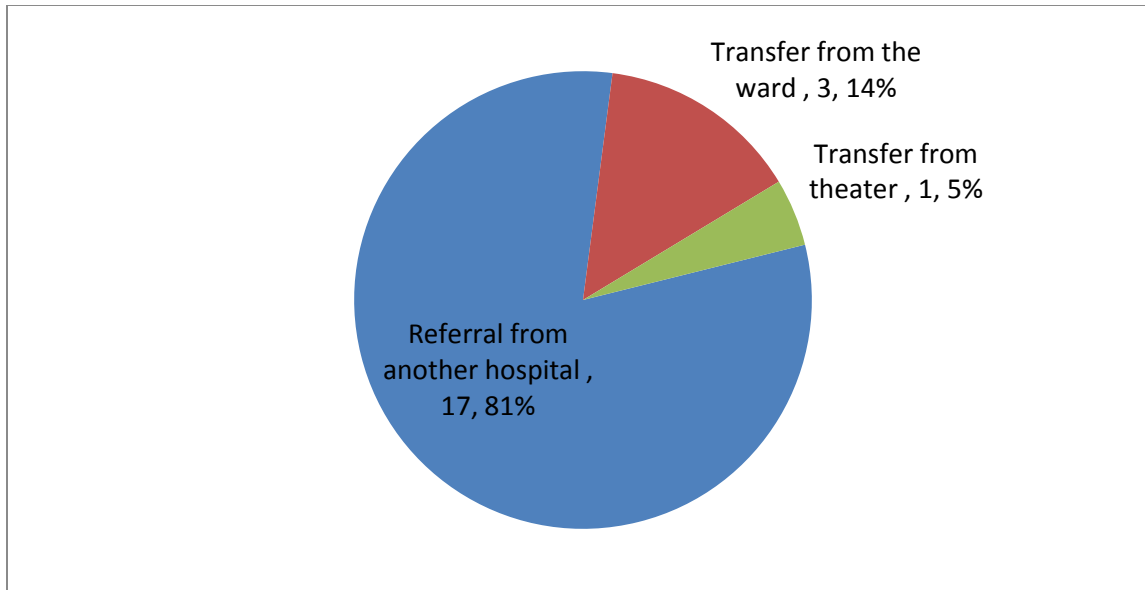
The others had either mild (14.3%) or moderate (9.5%) Glasgow coma scale (GCS).



**Figure 2: Admission history**

The leading cause of admission into the Critical care unit was severe eclampsia (40%), followed by obstetric hemorrhage (20%).





**Figure 3: Mode of Admission**

The majority of admissions into the Critical Care Unit were referrals from other hospitals (81%) followed by internal transfers from the KNH wards (14%).

**6.5 Obstetric History**

In Table 3 the obstetric history was analyzed; three subjects (14.3%) in the cases group had previous obstetric complications with 10 (20%) in the control group.

In these same subjects, eighteen (85.7%) in the cases and fifty (100%) in the control group attended antenatal clinics in their current pregnancy. These subjects also reported alarming signs in their pregnancy; six subjects (28.6%) in the cases versus thirteen (26.0%) in the control group.

Some subjects also reported associated illnesses in the current pregnancy; seven subjects (33.3%) in the cases versus fourteen (28%) in the control group.

Most of the subjects had caesarian deliveries; 12 subjects (57.1 %) in the cases group and thirty one (62%) in the control group

**Table 2: Obstetric history**

<b>Variable</b>	<b>Cases n (%)</b>	<b>Controls n (%)</b>	<b>OR (95% CI)</b>	<b>P value</b>
<b>Any previous obstetric complications</b>				
Yes	3 (14.3)	10 (20.0)	0.7 (0.2-2.7)	0.742
No	18 (85.7)	40 (80.0)	1.0	
<b>Attended ANC in current pregnancy</b>				
Yes	18 (85.7)	50 (100.0)	-	0.023
No	3 (14.3)	0		
<b>Alarming signs during ANC</b>				
Yes	6 (28.6)	13 (26.0)	1.1 (0.4-3.6)	0.823
No	15 (71.4)	37 (74.0)	1.0	
<b>Associated illness in pregnancy</b>				
Yes	7 (33.3)	14 (28.0)	1.3 (0.4-3.9)	0.653
No	14 (66.7)	36 (72.0)	1.0	
<b>Mode of delivery</b>				
Vaginal	9 (42.9)	19 (38.0)	1.2 (0.4-3.4)	0.702
C/S	12 (57.1)	31 (62.0)	1.0	

## 6.6 Analysis

In the overall analyses using logistic regression, various factors were analyzed; age in years, BMI, alcohol use, ANC attendance and Gestational age at delivery. The statistically significant factors were BMI and Gestational age at delivery. A BMI odds ratio of 1.13 (CI 1.01-1.26) with a  $p=0.036$  meaning that an increase of one unit of the BMI would have a 13% risk of admission into the CCU.

An odds ratio of 0.4(CI 0.2-0.7) for the gestational age at delivery with a  $p=0.005$ , was protective thus meaning there was a 60% reduced risk of admission into the CCU with increased gestational age at delivery.

The other factors; age, alcohol use, ANC attendance, mode of delivery, associated illness during pregnancy, previous obstetric complications and alarming signs during ANC were found not to be statistically significant.

**Table 3: Factors independently associated with CCU admission: Logistic regression table**

<b>Variable</b>	<b>OR (95% CI)</b>	<b>P value</b>
Age in years	1.0 (0.9-1.2)	0.884
BMI	1.13 (1.01-1.26)	0.036
Alcohol use	-	0.999
ANC attendance	-	0.999
Gestational age at delivery	0.4 (0.2-0.7)	0.005

## **7.0 CHAPTER SEVEN**

### **DISCUSSION, CONCLUSION AND RECOMMENDATIONS**

#### **7.1 Discussion**

The main objective for this study was to review all obstetric patients after delivery from 24 weeks gestation to 6 weeks post-partum at the CCU, Kenyatta National Hospital and to identify predictors associated with admission to the CCU. It was conducted in the maternity units for the control group and in the CCU for the cases. The sample size used was a representation of the general population.

In a majority of instances, pregnancy leads to successful completion with no complications except where existing co-morbidities could be present. Patients who may complicate may require critical care management by mechanical ventilation and modern monitoring techniques. It is usually unpredictable though preventable where existing comorbidities are present(21).

Team approach in obstetric care is essential in ensuring positive maternal and neonatal outcomes. Post-partum or peri-partum hospitalization and especially in the Critical Care Unit carries significant social weight and medical expense as well as poor outcomes. This study sought to analyze admission patterns for obstetric scenarios at KNH CCU.

In the study, age was not a significant factor that would lead to admission in the critical care unit. The mean age for the two groups was 28 years. This is similar to a study done by Adeniran et al (4) and Mungai(3)

Increased parity is thought to be a contributing factor to increasing morbidity in obstetric patients, however, in the study the mean parity for both groups was found to be para 2 ( $p= 0.884$ ) therefore not statistically significant. This is similar to a study by Githae(21) which showed that there was no direct correlation of risk with advancing parity.

A higher pre-partum BMI as shown in this study seems to be associated with adverse obstetric outcome. There was a 13% increase in CCU admission in those with high BMI. This was comparable to a study by Abenhaim et al(32) which concluded that an increase in BMI leads to severity of the obstetric condition.

From these results, gestational age of <36 weeks was a contributing factor to critical care admission. The mean for the two groups was 35.7 and 38.9, OR: 0.4, P value 0.005. This means that an increase in gestational age is 40% protective(33).

It was noted that the two main indications for critical care admission were severe eclampsia (40%) and obstetric hemorrhage (20%). This was comparable to a study done by Githae in Kenya at a CCU in a University Hospital (2011) (21) which showed that obstetric hemorrhage (44%) and sepsis (26%) were the leading causes. Another done in the United Kingdom by Daniel Oselo et al (34) had similar outcomes to this study. The findings are different in the HICs, where the leading indication for critical care admission is sepsis(17).

Referral of patients to KNH presents a major burden on the limited bed capacity. In general, KNH is meant to handle high risk pregnancies with difficult outcomes. However, the national policy changes in maternal care have changed the admission patterns and health seeking behaviors in antenatal care. The presence of a multidisciplinary team and highly experienced specialists in KNH has attracted more patients who expect better outcomes. That a higher proportion of CCU admissions in obstetric patients were referrals, may be a reflection of quality of both critical and in hospital care available in other facilities for which this study did not explore. This was similar to findings in a study done by Mungai(3).

In the study, the majority of the cases admitted to the CCU (76.2%) had low GCS (<8), necessitating mechanical ventilation. Most of these patients had severe eclampsia.

For patients admitted to the CCU, 85.7% did not have any previous obstetric complication which was similar to past studies that indicated that generally pregnant mothers are at risk of SAMM even when they have no underlying complications(4). 71.4% of the cases did not have any alarming signs during their ANC visits, however they presented with severe morbidity.

The UNICEF data on maternal health recommends at least four antenatal visits(12). Additional findings in the study were that 85.7% women attended ANC in their current pregnancy. The mean ANC visits in the cases group was 3 versus 4 in the control group. Three patients were admitted in the CCU (14.3%) who did not attend ANC. They had presented with severe eclampsia which would have probably been prevented earlier in the pregnancy through monitored ANC visits.

Most of the subjects accessed care with skilled health personnel. Care was offered by obstetric consultants (71.4%) obstetric registrars (71.4%), medical officers (23.8%) and skilled midwives (81%). Since the introduction of free maternity care in June 2013, up to 63% now have skilled attendance at birth compared to 46% previously(12).

57.1% of the cases had caesarean delivery, 7 subjects (33%) had severe eclampsia and 2 subjects (9%) had obstetric hemorrhage. These two indications are known to be the leading causes for CCU admission in low and middle income countries(22).

## 7.2 Conclusion

The results obtained after data analysis can thus be summarized as follows:

- The mean age for the two groups was 28 years. More than 90% of the women were married.
- In the two groups, 50% had higher education level.
- In the cases group the mean BMI was 33.7 (Class I obesity) and in the control group the mean BMI was 27.8 (Overweight).
- The mean ANC visits for the control group were 4 and 3 for the cases group.
- Majority of the subjects did not have a history of recreational drug use or alcohol abuse.
- The two commonest indications for admission to the CCU were severe pre-eclampsia/eclampsia and obstetric hemorrhage. Other indications included poor reversal from GA, respiratory distress, post-cardiac arrest.
- 81% of the cases admitted into the CCU were referrals from other facilities. These patients received various treatment interventions; blood transfusion, oxygen supplementation, hemodialysis cardiopulmonary resuscitation. 72% of these cases were also admitted with severe GCS <8
- In conclusion, the predictive factors associated with CCU admission were; an increase in pre-pregnancy Body Mass Index, an increase in gestational age is protective.

## 7.3 Recommendations

1. Healthcare providers should aim at timely antenatal and intrapartum care since this is helpful in identifying the high risk obstetric patients.
2. Obstetric units should spare resources and space to establish critical care units so as to prevent delayed interventions.

## 7.4 Study Limitations

1. The inability to follow up patients from the referral facilities
2. The quality of care and CCU facilities in other facilities were not assessed
3. The status and ability to manage maternal hemorrhage was not fully explored.

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## Appendix I: Preeclampsia with Severe Features

Blood pressure 170/110 mm Hg on two occasions 4 hours apart or > 170/110 mm Hg once plus >0.3 g in 24 hours proteinuria or >+ + on dipstick

OR

Diastolic blood pressure > 90 mm Hg plus proteinuria (as above) on one occasion plus one of the following signs/symptoms:

- Oliguria (< 30 ml/h for 2 hours)
- Visual disturbances (flashing lights or blurred vision)
- Epigastric/right upper quadrant pain or tenderness
- Thrombocytopenia ( $100 \times 10^9/l$ )
- Pulmonary oedema

### **Eclampsia**

Convulsions during pregnancy or in the first 10 days postpartum together with

- Elevated blood pressure (>170/100mmHg)
- Proteinuria (>+ on random dipstick analysis or >0.3 g in 24 hours)
- Thrombocytopenia (<  $100 \times 10^9/l$ )
- Increased aspartate aminotransferase (>42 U/l)

### **HELLP syndrome**

- Haemolysis (abnormal peripheral smear or raised total bilirubin concentration (>20.5 mmol/l))
- Raised liver enzyme activity (raised aspartate aminotransferase (>70 U/l)) or raised  $\alpha$ -glutamyltransferase (>70 U/l), and
- Low platelets (<  $100 \times 10^9/l$ )

### **Severe haemorrhage**

- Estimated blood loss > 1500 ml

### **Severe sepsis**

Sepsis is systemic response to infection manifested by two or more of:

- Temperature > 38°C or < 36°C (unless after prolonged caesarean)
- Heart rate > 100 beats/minute
- Respiratory rate > 20/min or PaCO<sub>2</sub> <32 mmHg
- White cell count >  $17 \times 10^9/l$  or <  $4 \times 10^9/l$  or > 10% immature forms
- Plus bacteraemia (that is, positive blood cultures) or positive swab culture

Severe sepsis is sepsis associated with one of:

- Organ dysfunction—for example, acute renal failure
- Hypoperfusion—for example, lactic acidosis, oliguria, or acute alteration in mental state
- Hypotension—that is, systolic blood pressure < 90 mm Hg or drop of >40mm Hg in the absence of other causes of hypotension

**Uterine rupture** Acute dehiscence of the uterus; leading to haemorrhage

## **Appendix II: Informed Consent Form**

### **Part 1: Information**

You are invited to participate in a study by me Dr. Racheal.W.Kimani. I am a postgraduate student in The University of Nairobi pursuing a degree in Master of Medicine in Anaesthesia.

This study is to determine the predicting factors that lead to pregnant women being admitted in the critical care unit after delivery.

You or your next of kin will be requested to consent. The data collected will be analyzed and then shared to the Department of Anaesthesia and Kenyatta National Hospital.

No extra cost shall be incurred during this study. There will no unauthorized interventions that will be carried out to the patient.

In case you feel you can't take part in the study, you are free to decline. There will be no victimization to this effect.

No risk shall be exposed to the patient. There will be no financial benefit to the investigator.

Confidentiality will be assured during the whole process. No name of the patient shall be taken; instead we will use serial numbers

### **Contact Persons**

In case of any questions about this study, you are welcome to contact any of the under mentioned:

Dr. Rachael W. Kimani (Researcher) - 0705112159

Dr. Patrick Olang (Supervisor) - 0722523116

Dr. Thomas Chokwe, (Supervisor) - 0722528237

Prof. Omondi-Ogutu (Supervisor) - 0722510215

## **Part 2: Consent Form:**

I understand the nature of the study explained to me. I, therefore grant the researcher permission to include me/next of kin into the study.

Participants Signature:..... Date:.....

## **Fomu ya Idhini**

### **Part 1: Maelezo:**

Jina langu ni Daktari Kimani R. Wanjiru, mwanafunzi wa shahada ya pili katika chuo kikuu cha Nairobi. Kama sehemu ya masomo yangu ninastahili kufanya utafiti wa kitabibu. Lengo langu ni kufanya utafiti katika Hospitali ya Taifa ya Kenyatta juu ya sababu wajaawazito wanao lazwa katika wadi ya watu wenye hali mahututi. Lengo la utafiti huu ni kusaidia madaktari kuboresha huduma inayotolewa kwa wagonjwa. Kwa kufanya hivyo, nitakuuliza maswali kadhaa. Baada ya hapo nitafanya mahesabu ya takwimu na taarifa hii na kutangaza habari hiyo katika kitabu ambacho kitakuwa chini ya ulinzi wa Chuo Kikuu cha Nairobi. Taarifa zote zilizokusanywa zitashughulikiwa na usiri. Hakuna majina au vitambulisho vingine vitakavyotumika katika utafiti. Kwa hiyo nitahitaji idhini yako kwa mwenzako (au tegemezi) kuwa mshiriki katika utafiti huu.

Ushiriki wako katika utafiti huu ni kwa hiari yako na unaweza kuondoa mwenzako (au tegemezi) katika hatua yoyote bila kuathiri matibabu atakayopewa mwenzako (au tegemezi) kwa njia yoyote. Taarifa zote zitakazopatikana katika mwendo wa utafiti huu ni manufaa kwa mgonjwa.

Kwa maelezo zaidi na ufafanuzi, unaweza kuwasiliana na:

Dr Kimani R. Wanjiru: 0705112159

Dr. Patrick Olang (Supervisor)-0722523116

Dr. Thomas Chokwe, (Supervisor)-0722528237

Prof. Omondi-Ogutu (Supervisor) - 0722510215

## **Part 2: Fomu ya Idhini**

Nathibitisha kwamba nimeelewa maelezo yote kutoka kwa daktari kuhusu utafiti huu. Nimetoa kibali hii cha kushiriki kwa huu utafiti kwa hiari yangu binafsi. Nimeelewa kwamba ninaweza kujiondoa kutoka utafiti huu wakati wowote bila masharti yoyote na kujiondoa kwangu hakutadhuru matibabu yangu kwa njia yoyote. Pia nimeelewa ya kwamba, habari yoyote nitakayoitowa itahifadhiwa kwa siri.

Sahihi ya Mhusika \_\_\_\_\_ Tarehe \_\_\_\_\_

Sahihi ya Mtafiti \_\_\_\_\_ Tarehe \_\_\_\_\_

**Appendix III: Data collection tool**

**Part 1: For Cases**

**SOCIO-DEMOGRAPHIC FACTORS:**

- I. Serial No.....
- II. Age....
- III. Marital status : ( Circle the appropriate choice)
  - I. Married
  - II. Single
  - III. Separated/Divorced
- IV. Parity.....
- V. Level of education
  - 1. None
  - 2. Primary
  - 3. Secondary
  - 4. Tertiary
- VI. Smoking
  - 1. Yes
  - 2. No
- VII. Drug use
  - 1. Yes
  - 2. No

If yes, which drug .....

Medicinal Drugs
  - 1. Yes
  - 2. No

if yes state the name of the drug
- VIII. Alcohol intake history if yes quantify the consumption
- IX. Weight..... Height.....
- X. Body Mass Index (BMI).....

**ADMISSION HISTORY IN CCU**

1. Indication for admission.....
  - I. Respiratory distress
  - II. Hypotension
  - III. Severe eclampsia
  - IV. Severe hypertension
  - V. Post- cardiac arrest
  - VI. Low GCS
  - VII. Poor reversal from GA
  - VIII. Post partum hemorrhage
  - IX. Drug toxicity in pregnancy
  - X. Others
  
2. Mode of admission:
  - I. Referral from another hospital  
Nursing home
  - II. Transfer from the ward(KNH) state the ward
  - III. Transfer from theatre
  - IV. From home
  
3. Cadre of the obstetric team that managed the patient pre- admission to the CCU
  - I. Obstetric consultant
  - II. Obstetric Registrar
  - III. Medical officer
  - IV. Midwife
  - V. Clinical Officer
  - VI. Clinical Team management
  
4. Pre-admission lab and imaging findings:
 

If any: Normal..... Abnormal.....
  
5. Treatment interventions before CCU admission:
  - I. Blood and Blood products transfusion
  - II. Oxygen supplementation



- III. Hemodialysis
- IV. Cardiopulmonary Resuscitation
- V. Defibrillation
- VI. Central vein cannulation
- VII. Arterial cannulation

6. Admission parameters

- I. Pulse Rate:.....
- II. Respiratory Rate:.....
- III. Systolic Blood Pressure: .....
- IV. SpO2: .....
- V. CNS
  - a) Mild: > 13.....
  - b) Moderate: 8-12.....
  - c) Severe:< 8.....

**OBSTETRIC HISTORY**

- a) Any previous obstetric complication: PE, PPH, Uterine rupture.....
- b) Have you attended Antenatal clinics in the current pregnancy 1. Yes 2. No  
If Yes, how many times.....
- c) Have there been any alarming signs noted during the Ante-natal clinics 1 Yes 2.No  
If Yes state which ones.....
- d) Do you have any associated illnesses in the current pregnancy 1. Yes 2.No  
State:.....
- e) Gestation at delivery.....
- f) Mode of delivery
  - 1. Vaginal
  - 2. C/S
  - 3. Vacuum delivery

**Part 2: For Cases**

**SOCIO-DEMOGRAPHIC FACTORS:**

1. Serial No.....
2. Age.....
3. Marital status : ( Circle the appropriate choice)
  - a) Married
  - b) Single
  - c) Separated/Divorced
4. Parity.....
5. Level of education

	1. None	3. Secondary
	2. Primary	4. Tertiary
6. Smoking

	1. Yes	2. No
--	--------	-------
7. Drug use

	1. Yes	2. No
--	--------	-------

  - a. If yes, which drug .....

	1. Yes	2. No
--	--------	-------
8. Alcohol intake history
9. Weight..... Height.....  
Pre-pregnancy Body Mass Index (BMI).....  
Admission parameters
  - VI. Pulse Rate:.....
  - VII. Respiratory Rate:.....
  - VIII. Systolic Blood Pressure: .....
  - IX. SpO2: .....
  - X. CNS

- d) Mild: > 13.....
- e) Moderate: 8-12.....
- f) Severe:< 8.....

**OBSTETRIC HISTORY**

- a) Any previous obstetric complication: PET, PPH, Uterine rupture.....
- b) Have you attended Antenatal clinics in the current pregnancy 1. Yes 2. No  
 If Yes, how many times.....
- c) Have there been any alarming signs noted during the Ante-natal clinics 1 Yes 2.No  
 If Yes state which ones.....
- d) Do you have any associated illnesses in the current pregnancy 1. Yes 2.No  
 If Yes state which ones:
- e) Gestation at delivery.....
- f) Mode of delivery 2. Vaginal 2. C/S

If C/S what was the indication.....

## APPENDIX IV: ETHICAL APPROVAL LETTER



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

### KNH-UON ERC

Email: [uonknh\\_erc@uonbi.ac.ke](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)



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

Ref: KNH-ERC/A/309

18<sup>th</sup> October, 2017

Dr. Rachael Kimani  
Reg. No. H58/68894/2013  
Department of Anaesthesia  
School of Medicine  
College of Health Sciences  
University of Nairobi



Dear Dr. Kimani,

**REVISED RESEARCH PROPOSAL –PREDICTORS OF ADMISSIONS AMONG OBSTETRIC PATIENTS AT THE CRITICAL CARE UNIT, KENYATTA NATIONAL HOSPITAL (P276/05/2017)**

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above proposal. The approval period is from 18<sup>th</sup> October 2017 –17<sup>th</sup> October 2018.

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- 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.
- 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.
- 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*).
- Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

Protect to discover

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

Yours sincerely,



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

- c.c. The Principal, College of Health Sciences, UoN  
The Director, CS, KNH  
The Assistant Director, Health Information, KNH  
The Chairperson, KNH-UoN ERC  
The Dean, School of Medicine, UoN  
The Chair, Dept. of Anaesthesia, UoN  
Supervisors: Dr. Patrick Otieno Ragot Olang', Dr. Thomas M. Chokwe, Prof. J. Omondi- Ogutu

## Appendix V: Anti Plagiarism Report

### PREDICTORS OF ADMISSIONS AMONG OBSTETRIC PATIENTS AT THE CRITICAL CARE UNIT, KENYATTA NATIONAL HOSPITAL

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