

**UNIVERSITY OF NAIROBI**

**COLLEGE OF HEALTH SCIENCES**

**DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY**

**PIERS MODEL FOR THE PREDICTION OF ADVERSE MATERNAL AND  
PERINATAL OUTCOMES IN PRECLAMPSIA AT KENYATTA NATIONAL  
HOSPITAL, NAIROBI, KENYA**

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THE DEGREE OF MASTER OF MEDICINE (OBSTETRICS AND GYNECOLOGY) OF  
THE UNIVERSITY OF NAIROBI.**

**2019**

**DECLARATION**

This is to certify that the work presented herein is my original work, it has not been presented for a degree course in any other university and was supervised by senior members of the Department of Obstetrics and Gynaecology, School of Medicine, College of Health Sciences, University of Nairobi, Kenyatta National Hospital Campus, Nairobi, Kenya.

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## **DEDICATION**

This work is dedicated to Nathan and Natasha.

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## **ABSTRACT**

**Introduction:** Preeclampsia is a subset of hypertensive disorders in pregnancy (HDP) and contributes to the top 3 causes of maternal morbidity and mortality worldwide. Because of the enormous burden of adverse maternal outcomes among patients with preeclampsia, there is a need to correctly identify women at high risk of developing adverse outcomes in time to avoid their occurrence and aid decision making around the management of preeclampsia. The PIERS model (Preeclampsia Integrated Estimate of Risk) was developed to predict adverse maternal outcomes using easy to assess predictors collected within the first 48 hours of hospital admission among patients with preeclampsia. In validation studies, the fullPIERS model had a sensitivity of 85.1% while the miniPIERS model had a sensitivity of 73.8% for adverse maternal outcomes (Uber et al, 2009). The performance of PIERS model has not been evaluated in our Kenyan setting.

**Objective:** To determine the performance of the PIERS model in predicting the risk of adverse maternal and perinatal outcomes among patients with preeclampsia at Kenyatta National Hospital, Nairobi, Kenya.

**Methodology:** This was a descriptive prospective cohort study. Patients admitted with preeclampsia were recruited from the labour ward and antenatal wards. These patients were interviewed using a questionnaire to determine the presence of the symptom based predictor variables and their files were analysed to get the laboratory predictor values. Enrolled patients were recruited and followed up to document development of any adverse maternal and perinatal outcomes. We estimated the performance of the mini and fullPIERS model using receiver operator curves, area under the curve.

**Results:** Of 197 women recruited within 48 hours of admission, 12.2 % experienced an adverse maternal and 49.7% experienced adverse perinatal outcomes. The mean maternal age was 29.1 years while the mean gestational age was 34 weeks 6 days. 97 patients (49.2%) had preeclampsia with severe features. The fullPIERS model predicted adverse maternal outcomes with AUC ROC 0.647, 95% CI 0.539-0.755 while the miniPIERS model predicted adverse maternal outcomes with AUC ROC 0.654, 95% CI 0.553-0.754 within 48 hours of inclusion. The fullPIERS model predicted adverse perinatal outcomes with AUC ROC 0.62, 95% CI 0.54-0.71 while the miniPIERS model predicted adverse neonatal outcomes with AUC ROC 0.59, 95% CI 0.5-0.69 within 48 hours after inclusion.

**Conclusion:** These results confirm the usability of the fullPIERS model for prediction of adverse maternal and perinatal outcomes, and the usability of the miniPIERS for the prediction of adverse maternal outcomes in women admitted with preeclampsia within the first 48 hours of admission. Additional research should target stratification of patients into those presenting with early onset preeclampsia (less than 34 weeks gestation) and those presenting with late onset preeclampsia (34 weeks of gestation and above). In addition, further studies involving multicenter sites in smaller, peripheral hospitals should be conducted to assess the performance of this model in non-teaching/referral hospitals.

**KEY WORDS:** Preeclampsia, predictors of adverse maternal outcome, PIERS

## **LIST OF ABBREVIATIONS**

AST	Aspartate Transaminase
Cr	Creatinine
dBp	diastolic Blood Pressure
Hb	Haemoglobin
HDP	Hypertensive Disorders of Pregnancy
HELLP	Haemolysis, Elevated Liver enzymes, Low Platelets
HTN	Hypertension
KNH	Kenyatta National Hospital
LMIC	Low and Middle Income Countries
LMP	Last Menstrual Period
NBU	New Born Unit
PE	Preeclampsia
PIERS	Preeclampsia Integrated Estimate of RiSk
Plt	Platelets
sBP	systolic Blood Pressure
sO <sub>2</sub>	Oxygen saturation (via pulse oximetry)
WHO	World Health Organization

## **DEFINITION OF TERMS:**

**Adverse outcomes** in this study are the potential medical complications that arise in the patient or her fetus/newborn as a result of the patient suffering from preeclampsia and includes maternal and perinatal death.

**HELLP** is a syndrome manifesting as haemolysis, elevated levels of liver enzymes and lowered count of platelets among pregnant patients with elevated blood pressure.

**Hypertension** is development of high blood pressure defined as a systolic blood pressure (sBP)  $\geq 140\text{mmHg}$  and/or a diastolic pressure (dBP)  $\geq 90\text{mmHg}$ , measured twice at least 4 hours apart.

**Hypertensive disorders of pregnancy** is the presence of, or new onset of, hypertension during pregnancy or the post-partum period, with or without proteinuria.

**Laboratory parameters** are the accepted reference range of a biochemical test that involves a sample of blood or urine analysed and compared to the standards of the reference laboratory (which in this study research is the KNH Laboratory)

**LMP** refers to the first day of a woman's last normal menses.

**Maternal mortality:** Maternal mortality is the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes (WHO, 1992; ICD 10)

**Preeclampsia** is new onset hypertension arising from  $\geq 20+0$  weeks of gestation with proteinuria or HELLP syndrome (hemolysis, elevated liver enzyme levels, and low platelet levels) (International Society for the Study of Hypertension in Pregnancy, ISSHP, 2014).

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## **CHAPTER 1                    INTRODUCTION AND LITERATURE REVIEW**

### **1.1 INTRODUCTION**

Hypertensive disorders of pregnancy refer to presence of systolic blood pressure  $>140$  mmHg or diastolic blood pressure  $\geq 90$  mmHg as measured twice, using an appropriate cuff, more than 4–6 hours and less than 7 days apart. Hypertensive disease in pregnancy (HDP) complicate  $\approx 5\%$  to 10% of pregnancies worldwide and contributes to the top 3 causes of maternal morbidity and mortality worldwide (von Dadelszen P et al, 2014). Hypertensive disorders of pregnancy (HDPs) are divided into preeclampsia (de novo or superimposed on chronic hypertension), gestational hypertension, white coat hypertension and chronic hypertension (ISSHP, 2014).

Preeclampsia is defined as a systolic blood pressure  $>140$  mmHg or diastolic blood pressure  $\geq 90$  mmHg as measured twice, using an appropriate cuff, more than 4–6 hours and less than 7 days apart with onset at  $>20$  weeks' gestational age, with 24-hour proteinuria  $\geq 30$  mg/day or, if not available, a protein concentration  $\geq 30$  mg ( $\geq 1+$  on dipstick) in a minimum of two random urine samples collected at least 4–6 hours but no more than 7 days apart, or the presence of maternal organ damage (ISSP, 2014). Risk factors for preeclampsia include chronic hypertension, diabetes mellitus, obesity, nulliparity, multiple pregnancies and conception in older women ( $> 35$  years) (Redman CW et al, 2007, Sibai B et al, 2005).

Pre-eclampsia has a complex pathophysiology with the primary cause thought to be related to abnormal placentation (Fischer SJ et al, 2009). Preeclampsia is associated with defective invasion of spiral arteries by cytotrophoblast cells due to abnormalities related to the nitric oxide pathway, which contributes substantially to the control of vascular tone (Duran et al, 1999).



Increased uterine arterial resistance induces higher sensitivity to vasoconstriction and thus leads to chronic placental ischemia and oxidative stress.

Chronic placental ischemia causes fetal complications, including intrauterine growth retardation and intrauterine death. In addition, oxidative stress induces release of free radicals, oxidized lipids, cytokines, and serum soluble vascular endothelial growth factor 1 into the maternal circulation leading to endothelial dysfunction with vascular hyperpermeability, thrombophilia, and hypertension, so as to compensate for the decreased flow in the uterine arteries due to peripheral vasoconstriction (Roberts JM., 1998).

The risk of death among women with preeclampsia is 4 times higher when compared with non preeclamptic women and the maternal near-miss cases are 8 times higher than in non preeclamptic women (Abalos et al, 2014). Maternal morbidity from preeclampsia include stroke, eclampsia, and renal dysfunction (Hutcheon et al, 2011).

The main impact of preeclampsia on the fetus is under nutrition as a result of utero-placental vascular insufficiency, which leads to growth retardation (Mandana s. et al, 2000). This utero-placental vascular insufficiency leads to adverse fetal outcomes which include stillbirth, preterm delivery, and cerebral palsy (Hutcheon, 2011).

The adverse outcomes associated with hypertension in pregnancy make them a global health burden, especially in the low- and middle-income countries (LMICs) where >90% of HDP-related deaths occur (Wulf S, 2010).

Because of the enormous burden of adverse maternal outcomes among patients with hypertensive in pregnancy, there is a need to correctly identify women at high risk of developing adverse outcomes in time to avoid their occurrence.

Accurate risk assessment can aid decision making around the management of HDPs, including preeclampsia to help in decisions relating to timing of delivery, administration of antenatal corticosteroids for acceleration of fetal pulmonary maturity or Magnesium sulfate for seizure prophylaxis, and maternal transfer to a higher level of care.

The Pre-eclampsia Integrated Estimate of RiSk (PIERS) model for patients with preeclampsia is a recently externally validated tool to predict adverse maternal and neonatal outcomes among patients with preeclampsia (Ukah U. et al, 2017). The model was developed and internally validated in a cohort of 2023 women with in tertiary perinatal units in Canada, the UK, New Zealand and Australia. The PIERS model identifies women at increased risk of adverse outcomes up to 7 days before complications arise using the worst values for predictor variables measured within 48 hours of admission. It has two variations, a mini PIERS calculator for use in low resource settings where laboratory support is inadequate, and the full PIERS calculator which incorporates basic laboratory parameters. The predictor variables used in the fullPIERS model are gestational age, chest pain/dyspnea, lowest oxygen saturation and laboratory parameters - worst values of creatinine, aspartate transaminase and platelets while the predictor variables for the miniPIERS are gestational age, presence or absence of chest pain/dyspnea, headache/visual disturbance, vaginal bleeding with abdominal pain. The PIERS model inputs those variables into the PIERS calculator to stratify patients into a high or low risk of developing an adverse maternal outcome (Peter von Dadelszen et al, 2002).

This study used the validated mini and fullPIERS calculators

(<http://piers.cfri.ca/PIERSCalculatorH.aspx>) to calculate the risk score for each patient.

**The adverse maternal outcomes are:**

- Maternal death
- Intensive care unit (ICU) admission
- Glasgow Coma Scale <13
- Reversible ischaemic neurological deficit
- Stroke
- Postpartum hemorrhage
- Requirement for transfusion of any blood product
- Hepatic haematoma or rupture
- Acute kidney injury
- Requirement for dialysis
- Pulmonary edema
- Need for oxygen for greater than 1 hour
- Intubation other than due to Caesarian delivery
- Retinal detachment
- Cortical blindness
- Myocardial ischaemia

**The adverse perinatal outcomes are:**

- Prematurity
- Respiratory distress
- Ventilation given
- New born unit admission
- Fresh still birth
- Macerated still birth
- Neonatal death

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pregnancy (HDP) account for nearly 18% of all maternal deaths worldwide, with an estimated 62 000–77 000 deaths per year (Khan KS et al, 2006). Preeclampsia, a subset of HDP, is a

pregnancy-specific disorder that affects 2 to 8% of all pregnancies worldwide and is a leading cause of maternal and perinatal morbidity and mortality. A WHO funded multi country study of 313 030 pregnant women noted that 8542 (2.73%) of these women had hypertensive disease during pregnancy and/or the intrapartum and early postpartum periods (Abalos E. et al, 2014). Of these, 914 women (0.29%) had chronic hypertension, 6753 (2.16%) were pre-eclamptic and 875 (0.28%) had eclamptic fits. This same study showed that in Africa, preeclampsia affected 1.56% of all pregnancies while in Kenya out of the 20,280 pregnant women sampled, 21 (0.1%) had chronic hypertension, 398 (1.97%) had preeclampsia and 63 (0.32%) had eclampsia. Therefore, preeclampsia contributed to 82.6% of all cases of hypertensive disease in pregnancy in Kenya.

According to a study done at Pumwani Maternity hospital, there was an overall incidence of 3.7% cases of preeclampsia, predominantly in primigravidas. The maximum occurrence in primigravidas in all forms of preeclampsia was in the age group 16-21 years of age (Bansal et al, 1985). Almost 22.6% of those babies born to preeclamptic mothers weighed less than 2500 g (Bansal, 1985).

As per the first Kenyan Confidential Enquiry into Maternal Deaths conducted in 2014, 15.3% of maternal deaths were due to hypertensive disorders in pregnancy. 36.5% of the women who died of hypertensive disorders were aged 25-29 years. In addition, 31.1% of these women were having their first pregnancy while eclampsia contributed to 78.4% of maternal deaths due to hypertensive disorders. (Ministry of Health, 2017).

Use of blood pressure alone as a predictor of adverse maternal outcome has not been shown a clinically useful measure for blood pressure as a prognostic test for adverse maternal outcomes even where significant associations (p-values <0.05) between blood pressure and adverse outcomes was noted (Ankumah N et al, 2014).

Use of AST, alanine transaminase (ALT), and Lactate dehydrogenase (LDH) were reported to have good discriminatory abilities, with AUROCs of >0.70 for prediction of adverse maternal outcome (Kozic JR *et al*, 2011)

Use of HELLP as a sole independent predictor of adverse maternal outcome predicted that one in four pregnancies with HELLP resulted in an adverse maternal event and 35% of pregnancies with HELLP resulted in an adverse fetal event hence the conclusion that clinical symptoms or laboratory parameters HELLP were not predictive of adverse events (Aziz n et al, 2011).

Studies using biomarkers like placental growth factor (PIGF) were reported not to have clinically useful measures to either rule in or rule out adverse maternal outcomes (Ghosh et al, 2012).

The preeclampsia severity criteria has been used and recognized by both the Canadian Hypertension Society and the National High Blood Pressure Education Program to guide management of preeclamptic patients but it has not been shown to be predictive of maternal or perinatal morbidity (Menzies et al, 2007).

The Acute Physiology and Chronic Health Evaluation (APACHE) III Scoring system (Knaus WA et al, 1981) measures the severity of disease among intensive care unit (ICU) patients to assess their risk for death but when applied to ICU patients with preeclampsia, it has been shown to have poor prediction of adverse maternal outcome (Menzies, 2007)

Use of proteinuria as a single predictor of adverse outcome revealed that proteinuria increases over time in most women with severe preeclampsia (Shiff E. et al, 1996). However, no differences in maternal or fetal outcomes were found between pregnancies with marked increases in proteinuria and those with modest or no increases among patients with severe preeclampsia managed conservatively (Shiff, 1996)

The fullPIERS model has been tested in India in a prospective hospital based observational study carried out in Sultania Zanana Hospital, Gandhi Medical College, Bhopal. The study recruited 125 women with preeclampsia who fulfilled the inclusion criteria. The fullPIERS calculator was used to calculate the risk of adverse maternal outcome and it revealed that 82(65.6%) women were in the low risk category and only 4 of these patients (4.87%) had adverse maternal outcome. High risk patients were 6 (4.8%) and amongst them 5 (83.33%) women had adverse maternal outcome (p-value <0.00001). The result was statistically significant in identifying patients at risk of developing adverse maternal outcomes (Srivastava S et al, 2017).

The fullPIERS model predicted, with moderate accuracy, adverse maternal outcomes within 48 hours of eligibility, using predictor variables available within 6 hours of admission (AUC ROC 0.76; 95% CI 0.72–0.81), and within 24 hours of admission (AUC ROC 0.81, 95% CI 0.77–0.86) in a multicentre prospective study (Payne et al, 2012).

A retrospective cohort study done to investigate the utility of an admission battery of findings and laboratory data in the discrimination of patients with severe preeclampsia including nausea and vomiting, epigastric pain, LDH, AST ALT, Uric acid and serum creatinine reported that concentrations of lactate dehydrogenase, aspartate aminotransferase, and uric acid have the strongest predictive value and are risk additive with worsening thrombocytopenia (Martin JN et al, 1999).

### **1.3 CONCEPTUAL FRAMEWORK**

The exact underlying cause of preeclampsia is unknown, however, the maternal endothelial dysfunction hypothesis is the most well accepted hypothesis. The endothelial dysfunction is thought to be due to placental ischemia/hypoxia arising from inadequate uteroplacental vascular remodeling, which leads to a decrease in placental blood flow. Maternal endothelial dysfunction is characterized by elevated circulating endothelin (ET-1), reactive oxygen species (ROS), and enhanced vascular sensitivity to angiotensin II. These factors act together to decrease renal and

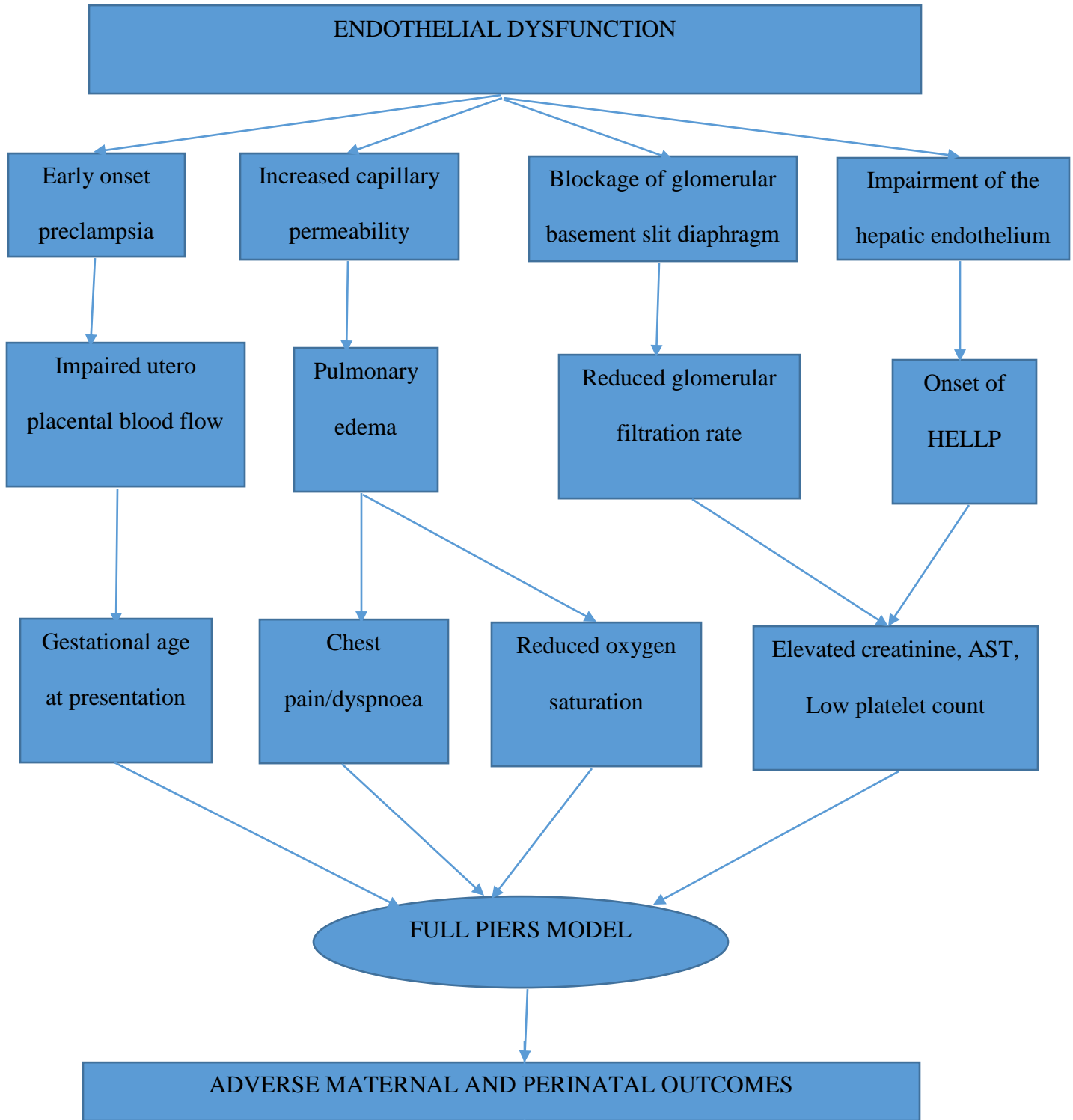
hepatic function, increase capillary permeability hence leading to dependent oedema or pulmonary oedema and cause hypertension during pregnancy.

The derangements in renal, haematological, pulmonary, hepatic and placental organ systems bring about patient symptoms like dyspnea, epigastric/right upper quadrant abdominal pain, vaginal bleeding together with derangements of oxygen saturation and abnormal laboratory parameters involving creatinine, aspartate transaminase and platelets.

These patient symptoms and laboratory parameters are utilized in the PIERS calculator model to predict patients who will develop adverse maternal and perinatal outcomes.



FIGURE 1: CONCEPTUAL FRAMEWORK



## **1.4JUSTIFICATION**

Pre eclampsia presents a challenge to clinicians in identifying patients who are likely to suffer subsequent adverse outcomes from preeclampsia and those unlikely to suffer adverse outcomes. Currently, assessment of preeclampsia patients is directed by expert opinion based guidelines which perform poorly when operationalised.

This ability to predict preeclampsia patients who are likely to develop an adverse outcome would be helpful in order to intervene appropriately while minimizing unnecessary and potentially harmful interventions in patients who do not require them.

By identifying such women, the PIERS model may help in reducing the morbidity and mortality associated with PE.

The feasibility and validity of the PIERS model has not been studied in this setting yet its key variables are routinely measured. The findings of this study will inform decisions on possible routine use of the PIERS model in this setting.

## **1.5 RESEARCH QUESTION**

What is the performance of the PIERS model in predicting the risk of adverse maternal and perinatal outcomes among women with preeclampsia at Kenyatta National Hospital in 2018?

## **1.6 BROAD OBJECTIVE**

To determine the sensitivity and specificity of the PIERS model in predicting the risk of adverse maternal and perinatal outcomes among patients with preeclampsia at Kenyatta National Hospital.

## **1.7 SPECIFIC OBJECTIVES**

Among women presenting with preeclampsia-eclampsia at KNH:

1. To determine the sensitivity and specificity of the fullPIERS model in predicting the risk of adverse maternal outcome.
2. To determine the sensitivity and specificity of the miniPIERS model in predicting the risk of an adverse maternal outcome.
3. To determine the sensitivity and specificity of the fullPIERS and miniPIERS model in predicting the risk of adverse perinatal outcomes.

## **CHAPTER 2            METHODOLOGY**

### **2.1 STUDY DESIGN**

This was a prospective descriptive cohort study. This study identified patients exposed to preeclampsia but did not have any adverse outcome present at the time of recruitment. The patients were then followed up for a short duration (only for the time period between admission and development of an adverse outcome/ discharge, whichever occurred earlier). This made a descriptive cohort study design appropriate for this research. In addition, being a prospective study, it minimized instances of recall bias and instances of missing data.

### **2.2 STUDY SITE**

The study site was at the Kenyatta National Hospital, a National teaching and referral hospital in Nairobi, Kenya

### **2.3 STUDY SETTING**

Labor ward

Antenatal/Postnatal wards

The above-mentioned units are the wards within Kenyatta National Hospital where patients diagnosed with preeclampsia are admitted and managed. Kenyatta National Hospital is the premier public tertiary facility in Kenya that receives referrals of pregnant patients with pregnancy related complications. Preeclampsia is one of the common conditions leading to referral of a patient to KNH. This makes KNH well suited for this study because it has a high number of patients with preeclampsia as compared to County/peripheral hospitals.

In addition, at KNH, patients with preeclampsia undergo baseline laboratory tests upon diagnosis of preeclampsia (that includes platelet, liver and renal assessment) as part of standard care and these tests are repeated every 24 – 48 hours.

## **2.4 STUDY POPULATION**

The study population were patients with a diagnosis of preeclampsia admitted in Kenyatta National Hospital labour ward and antenatal wards between July and October 2018.

### **2.4.1 INCLUSION CRITERIA**

Hypertension ( $\geq 140/90$  mmHg, taken twice more than 4 h apart) after 20 weeks of gestation.

Proteinuria,  $\geq 0.3$  g/dl or  $\geq 1+$  dipstick proteinuria after 20 weeks of gestation

### **2.4.2 EXCLUSION CRITERIA**

Patients who at the time of admission already have adverse maternal outcomes

Patients with sonographically confirmed intrauterine fetal demise at the time of admission

Patients with missing/incomplete laboratory data

Patients admitted in spontaneous labour.

## 2.5 SAMPLE SIZE CALCULATION

Sample size was calculated using the Fisher's formula;

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

$n$  = 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 0.28); estimated at 28.0%, from a study conducted by Srivastava et al (2017) found 28.0% of patients had headache as a presenting symptom

$d$  = desired precision (0.05)

$$n = \frac{1.96^2 x 0.28(1 - 0.28)}{0.05^2} = 310$$

Adjusting the sample size for finite populations less than 10,000 (with the estimated number of patients presenting with preeclampsia at the Kenyatta National Hospital per month being approximately 80 per month, and within the 4 month period of study it was approximated to be 320)

$$nf = \frac{310}{1 + \frac{310-1}{320}} = 157 \quad \text{A Sample size of 157 were required for the study. 197 were taken up for}$$

this study to mitigate for missing data.

## **2.6 SAMPLING PROCEDURES**

Consecutive sampling method was used where all the patients who were admitted with a diagnosis of with preeclampsia were interviewed for presence or absence of symptom based predictor variables and their patient files reviewed for the recording of the worst laboratory and pulse oximetry parameters taken over the first 48 hours of admission. Patients with preeclampsia were identified using data abstraction from patient files to pick patients who are above 20 weeks of gestation with elevated blood pressure (Systolic blood pressure greater than 140mmHg or diastolic blood pressure greater than 90mmHg) and proteinuria (greater than or equal to 1+ on dipstick examination).

The laboratory parameters that were recorded in the data abstraction form were the platelet number, aspartate transaminase and creatinine – where a test had been repeated more than once within the first 48 hours of admission/diagnosis, the worst value was recorded.

These patients were followed up by the primary investigator and his assistants to determine the occurrence of any adverse maternal or fetal outcomes in the course of that admission.

## 2.7 DATA VARIABLES

Outcome and exposure variables according to each objective as shown in table 1 below:

*Table 1: Outcome and exposure variables according to each objective*

SPECIFIC OBJECTIVE	INDEPENDENT VARIABLE	DEPENDENT VARIABLE
<b>1. To determine the sensitivity and specificity of the fullPIERS model in predicting the risk of adverse maternal outcome.</b>	gestational age, chest pain/dyspnea, oxygen saturation Laboratory parameters	Adverse maternal outcomes maternal death, intensive care unit (ICU) admission, Glasgow Coma Scale <13, reversible ischaemic
<b>2. To determine the sensitivity and specificity of the miniPIERS model in predicting the risk of adverse maternal outcome.</b>	gestational age, chest pain/dyspnea headache/visual disturbance, vaginal bleeding with abdominal pain	neurological deficit, stroke, postpartum hemorrhage, requirement for transfusion of any blood product, hepatic haematoma or rupture, acute kidney injury, requirement for dialysis, pulmonary edema, need for oxygen for greater than 1 hour, intubation other than due to caesarian delivery, retinal detachment, cortical blindness and myocardial ischaemia
<b>3. To determine the sensitivity and specificity of the fullPIERS and mini PIERS model in</b>	gestational age, chest pain/dyspnea, oxygen saturation	Adverse neonatal outcomes: Prematurity, respiratory distress, ventilation given, new born unit



<b>predicting the risk of adverse neonatal outcome.</b>	Laboratory parameters (the same as fullPIERS)	admission, fresh still birth, macerated still birth and neonatal death.
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## **2.8 DATA COLLECTION AND ANALYSIS**

Patient data was collected using a structured questionnaire and data abstraction form. Pretesting on 10 clients was done prior to commencement of the study. Data collection was done by the principal investigator and by two trained assistants. The forms were stored securely under lock and key. The data collected was checked for completeness prior to entry into SPSS version 21 software database. Statistical analysis was conducted using IBM SPSS version 21. Accuracy of prediction was assessed using sensitivity, specificity, likelihood ratios and area under the receiver operating curve (AUROC). Strong evidence of prediction was taken to be a positive likelihood ratio  $>10$  or a negative likelihood ratio  $<0.1$ , and for multivariable model analysis, an AUROC  $\geq 0.70$  while moderate evidence of prediction for the multivariate model analysis was an AUROC  $>0.60$ .

Using the worst measured predictor variables within 48 hours of admission measured before any outcome occurrence, the published PIERS model equation was applied to the combined data set to calculate the predicted probabilities of experiencing an adverse outcome for each woman.

The calculated probabilities were then used to assess the model performance for predicting adverse maternal outcomes within 48 hours of admission based on discrimination, stratification and classification accuracy via plotting of receiver operating curves.

Discriminative ability was interpreted as non-informative (area under the curve  $\leq 0.5$ ), poor discrimination ( $0.5 < \text{area under the curve} < 0.6$ ), moderate discrimination ( $0.6 - < 0.7$ ) or good discrimination (area under the curve  $\geq 0.7$ ) Hanley JA et al the meaning and use of the area under a receiver operating characteristic (ROC) curve Radiology 1982; 143: 29 – 36. Doi: 10.1148/radiology.143.1.7063747

## **2.9 DATA QUALITY CONTROL MEASURES**

Each study participant was assigned their unique patient identifier number to ensure that neither the patient name nor her inpatient number was indicated in the data abstraction form.

Laboratory results were checked to ensure that patient identifiers indicated on the laboratory result slip correspond to the patient in whose file the results were lodged in during data abstraction.

Questionnaires and data abstraction forms were reviewed daily to assess for completeness and accuracy.

## **2.10 DATA DISSEMINATION**

The study findings arising from the completion of this research will be shared with Kenyatta National Hospital research office, the department of Obstetrics and gynecology, University of Nairobi and also presented for publication after submission to the KNH-UoN ERC.

## **2.11 ETHICAL CONSIDERATIONS**

Permission was sought from the Kenyatta National Hospital and UON Ethics Research Committee to carry out this study. Copies of this protocol were presented to the committee for written approval prior to commencing the study.

All the information collected was handled with confidentiality throughout the period of the study, held in trust by the investigator, research assistants and the study institution. No patient identifiers were collected. A password-protected computer with access to only the primary investigator and research assistants was used. The research assistants were fourth and fifth year medical students trained on ethical research conduct and data confidentiality before the research is conducted. Their role was to interview patients and complete the provided study questionnaires and data extraction form. Questionnaires were assigned study identification numbers and no information concerning the study subjects was released to an unauthorized third party.

## **2.12 STUDY LIMITATIONS/DELIMITATIONS**

The study is limited by the fact that study participants were derived from patients admitted at one public health institution (KNH). This is however, mitigated by the fact that KNH is a national referral hospital that receives patients from both public and private health facilities countrywide.

### **CHAPTER 3           STUDY RESULTS**

A total of 280 patients who were admitted with preeclampsia in the antenatal and labour wards at the Kenyatta National Hospital between July and October 2018 were interviewed and their files scrutinized for laboratory predictor variables. Eighty three (83) patients were excluded due to missing laboratory predictor values within the first 48 hours of admission. A total of 197 patients met the inclusion criteria and were recruited and followed up during the course of their admission to observe for development of any adverse outcome.

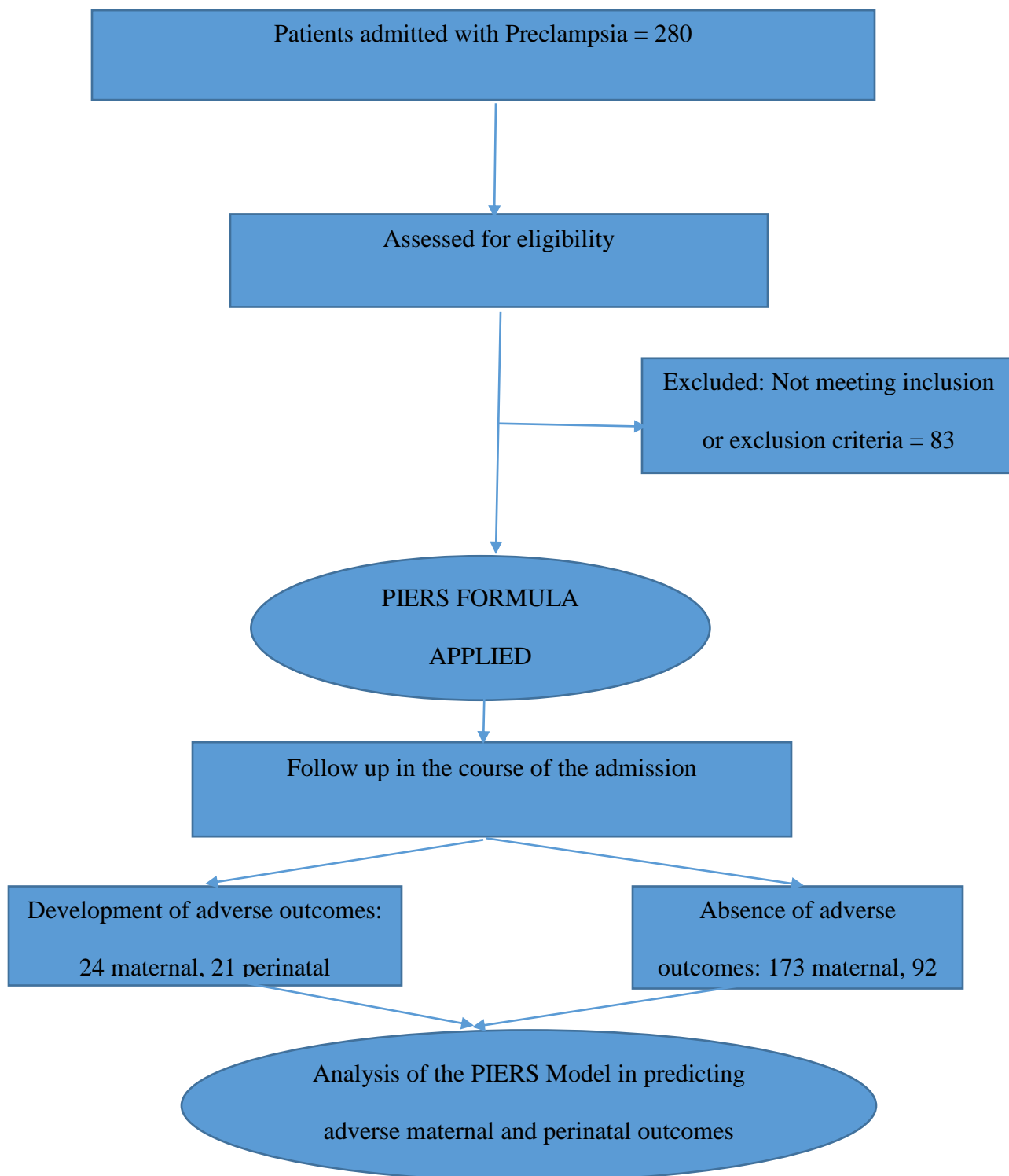


Figure 1: Study flow diagram of patients admitted and managed for preeclampsia diagnosed between July 2018 and October 2018.

## DEMOGRAPHIC AND CLINICAL CHARACTERISTICS

Observations and laboratory parameters of 197 patients who were admitted between July 2018 and December 2018 with a diagnosis of preeclampsia were analysed. Their general characteristics are summarized in table 2 below.

*Table 2: Socio-demographic characteristics of preeclampsia patients admitted with preeclampsia in KNH July – October 2018*

FACTOR		ADVERSE OUTCOME PRESENT		ADVERSE OUTCOME ABSENT	
		NUMBER (%)	%	NUMBER (%)	%
		N=24		N=173	
<b>AGE</b>	<=35 YEARS	22 (91.7)	91.7	141	81.5
	>35 YEARS	2 (8.3)	8.3	32	18.5
<b>EDUCATION</b>	PRIMARY OR NONE	6 (25.0)	25.0	54	31.2
	SECONDARY AND ABOVE	18 (75)	75.0	119	68.8
<b>ECONOMIC STATUS</b>	UNEMPLOYED/ HOUSEWIFE	7	29.2	66	38.2
	EMPLOYED/ SELF EMPLOYED	17	70.8	107	61.8
<b>PARITY</b>	PRIMIPAROUS	10	41.7	46	26.6
	MULTIPAROUS	14	58.3	127	73.4
<b>GESTATION</b>	SINGLETON	23	95.8	161	93.1
	MULTIPLE	1	4.2	12	6.9

The mean patient age was 29.1 years with a standard deviation of 6.6 years

The mean gestational age was 34 weeks 6 days with a standard deviation of 4 weeks 2 days

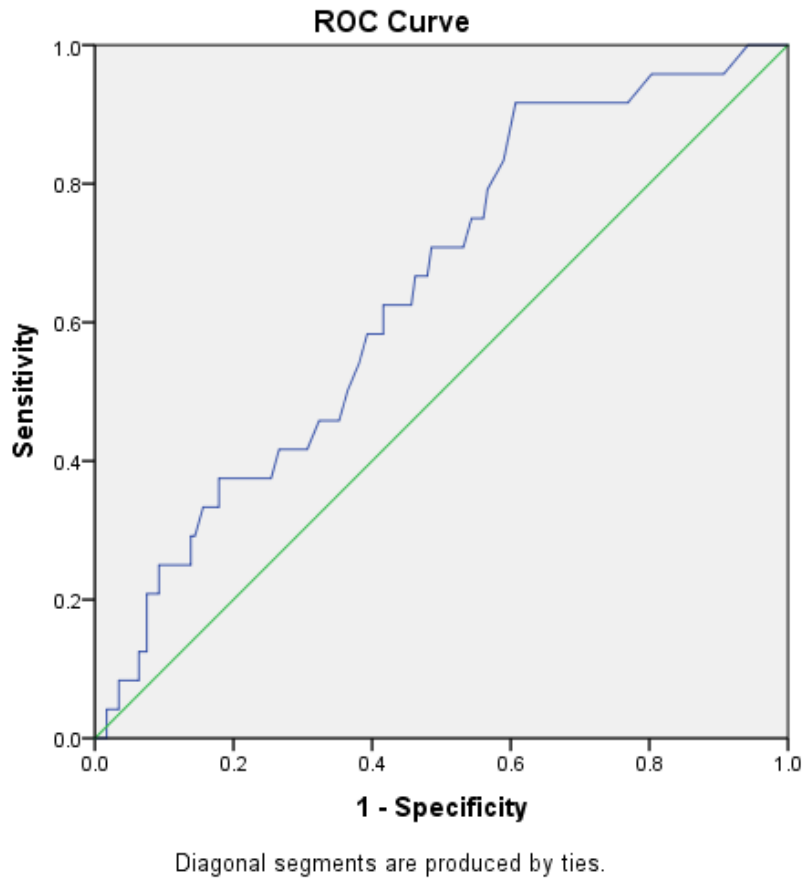


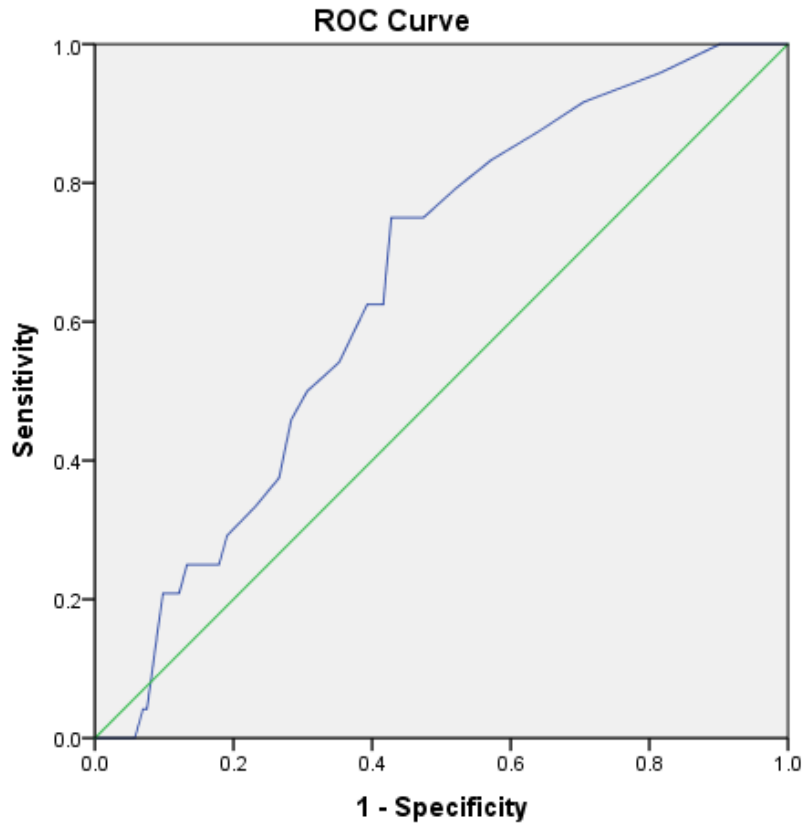
Figure 2: Receiver Operating characteristics Curve for FullPIERS in determining adverse Maternal outcomes among patients admitted with preeclampsia at KNH July – October 2018 – Objective 1



<b>Area under the curve</b>								
Test result	Area	Standard	Asymptotic	Asymptotic 95%		Cut	Sensitivity	Specificity
Variable(s)		Error	Significance	Confidence interval		Off		
				Lower	Upper			
				bound	bound			
Maternal	0.647	0.055	0.019	0.539	0.755	1.55	91.7	60.7
outcome								

*Table 3: Receiver Operating characteristics Curve for FullPIERS in determining adverse Maternal outcomes among preeclampsia patients admitted in KNH July – October 2018- Objective 1*

The value for area under the curve (AUC) for maternal outcome is moderate, indicating that the cut off value is fair for evaluation of adverse maternal outcome. The value of the area under the curve (AUC) has achieved statistical significance with p-values < 0.05, which means they have a favorable sensitivity and specificity characteristics.



Diagonal segments are produced by ties.

*Figure 3: Receiver Operating characteristics Curve for MiniPIERS in determining adverse Maternal outcomes among preeclampsia patients admitted at KNH July – October 2018 – Objective 2*

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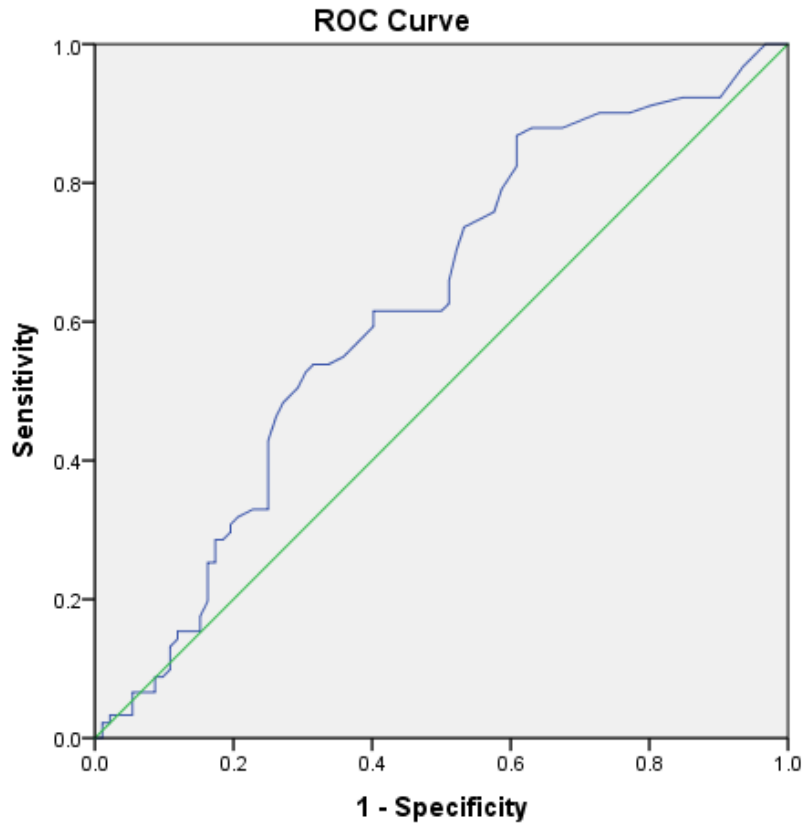
**Area under the curve**

Test result	Area	Standard	Asymptotic	Asymptotic 95%		Cut	Sensitivity	Specificity
Variable(s)		Error	Significance	Confidence interval		Off		
				Lower	Upper			
				bound	bound			
Maternal	0.654	0.051	0.015	0.593	0.754	1.55	75%	42.8%
outcome								

---

*Table 4: Receiver Operating characteristics Curve for MiniPIERS in determining adverse Maternal outcomes among preeclampsia patients admitted at KNH July – October 2018 - Objective 2*

The value for area under the curve (AUC) for maternal outcome is moderate, indicating that the cut off value is fair for evaluation of adverse maternal outcome. The value of the area under the curve (AUC) has achieved statistical significance with p-values < 0.05, which means they have a favorable sensitivity and specificity characteristics.



Diagonal segments are produced by ties.

*Figure 4: Receiver Operating characteristics Curve for FullPIERS in determining adverse Neonatal outcomes among patients admitted with preeclampsia at KNH July – October 2018- Objective 3*

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**Area under the curve**

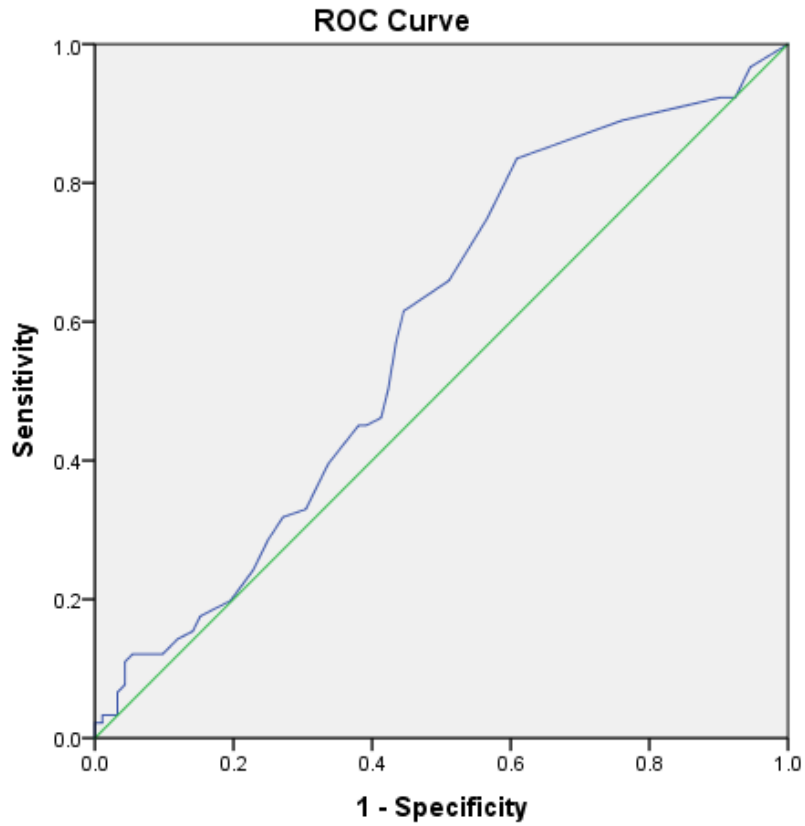
Test result	Area	Standard	Asymptotic	Asymptotic 95%		Cut	Sensitivity	Specificity
Variable(s)		Error	Significance	Confidence interval		Off		
				Lower	Upper			
				bound	bound			
Neonatal	0.622	0.042	0.004	0.540	0.703	1.05	86.8	60.9

outcome

---

*Table 5: Receiver operating characteristics Curve for FullPIERS in determining adverse Neonatal outcomes among preeclampsia patients admitted at KNH July – October 2018 – Objective 3*

The value for area under the curve (AUC) for neonatal outcome is moderate, indicating that the cut off value is fair for evaluation of adverse maternal outcome. The value of the area under the curve (AUC) has achieved statistical significance with p-values < 0.05, which means they have a favorable sensitivity and specificity characteristics.



Diagonal segments are produced by ties.

*Figure 5: Receiver Operating characteristics Curve for MiniPIERS in determining adverse Neonatal outcome among preeclampsia patients admitted at KNH July – October 2018 – Objective 3*

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**Area under the curve for miniPIERS in predicting adverse neonatal outcomes**

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Test result	Area	Standard	Asymptotic	Asymptotic 95%		Cut	Sensitivity	Specificity
Variable(s)		Error	Significance	Confidence interval		Off		
				Lower	Upper			
				bound	bound			
Neonatal	0.585	0.042	0.048	0.501	0.688	1.05	83.5%	60.9%

outcome

---

*Table 6: Receiver Operating characteristics Curve for MiniPIERS in determining adverse Neonatal outcomes among preeclampsia patients admitted at KNH July – October 2018 – Objective 3*

The value for area under the curve (AUC) for neonatal outcome using the miniPIERS calculator model is poor with the area under the curve reported as 0.585. This indicates that the cut off value is poor for evaluation of adverse neonatal outcome.

## **CHAPTER 4                   DISCUSSION, CONCLUSION AND RECOMMENDATIONS**

### **4.1 DISCUSSION**

This study sought to determine the sensitivity and specificity of the PIERS model in predicting the risk of adverse maternal outcomes among patients admitted with preeclampsia at Kenyatta National Hospital. The main findings of the study were that more than 10% of patients admitted with preeclampsia developed adverse maternal outcomes and 49% of the fetuses delivered developed an adverse outcome. The fullPIERS model predicted with moderate accuracy the occurrence of adverse maternal and neonatal outcomes, while the miniPIERS predicted with moderate accuracy the occurrence of adverse maternal outcomes but predicted adverse neonatal outcomes with poor accuracy.

This study findings of 49.7% adverse perinatal events is to a similar study done by Shruti Agrawal (Prediction of Adverse Maternal Outcomes in Preeclampsia Using a Risk Prediction Model, 2016) which reported a 43.16 % rate of adverse perinatal events among women admitted with preeclampsia.

Our study reported a rate of 12.2% adverse maternal outcome among the 197 patients recruited. This is similar to the study done by Emily E. et al, 2016 (External validation of the fullPIERS (Preeclampsia Integrated Estimate of RiSk) model – retrospective cohort study) which reported a rate of 12.3%.

The fullPIERS model in this study performed moderately well in identifying the risk of composite maternal morbidity (ROC: AUC 0.647) which is similar to the study conducted by Emily et al, 2016 (ROC: AUC 0.68).



The miniPIERS model in prediction of adverse maternal outcomes performed moderately well with an ROC: AUC of 0.654. This is inferior to the study performed by Beth A.P. (A Risk Prediction Model for the Assessment and Triage of Women with Hypertensive Disorders of Pregnancy in Low-Resourced Settings: The miniPIERS (Pre-eclampsia Integrated Estimate of RiSk) Multi-country Prospective Cohort Study, 2014) where the ROC: AUC was 0.768. The difference may be due to the higher numbers of recruited patients in the study by Beth A.P.

The study was limited by the fact that the study population was derived from patients admitted at Kenyatta National Hospital only which may not be representative of the general population hence the findings may not be generalizable. The PIERS model apportions equal weight to diverse adverse outcomes without grading severity of the various adverse outcomes. The strength of this study is that it was a prospective study hence it was able to capture all the components required in the PIERS model hence giving better information than a retrospective study. This is the index study performed in this country to assess the utility of a predictive model in preeclampsia hence it is likely to impact positively on the management of future patients admitted with preeclampsia.

## **4.2 CONCLUSION**

The fullPIERS model has moderate stratification ability in predicting the development of both adverse maternal and perinatal outcomes within 48 hours among patients admitted with preeclampsia while the miniPIERS has poor stratification ability for predicting neonatal outcomes but maintains moderate stratification ability in predicting adverse maternal outcomes.

### **4.3RECOMMENDATIONS**

Following the findings of this study, this model may be considered as an additional tool in smaller peripheral health facilities to help them in decision making of which preeclampsia patient requires urgent referral to more specialized facilities. We recommend that subsequent researchers consider use of larger sample sizes and multicenter participation to further validate this tool in our local setting and to assess the performance of this model in non-teaching/referral hospitals.

Additional research should target stratification of patients into those presenting with early onset preeclampsia (less than 34 weeks gestation) and those presenting with late onset preeclampsia (34 weeks of gestation and above).

## STUDY TIMELINES

Activity	Sept – Decem ber 2017	Jan 2018	June 2018	July – Oct 2018	Nov 2018	Dec 2018
Proposal development						
Ethical approval						
Data collection						
Data analysis and results write up						
Presentation of results						

## APPENCICES

<b>Item</b>	<b>Unit cost</b>	<b>Required</b>	<b>Total cost (Kshs.)</b>
Printing paper	1000/=	4	4000
Pens	250/=	4	1000
Flash disk	2500/=	4	10000
Research assistant training	5000/=	2	10000
Research assistants	10 000/=	2	20000
Airtime	5000/=	2	10000
Pulse oximeters	5000/=	2	10000
Data entry	20000/=	1	20000
Statisticians fee	25000/=	1	25000
Results dissemination	10000/=	1	10000
<b>TOTAL</b>			<b>120,000</b>

## BUDGET

## REFERENCES

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## **Annexes 1: Letter to ERC and ERC Approval**

Dr. George Kiere Njatha (MBChB)

H58/74128/2014

14<sup>th</sup> December 2017

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

Through,  
The Chairman,  
Department of Obstetrics and Gynaecology,  
University of Nairobi

Dear Sir,

### **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. George Kiere Njatha,  
Senior House Officer,  
Department of Obstetrics and Gynecology,  
College of Health Sciences  
University of Nairobi



## **Appendix 2: Informed Consent**

### **INFORMED CONSENT FORM**

#### **PIERS MODEL FOR PREDICTION OF ADVERSE MATERNAL AND NEONATAL OUTCOMES IN PREECLAMPSIA**

##### **Investigator:**

Dr. George Kiere Njatha

Resident, Department Of Obstetrics and Gynaecology

University of Nairobi

P.O Box 342-00200 Nairobi

0721 616 494

##### **Supervisors:**

Professor S.B.O. Ojwang,

Department of Obstetrics and gynaecology

University of Nairobi

Dr. Alfred Osoi,

Department of Obstetrics and gynaecology,

University of Nairobi

##### **Investigators statement**

I am requesting you to be a participant in my research study. The purpose of this consent form is to give you the information you will need to decide whether to be in the study or not. Please read this form carefully. You may ask questions about what you will be asked to do, the risks, the benefits and your rights as a volunteer, or anything about the research that is not clear in this form. When all your questions have been answered, you can decide if you want to be in this study or not. This process is called “informed consent”.

### **Background, Purpose and Benefits**

Preeclampsia is a condition that affects pregnant mothers that manifests as raised blood pressure and presence of proteins in urine. This condition could lead to harmful effects among some patients diagnosed with this condition.

This study seeks to establish whether the PERS model (it is a model that incorporates patient symptoms and 3 basic laboratory results to calculate the estimated risk of developing an adverse outcome) can predict the risk of an adverse outcome among patients with preeclampsia.

### **Risks, Stresses, Discomfort and study dissemination**

There are no risks involved from participating in the study.

You will receive the care that is expected.

There will be no reimbursement provided as the study involves only patients already admitted into Kenyatta National Hospital

Completing the questionnaire will take you 10 - 15 minutes. The results of this study will be presented as an academic paper or in a published journal.

### **Expectations**

By agreeing to participate you are expected to answer questions regarding your bio data, medical and obstetric history. You are also agreeing to let the study team obtain information from your medical records about any further information that may be required.

### **Cost**

Cost of standard care will be incurred by the patient herself.

**Confidentiality**

Your confidentiality will be maintained at all times. The questionnaires will not have any names but will be assigned identifiers. Only the investigator and the University of Nairobi Ethics and Research committee will have access to information about you.

There shall be no mention of names or identifiers in the report or publications which may arise from the study. The information obtained will be used only for the purpose of the study.

You may withdraw from the study or refuse to answer any of the questions asked at any time without the loss of benefit or any penalty.

Your participation to the study is voluntary and will be highly appreciated.

**DECLARATION**

I have explained to the respondent the nature and purpose of the study as described above. The respondent has been informed of their right to ask questions and I have clarified any issues to the best of my ability.

Investigator's Signature: -----Date.....

**Consent To Participate In The Study**

**Participant's statement:**

This study has been explained to me. I volunteer to take part in this research. If I have questions later on about the research I can ask the investigator above.

If I have questions about my rights as a research subject I can call the university of Nairobi ethics and research committee on 2726300. I will receive a copy of this consent form.

Signature of participant: ----- Date.....

Name of participant: -----

In case of any Ethical concerns please contact:

Prof M.L. Chindia

Secretary, Kenyatta National Hospital/University of Nairobi Ethics and Research Committee

Hospital Road along Ngong Road

P.O. Box 20723, Nairobi

Telephone 2726300 Ext: 44102

Copies to: 1. participant 2. Investigators file

### **Appendix 3: Fomu Ya Ridhaa**

**Kuchunguza PIERS MODEL kwajili ya kutabiri maokeo mabaya kwa mama na watoto wachanga walioadhirika na mimba iliyokuwa na shida ya Preeclampsia**

#### **Mpelelezi:**

Dr. George Kiere Njatha

Daktari,

Idara ya uzazi na magonjwa ya wanawake

Chuo Kikuu cha Nairobi

Sanduku la posta 342-00200 Nairobi

0721 616 494

#### **Wasimamizi:**

Profesa S.B.O. Ojwang,

Idara ya uzazi na magonjwa ya wanawake

Chuo Kikuu cha Nairobi

Sanduku la posta 342-00200 Nairobi

Dr. Alfred Osoti,

Idara ya uzazi na magonjwa ya wanawake

Chuo Kikuu cha Nairobi

Sanduku la posta 342-00200 Nairobi

## **Taarifa ya mchunguzi mkuu**

Mimi nakuomba uwe mshiriki katika utafiti wangu. Madhumuni ya fomu hii ya idhini ni kukupa taarifa unayohitaji kuamua kama utashiriki katika utafiti huu au la. Tafadhali soma fomu hii kwa makini. Unaweza kuuliza maswali kuhusu nini utatakiwa kufanya, hatari yoyote, faida na haki zako kama mtu ambaye amejitolea, au kitu chochote kuhusu utafiti huu ambacho sio wazi katika fomu hii. Wakati maswali yako yote yamejibiwa kikamilifu, unaweza kuamua kama wewe unataka kuwa katika utafiti huu au la. Utaratibu huu unaitwa "utoaji idhini".

## **Historia, nia na faida ya utafiti huu**

Preeclampsia ni hali ambayo huathiri mama wajawazito na hudhihirishwa na shinikizo la damu na uwepo wa protini katika mkojo. Hali hii inaweza kusababisha madhara kati ya wagonjwa wengine ambao wamekukutwa na hali hii.

Utafiti huu unalenga kuangalia kama mpangilio wa PIERS (ni mpangilio ambao unashirikisha dalili alizonazo mgonjwa pamoja na matokeo tatu msingi ya maabara ili kufanya hesabu ya makadirio ya hatari ya matokeo mabaya) unaweza kutabiri hatari ya matokeo mabaya kati ya wagonjwa wenye preeclampsia.

## **Hatari, usumbufu na usambazaji wa matokeo ya utafiti huu**

Hakuna hatari yeyote inayokadiriwa kutokea kwa kushiriki katika utafiti huu. Utapokea huduma ambayo inatarajiwa. Hakutakuwa malipo yoyote itakayotolewa kwa minajili ya kushiriki kwa utafiti huu. Hii ni kwa sababu utafiti huu unahusisha tu wagonjwa ambao tayari wamelazwa katika hospitali kuu ya taifa ya Kenyatta. Kukamilisha dodoso itachukua wewe dakika kumi mapa dakika kumi na tano. Matokeo ya utafiti huu yatawasilishwa kama karatasi ya kielimu au kuchapishwa katika jarida la kisayansi.

## **Matarajio**

Kwa kukubaliana na kushiriki, utatarajiwa kujibu maswali kuhusu taarifa yako ya wasifu, historia ya matibabu na uzazi. Hii idhini pia itaruhusu timu ya watafiti kupata taarifa kutoka kwa rekodi yako ya matibabu kuhusu taarifa yoyote zaidi ambayo inaweza kuwa inahitajika.

## **Gharama**

Gharama ya huduma ya matibabu inayodaiwa itagharamiwa na mgonjwa mwenyewe.

## **Usiri**

Usiri wako utadumishwa wakati wote. Dodoso hazitawekwa majina yeyote wagonjwa, badala yake dodoso zitawekwa nambari za kipekee kwa ajili ya vitambulisho. Ni wapelelezi pekee pamoja na Chuo Kikuu cha Nairobi na Maadili na Kamati ya Utafiti ambao wanaweza kupata taarifa juu yako.

Hakutakuwa majina au vitambulisho vyovyote katika taarifa au machapisho ambayo yanaweza kutokea kutokana na utafiti huu. Taarifa itakayopatikana kutokana na utafiti huu itatumika tu kwa madhumuni ya utafiti.

Unaweza kuondoka kutoka utafiti huu au kukataa kujibu yoyote ya maswali yoyote ambayo utauliuliza wakati wowote bila hasara ya faida au adhabu yoyote. Kushiriki kwako katika utafiti huu ni wa hiari na itakuwa yenye kukubaliwa.

## **TANGAZO**

Mimi nimemweleleza mhojiwa hali na lengo la utafiti kama ilivyoelezwa hapo juu. Mhojiwa ameelezwa haki yake ya kuuliza maswali na mimi nimemjibu masuala yoyote alikuwa nayo kwa kadri ya uwezo wangu.

Signature Mpelelezi .....

Tarehe.....

## **FOMU YA OMBI LA RIDHAA**

Mimi, \_\_\_\_\_ nina umri wa miaka 18 au zaidi nina mamlaka kamili wa kushirikikwenye utafiti huu wa **“KUPIMA UWEZO WA PIERS MODEL KUWEZA KUTABIRI MATOKEO MABAYA KWA WAJAWAZITO WALIO NA SHIDA YA PREECLAMPSIA KATIKA HOSPITALI YA KENYATTA NATIONAL HOSPITAL”** Utafiti ambao unaendeshwa na Daktari George Kiere Njatha na nimefahamishwa na nimesoma maelezo ya utafiti huu, nimeona umbile la kazi hii, faida zake, madhumuni yake, muda utakaochukuwa kazi hii, ushiriki katika kazi hii si wa kulazimishwa na nimeona hauna madhara kwa yeyote na yale yote yatakayotokeya ni mambo ambayo hayatarajiwi kwa jinsi nilivyoelewa kwa maelezo niliyopewa na \_\_\_\_\_ *(Jina la aliyetowa taarifa hiyo kwa mgonjwa)*

Nimepewa nafasi ya kuhoji na kutaka ufafanuzi kwa lolote linalohusiana na utafiti huu, nimehoji, na nimeridhika kwa jawabu nilizopata, ikiwa nitakuwa na suali lolote wakati wote wa kazi hii nitamuona \_\_\_\_\_ *(Jina la mfanyakazi wa Kituo au Mtafiti Mkuu)* Nimefahamishwa na ninaelewa ya kwamba ninaweza wakati wowote kujiondoa kwenye utafiti huu iwapo ninataka kufanya hivyo, uamuzi wangu huo hautanipelekea kuadibiwa kwa njia yeyote ile.

**NDIO**

Sahihi ya mgonjwa \_\_\_\_\_ Tarehe \_\_\_\_\_

Anuani ya makaazi \_\_\_\_\_

Nambari ya mgonjwa \_\_\_\_\_

Sahihi ya shahidi \_\_\_\_\_ Tarehe \_\_\_\_\_

Jina la Shahidi \_\_\_\_\_



Appendix 4: Questionnaire and Data Collection Form

**DATE**

**SERIAL NUMBER**

**INSTRUCTIONS:**

**Kindly respond truthfully to all the questions listed below.**

**Ask for clarifications from the principal investigator or his assistants where any question is not clear to you.**

1. Patient's study number
2. Age in completed years
3. Education
  - 3.1.1. None
  - 3.1.2. Primary
  - 3.1.3. Secondary
  - 3.1.4. Tertiary
4. Marital status
  - 4.1.1. Single
  - 4.1.2. Married
  - 4.1.3. Separated/widowed
5. Economic status
  - 5.1. Employed
  - 5.2. Self employed
  - 5.3. Unemployed
  - 5.4. Housewife
6. History of chronic illness prior to current pregnancy:
  - 6.1. Hypertension
  - 6.2. Diabetes
  - 6.3. Cardiac disease
  - 6.4. Thyroid disease
  - 6.5. Other chronic disease (specify)
7. Preceding deliveries

PREGNANCY NUMBER	TERM	PRETERM	ABORTION	PRE ECLAMPSIA	ECLAMPSIA	LIVE BIRTH	STILL BIRTH	SVD	C/S
1 <sup>st</sup>									
2 <sup>nd</sup>									

3 <sup>rd</sup>									
4 <sup>th</sup>									
5 <sup>th</sup>									
6 <sup>th</sup>									

**8. CURRENT PREGNANCY**

- 8.1. Parity
- 8.2. LMP
- 8.3. EDD by LMP:
- 8.4. EDD by earliest available ultrasound
- 8.5. Date ultrasound done
- 8.6. Gestational age (in weeks) at diagnosis of preeclampsia

**9. CURRENT ADMISSION**

- 9.1. Gestational age at admission
- 9.2. Diagnosis of DVT in this pregnancy
- 9.3. History of cardiac disease in this pregnancy

**10. Within the first 48 hours of admission:**

- 10.1. Presence of chest pain or dyspnea
- 10.2. Presence of headache
- 10.3. Presence of visual blurring/disturbances
- 10.4. Presence of epigastric or right upper quadrant abdominal pain
- 10.5. Presence of vomiting
- 10.6. Presence of per vaginal bleeding associated with abdominal pain
- 10.7. Highest systolic blood pressure
- 10.8. Highest diastolic blood pressure
- 10.9. Lowest oxygen saturation by pulse oximetry
- 10.10. Lowest Hb
- 10.11. Lowest platelet level
- 10.12. Highest AST/SGOT
- 10.13. Highest Creatinine

**11. Medications and select management in current admission**

- 11.1. Aldomet/Methydoxa
- 11.2. Nifedipine
- 11.3. Hydralazine
- 11.4. Labetalol
- 11.5. Magnesium sulphate
- 11.6. Phenytoin
- 11.7. Diazepam
- 11.8. Labor induction

**12. PIERS Calculation using the PIERS Calculator**

- 12.1. miniPIERS score
- 12.2. FULLPIERS Score

### **13. ADVERSE MATERNAL OUTCOMES**

- 13.1. Death
- 13.2. ICU/HDU admission
- 13.3. Glasgow Coma Scale <13
- 13.4. Stroke
- 13.5. Reversible ischemic neurologic deficit
- 13.6. Cortical blindness
- 13.7. Retinal detachment
- 13.8. Acute renal insufficiency
- 13.9. Dialysis
- 13.10. Hepatic hematoma/rupture
- 13.11. Postpartum hemorrhage requiring transfusion
- 13.12. Number of units transfused
- 13.13. Transfusion of blood products
- 13.14. Positive inotropic support
- 13.15. Myocardial ischemia/infarction
- 13.16. Need for >50% oxygen for >1 hour
- 13.17. Intubation other than for C/S
- 13.18. Pulmonary edema

### **14. ADVERSE NEONATAL OUTCOMES**

- 14.1. Prematurity/preterm birth
- 14.2. Respiratory distress
- 14.3. Ventilation given
- 14.4. NBU Admission
- 14.5. Fresh still birth
- 14.6. Macerated still birth
- 14.7. Neonatal death