# UNIVERSITY OF NAIROBI SCHOOL OF HEALTH SCIENCES OBSTETRICS AND GYNECOLOGY DEPARTMENT

# PREVALENCE AND RISK OF ADVERSE OUTCOMES OF HYPERTENSIVE DISORDERS IN PREGNANCY AT PUMWANI MATERNITY HOSPITAL IN 2018-2019,

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A research dissertation submitted to the University of Nairobi, Department of Obstetrics and Gynecology in partial fulfilment of the requirements, of a degree in Masters of Medicine in Obstetrics and Gynecology.

2021

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# **ABBREVIATIONS AND ACRONYMS**

- ANC-antenatal care
- AKI- Acute kidney injury
- **BP- Blood Pressure**
- CH Chronic hypertension
- EC- Eclampsia
- ERC- Ethics and Research Committee
- **GH-** Gestational Hypertension
- HDP-Hypertensive disorders in pregnancy
- ISSHP-International society for the study of hypertension in pregnancy
- KNH- Kenyatta National Hospital
- LMIC-Low and middle-income countries
- MAP- mean arterial pressure
- MDG's Millennium Development Goals
- MMR -Maternal Mortality Ratio
- MoH- Ministry of Health
- PIGF placental growth factor
- PMH- Pumwani Maternity Hospital
- PE- preeclampsia
- PMR-Perinatal mortality rate.
- PAPP-A- pregnancy-associated plasma protein
- SSA-sub-Saharan Africa
- UoN- University of Nairobi
- WHO- World Health Organization

# **DEFINITION OF OPERATIONAL TERMS**

Millennium development goals (MDG): this is a roadmap (8 goals), committing countries to a global partnership to reduce poverty by the year 2015, and was revised to (sustainable development goals) SDG in 2015 to end poverty by 2030.

Antenatal care (ANC): is prenatal care provided by skilled health care providers, where regular checkups are done during the prenatal period currently 8 checkups are recommended

Maternal mortality ratio (MMR): the maternal mortality ratio is the number of women who die as a result of childbearing estimated per 100000 live births in a given period.

Mean arterial pressure (MAP): the average arterial pressure during a single cardiac cycle and is equal to (systolic blood pressure-diastolic blood pressure) /3+ diastolic blood pressure.

Hypertensive Disorders in Pregnancy (HDP): refers to pregnancy-specific hypertensive disorders which include chronic hypertension, chronic hypertension with superimposed preeclampsia, gestational hypertension, preeclampsia, eclampsia, and HELLP syndrome.

Hemolysis Elevated liver enzymes Low Platelets (HELLP) Syndrome: In a setting of preeclampsia having end-organ damage evident as elevated liver enzymes and low platelets.

Prevalence of hypertensive disorders in pregnancy: the total number of pregnant and postpartum women with hypertensive disorders in pregnancy per total number of pregnant and postpartum women who received care at PMH.

Pre-eclampsia: Preeclampsia is a pregnancy-specific hypertensive disorder that occurs after 20 weeks of gestation until 6 weeks postpartum and is characterized by elevated blood pressure above 140/90 mmHg and is evidenced by end-organ damage.

Adverse outcomes: refers to complications that occur due to HDP and result in organ dysfunction, which may vary from the mildest affecting a particular organ to very severe involving multiple organs and may lead to long-term morbidity and even death.

In this study, maternal adverse outcomes included derangement in organ function including renal function, liver function, the central nervous system function, as evidenced by the lab investigations and parameters. Adverse neonatal outcomes included preterm birth, delivery of small for gestational age infants, stillbirth, and intrauterine fetal demise.

### ABSTRACT

**Background:** About 500,000 women die yearly due to pregnancy-related causes and 99% of these occur in low and middle-income countries. Hypertensive disorders in pregnancy (HDP) are the second leading cause of maternal deaths. Preeclampsia (PE) results in 76,000 maternal deaths and 500,000 perinatal deaths per annum globally. HDP affects 5-10% of pregnancies word wide, in Australia affects 9.8%, in Africa, most studies found a higher prevalence of HDP at 13% while that in Kenya is 10% and limited data according to the United States National Discharge survey suggests an upward trend. PE with severe features affects 51.9% and eclampsia 23.4% of pregnancies with HDP. Globally the rate of adverse maternal and perinatal outcomes in HDP stands at 40%. In the US the most common adverse outcomes in PE were; placenta abruptio 10%, neurological deficits 7%, aspiration pneumonia 7%, pulmonary edema 7%, cardiac arrest 4%, Acute kidney injury (AKI) 4%, and maternal death 1%. In Tanzania, the prevalence of eclampsia has been estimated at 1.6% and the perinatal mortality rate was 30%. In Kenya Wasiche at Kenyatta National Hospital (KNH) reported maternal complications in 67% of patients with eclampsia, with the commonest complications being sepsis 40.4%, pulmonary edema 25.3%, AKI 10.4%, and cerebral hemorrhage 10.4%.

#### **Objective:**

This study aimed to determine the prevalence of HDP and the risk of adverse maternal and perinatal outcomes among pregnant and postpartum women who received care at Pumwani Maternity Hospital between January 2018 and December 2019.

#### Methodology

This was a cross-sectional study in which records of 3990 patients were sampled from 39,711 maternal deliveries during the study period. The study population was described by summarizing socio-demographic and obstetric characteristics into percentages and means or medians for categorical and continuous variables respectively. Prevalence of HDP was calculated out of the total admissions and 95% confidence interval was presented while that of adverse maternal complications and neonatal outcomes was calculated out of all women with HDP and 95% confidence interval was presented. Factors associated with HDP, adverse maternal outcomes, and neonatal outcomes was determined using; chi square test for categorical variables and comparison of means using independent t test for continuous data. Odds ratios were calculated to estimate the odds of developing the outcomes associated with each independent variable. P value of <0.05 was considered statistically significant. Data was presented in tables, pie charts, and bar graphs.

# **Results:**

Between January 2018 and December 2019, a total of 3990 records were reviewed and data extracted. A total of 338 were excluded, 159 due to missing LNMP, 66 due to missing BP, 25 due to missing LNMP and BP, and 88 due to missing of greater than 5% of data. The mean age of all participants was 26 years and median (IQR) of 25.0 (22.0-30.0). Nearly all (99.2%) attended ANC and 78.4% had SVD. The prevalence of HDP was 14.5% (95% CI13.3-15.6%), n=528 out of 3124 while that of PE was 49.8% (n=154) of patients with HDP. We had 47.5% n=251 of patients with HDP who were unclassified. The mean birth weight of the neonates was 3042.8g. Among women with HDP, the prevalence of maternal complications was 3.2% (95%CI1.7-4.9) n=17 out of 528, and post-partum hemorrhage was the leading cause n=8 out of 17 thus 47.1%. The prevalence of adverse neonatal outcomes was 16.9% (95%CI13.7-20.0) reported in 16.9 % (13.5-20.1 %) and birth asphyxia was the leading cause n=48 out of 89 thus 53.9%.

# **Conclusion:**

The prevalence of HDP among pregnant and postpartum women at PMH from January 2018 to December 2019 was 14.5% and the prevalence of adverse maternal outcomes among women with HDP was 3.2% while that of adverse neonatal outcomes was 16.9%. We had 47.5% of patients with HDP who were unclassified. There were no factors that were significantly associated with HDP in this setting during our study period.

# **Recommendations:**

There is a high prevalence of HDP at PMH hence the need for heightened awareness, the institution of prevention measures, to ensure the provision of good quality care and enhance the achievement of good maternal and perinatal outcomes.

# **CHAPTER 1: INTRODUCTION**

# 1.1 BACKGROUND

Over 500,000 women die yearly due to causes associated with pregnancy and 99% of these deaths occur in low and middle-income countries (1). Sub-Saharan Africa contributes more than half of these maternal mortalities(2). Hypertensive disorders of pregnancy (HDP) affect 10% of pregnancies globally (1,2). The prevalence of HDP in Australia is 9.8%, higher than that in India at 7.8% (3). Recent data from the united stated national discharge survey (USNDS) points to an increase in the rate of preeclampsia in the US by 25% from 1987 to 2004 (4). There is a paucity of current and reliable data on the burden of HDP in sub-Saharan Africa. Most of these studies found a higher prevalence of HDP and pre-eclampsia at 13% in Africa compared to the rest of the world and about 10% in Kenya (5,6). According to a confidential inquiry into maternal death in 2014, HDP accounted for 3 out of 20 (6).

HDP are a major genesis of maternal and newborn mortality, morbidity, and disability. Hypertensive disorders in pregnancy are categorized as gestational hypertension, chronic hypertension, preeclampsia, chronic hypertension with superimposed preeclampsia and, eclampsia. Preeclampsia and gestational hypertension are the most common(7). Preeclampsia complicates 2-8% of pregnancies, occurs after 20 weeks of gestation, and is characterized by hypertension and proteinuria. If not treated may progress to eclampsia which is characterized by the presence of convulsions. Preeclampsia has the highest prevalence of maternal and perinatal complications(7). Around 10% to 15% of direct maternal deaths are attributed to preeclampsia and eclampsia(1,8,9) and where maternal deaths are high they are due to eclampsia rather than preeclampsia similarly??, PMR is higher in eclampsia as compared to preeclampsia and higher in low and medium-income countries due to limited access to neonatal intensive care(1). HDP was sighted as the leading cause of maternal mortality in Maroua Provincial Hospital Cameroon,2005 at 17.5%(10)

Severe disability related to preeclampsia and eclampsia affects multiple organs including renal failure, stroke cardiac dysfunction or arrest, respiratory compromise coagulopathy, and liver failure(4). HDP and more so preeclampsia (PE) is related with AKI and an increase in maternal and perinatal mortality(11). Preeclampsia was found to be the leading cause of obstetric intensive care unit (ICU) admissions after pregnancy-related hemorrhage in Hospital Corporation of America (HCA) hospitals (12).

Fetal growth restriction at 15% and 20% and small for gestation age infants as well as 15-20% of preterm births are attributed to preeclampsia(13). A quarter of stillbirths and neonatal deaths in low-income countries are attributed to preeclampsia/ eclampsia and infant mortality is three times higher than in high-income countries largely due to lack of neonatal intensive care facilities(1).

Accurate data on HDP in sub-Saharan Africa remains a big challenge even as most studies indicate a higher prevalence of HDP and pre-eclampsia in Africa compared to

the rest of the world (5). In Kenyatta national hospital (KNH) the incidence among 14,730 deliveries during two years from 1<sup>st</sup> January 1999-31<sup>st</sup> December 2000 was found to be 10% (Division of Reproductive Health,2001)(14), while in Central Kenya eclampsia was found to affect 7% of pregnant women during the study period 1<sup>st</sup> July 2009 to 30<sup>th</sup> June 2010(14,15). Yego et al at Moi Teaching and Referral Hospital (MTRH) period from January 2004 to December 2011 Eldoret showed that pregnancies complicated by eclampsia at 22%, were the leading cause of maternal mortality at Moi Teaching and Referral Hospital (16).

## **1.2 LITERATURE REVIEW**

#### 1.2.1 Epidemiology

World Health Organization (WHO) estimates that more than 800 women die from childbirth and obstetric complications daily(2), and an approximate 99% of these mortalities occur in low and middle-income countries (LMIC) with sub-Saharan Africa accounting for greater than half of these mortalities (17). Despite the substantial gains made globally and in Sub-Saharan Africa where mortalities have reduced by 50% in the last two decades. The maternal mortality ratio (MMR) in Africa remains unacceptably high at 525/100000 live births compared to the global average of 211/100000 live births (18).

The leading causes of maternal mortality include; hemorrhage (27%), sepsis (10.7%), hypertensive disorders (14.0%), and unsafe abortion (7.9%) (19). Hypertensive disorders of pregnancy (HDP) are associated with avoidable morbidity, long-term disability and, the mortality of mothers and babies, making them a public health problem of concern (4). Of the HDPs, pre-eclampsia and eclampsia have the biggest impact and are responsible for a significant proportion of adverse maternal and neonatal outcomes (20).

The WHO estimates that HDP affects 10% of pregnancies globally (21) this corresponds to a study on the epidemiology of hypertensive disorders in pregnancy that found the prevalence of HDP between 5-10% worldwide (7). In India, HDP was found to have a prevalence of 7.8% with preeclampsia affecting 5.4% of the study population (22), while in southern India a hospital-based study conducted from 1996-2010 on 194,250 patients found a prevalence of 4-12.3%(17).

In sub-Saharan Africa, reliable data on HDP remains scanty and most of the studies performed in African find a higher prevalence of HDP and pre-eclampsia compared to the rest of the world (5). In South Africa, a population-based study found an incidence of 12% in an urban township(23). Similarly, among black South –African women the incidence of HDP and pre-eclampsia was reported to be 12.5% and 5.2% respectively(24). However, this study was limited to nulliparous women and as such may not be representative of the entire population. In Ethiopia 2010, the incidence rate of HDP was 8.5%, and 51.9% of these, were cases of severe-pre-eclampsia and 23.4% eclampsia(25). Similarly in Nigeria 2008, the incidence of HDP was found to be 3.7% (26).

In Kenya at KNH, the incidence among 14,730 deliveries during two years from 1<sup>st</sup> January 1999-31<sup>st</sup> December 2000 was 10% (Division of Reproductive Health,2001)(14). There were no current studies on the prevalence of preeclampsia and eclampsia at PMH according to a study by Kinuthia on ANC practices and outcomes at PMH (27).

In Central Province, Kenya, eclampsia affected 7% of pregnant women (15). Yego et al at Moi Teaching and Referral hospital showed that pregnancy complicated by eclampsia at 22% was the leading cause of maternal mortality (16).

At Pumwani maternity hospital in 2015, it was found that the perinatal mortality rate in women with hypertension was 203/1000 live births (28).

# **1.2.2 Classification of Hypertensive disorders in pregnancy**

Hypertensive disorders in pregnancy (HDP) is used to define a wide spectrum of patients based on their signs and symptoms from those experiencing mild elevations in blood pressure (BP) to those with severe hypertension which may also be accompanied by organ dysfunction (25). HDP is responsible for 16% of all obstetric deaths in high-income countries, 9% of obstetric deaths in Africa and Asia, and as high as 26% in Latin America and the Caribbean(29).

HDP are classified into 6 categories based on time of onset, the severity of features, elevated blood pressure, and presence of proteinuria. HDP can be grouped into chronic hypertension (CH), pre-eclampsia (PE) (with or without severe features), PE superimposed on chronic hypertension, gestational hypertension (GH), eclampsia (EC), and HELLP syndrome (30). Summary of classification guided by National Institute for Health and Care Excellence (NICE) 2019.

Classification	Gestation	Blood pressure	Proteinuria (24 hr. urine collection)	Organ dysfunction	Resolution 12 weeks post- partum
PE without severe features	≥20 weeks	>140/90 mmHg*	≥0.3gm / ≥1+ dipstick	Absent	Yes
PE with severe features	≥20 weeks	>160/110 mmHg*	≥0.3gm / ≥2+ dipstick	Present	Yes
PE superimposed on chronic hypertension	≥20 weeks	>140/90 mmHg*	≥0.3gm / ≥1+ dipstick	No	Yes
GH	≥20 weeks	>140/90 mmHg*	No proteinuria	No	Yes
СН	<20 weeks	>140/90 mmHg*		No	No
Eclampsia	≥20 weeks	>140/90 mmHg* Can be normotensive	≥0.3gm / ≥1+ dipstick	Present	Yes

Table 1.A summary of hypertensive disorders in pregnancy

HELLP syndrome	≥20 weeks	>140/90	≥0.3gm /	Present	Yes
		mmHg*	≥1+ dipstick		

\*Either systolic or diastolic

#### 1.2.2.1 Pre-eclampsia

PE is new-onset hypertension (systolic or diastolic blood pressure  $\geq$ 140/90), or hypertension, and multiple organ dysfunction with or without proteinuria after 20 weeks gestation(1,20). PE is further classified as pre-eclampsia with severe features, PE without severe features and PE superimposed on chronic hypertension. (Table 1) (30).

Pre-eclampsia with severe features is the presence of either one or more of the following: systolic or diastolic blood pressure  $\geq$ 160/110, neurological disturbances, pulmonary edema, hepatic dysfunction, renal compromise, or thrombocytopenia. If proteinuria is absent but multiple organ dysfunction is evident a diagnosis of preeclampsia can be made(1) Preeclampsia superimposed on chronic hypertension is defined as the presence of features of preeclampsia in the setting of chronic hypertension. Eclampsia is the occurrence of seizures that are not attributable to other causes in the setting of preeclampsia (30).

# 1.2.2.2 Gestational hypertension

Gestational hypertension is new-onset persistent hypertension with BP greater than 140/90mmHg after 20 weeks gestation(31)(32). It is seen in 6% of pregnancies and is not associated with features of target organ involvement like proteinuria however 25% of women may eventually develop PE (33). The development of adverse maternal and perinatal outcomes depends highly on the time of onset with occurrence before 35 weeks gestation linked with the eventual development of preeclampsia in approximately 35% of women, it takes about 5 weeks for preeclampsia to develop (17).

# 1.2.2.3 Chronic hypertension

This is hypertension that occurs before pregnancy or before 20weeks of gestation, it complicates around 1% of pregnancies. And is at times present with comorbidities like kidney disease or type I or II diabetes mellitus(17).

# 1.2.2.4 Superimposed PE on chronic hypertension

This is defined as women with CH who get multiple organ/ target organ involvement consistent with preeclampsia, an elevated BP in the absence of virgin proteinuria, an elevated BP is sufficient to diagnose superimposed PE(17).

# **1.2.2.3 Risk factors for HDP and adverse outcomes in pregnancy**

These are maternal characteristics that are strongly associated with an increased likelihood to develop HDP(17). Their identification is vital for the prioritization of interventions, identification of high-risk women for closer monitoring and care.

According to a study by V. Luannni et al on risk factors of P.E/E.C and its adverse outcomes 2104, the major individual risk factors for developing PE/EC included maternal age >30, lower than secondary education status (AOR:1.11;95%CI1.01-(AOR:1.22;95%CI1.07-1.39) 1.39). education and nulliparity no (AOR:2.04;95%CI1.92-2.16), clinical risk factors included a history of chronic (AOR:7.75;95%CI6.77-8.87), gestational hypertension diabetes (AOR:2.00;95%CI1.63-2.45), cardiac or renal disease (AOR: 2.83;95%CI1.86-3.05), urinary tract infection, pyelonephritis and severe anemia (34). Having >8 antenatal visits was found to be protective, while lack of ANC attendance was found to have significantly higher risks(34). Other documented risks for developing PE/EC include PE in a previous pregnancy, diabetes mellitus, multiple pregnancies, family history of PE, obesity, antiphospholipid syndrome, and chronic kidney disease (35,36). Other factors such as assisted reproductive technology and genetic susceptibility are also associated with increased risk (Rana et al., 2019). Lack of ANC attendance, poor social-economic status, and high diastolic admitting pressures, preterm birth, and low birth weight were identified as predictors for the development of adverse outcomes (37) Early identification of pre-eclampsia risk factors provides an opportunity for prevention and is, therefore a critical component of pre-eclampsia management (38)

# 1.2.5 Pathogenesis of HDP

The mechanisms by which PE occurs are not fully understood, however various theories have been hypothesized(24,39). Multiple factors have been implicated in the pathogenesis. These include; abnormal trophoblastic invasion, vascular endothelial damage, maternal immunologic tolerance, abnormal genetic variations, cardiovascular and inflammatory changes(40,41).

In a seminal paper in 1991, Redman introduced the concept of pre-eclampsia as a two-stage placental disorder(42). Redman postulated that the first stage of pre-eclampsia is preclinical and occurs before 20 weeks gestation whereby impaired placental invasion causes abnormal development of uteroplacental circulation. This is followed by the second stage where the deportation of toxic factors into the maternal circulation occurs as a result of placental hypoxia. Redman argued that the second stage is clinical and occurs during the last 20 weeks of pregnancy resulting in the maternal syndrome of hypertension, proteinuria and, eclampsia(42). Following this initial hypothesis, further research has been carried out to refine the two-stage model.

In 2014 Staff expanded the two-step model to a multistep model (see Figure 1)(39). In this model, Stages 1 and 2 entail defective trophoblast differentiation and poor placentation respectively. This is followed by poor placental perfusion in stage 3 leading to the discharge of inflammatory mediators into the maternal bloodstream and clinical pre-eclampsia in Stage 4. Staff further postulated that decidual inflammation increases the risk of acute atherosis in late pregnancy shown in Stage 5(39).

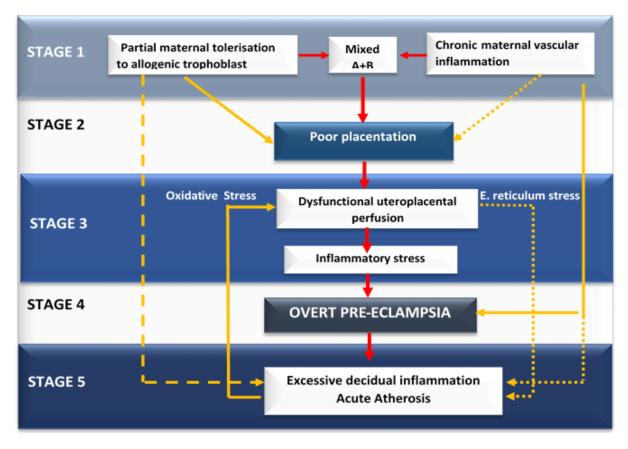


Figure 1 A multistage pre-eclampsia placenta model

Mixed A+B defective trophoblast differentiation and poor placentation lead to poor placental perfusion and consequently stages 2, 3, 4and 5 (Source: Staff et al., 2014).

# 1.2.6 Management of HDP

The management of HDP should start at the point of diagnosis all through the postpartum period. However, our study focuses on the period from the point of admission to the point of discharge.

# 1.2.6.1 Diagnosis

#### Biochemical and Biophysical markers for diagnosis/ prognosis

Some markers that reflect placental function like placental growth factor (PGIF) and pregnancy-associated plasma protein-A (PAPP-A) are significantly reduced in the first trimester and throughout pregnancy in patients that come with preterm preeclampsia. PGIF is a better marker as it has a higher sensitivity(1,43).

# The mean arterial blood pressure and pulsatile index

Both the mean arterial BP and mean artery pulsatile index at between 11 and 13+6 weeks gestation are higher in women that will later develop preeclampsia compared to unaffected women with unaffected pregnancies, and they are particularly elevated in women who develop early preeclampsia(1,43).

# Assessment of proteinuria

This can be done using an automated reagent-strip reading device and where a result of 1+ or more is obtained a spot urinary protein: creatinine ratio for estimating proteinuria in a secondary care setting or a 24-hour urine collection should be done to quantify proteinuria. A protein: creatinine ratio greater than 30mg/mmol or validated 24-hour urine collection greater than 300mg protein signifies marked proteinuria. If the 24-hour urine collection is done there should be a recognized way of evaluating the plenum of the sample (30).

### Monitoring and follow up

The clinical assessment should be conducted at every ANC visit and admission should be offered for close monitoring or medical action in case of; sustained systolic BP of 160mmHg or higher, alteration in biochemical or hematological investigations that may be alarming (eg a sudden or protracted elevation in creatinine 90 micromole/liter, rise in alanine transaminase over 70 IU/liter or a reduction in platelet number to less than 150000/microliters), indications of imminent eclampsia, pulmonary edema or suspected fetal compromise.

The fullPIERS or PREP-S validated risk prediction models may be used to assist in decision-making concerning the most appropriate threshold or point of intervention. When using the risk model take into account;

FullPIERS is a model used in the prediction of fatal life-threatening complications where routinely reported variables are included and a retrogressive elimination model is used to predict adverse obstetric outcomes. The various parameters evaluated include gestational age in weeks and days, the presence of chest pain or dyspnea, the platelet count, the level of creatinine, aspartate transaminase levels, and the SpO2. It is useful in distinguishing between patients with a high risk of adverse maternal outcomes and those with low risk within 48 hours and up to a week after assessment, a score of greater than 30% risk is related with a reduced chance of adverse outcomes. The model can be used at any time during pregnancy(44).

PREP-S is an external validation model for predicting the risk of complications in earlyonset PE and is purposed for use only up to 34 weeks of pregnancy. It's used in predicting the risk of adverse obstetric outcomes including early preterm delivery, within 48 hours PREP-S, and by using PREP-L under the context of the current care, these two models can be computed. This model takes into account the following variables, maternal age, gestational age in weeks and days, the presence of exaggerated tendon reflexes, the presence of prior existing medical conditions, the protein: creatinine ratio, the serum urea concentration, the platelet count, the systolic blood pressure if there is ongoing treatment with antihypertensive drugs if there is treatment with MgSO4, the SpO2, the alanine amino transaminase concentration, the serum creatinine concentration, and the time point from baseline. Women with a total risk score of complications less than 50% can circumvent needless referral to tertiary facilities and those classified as having a low risk using the PREP-L model can be reviewed as outpatients while those who come up as high risk or very high risk need monitoring as in patients with regular intensive monitoring(45).

Of note is that FullPIERS and PREP-S models do not predict outcomes for neonates(30).

#### Treatment of preeclampsia

The management of hypertensive disease in pregnancy adapted from

NICE guidelines 2019

#### Table 2 The management of pregnancy with pre-eclampsia

Interventions	Degree of hypertension	
	Hypertension;bloodpressureof140/90-159/109159/109159/109	Severe hypertension:
When to admit to the wards	All women with any clinical indicators of distress either maternal or fetal should be admitted or if at high risk of distress indicated by the fullPIERS or PREP-S risk prediction models	Admit however if the BP < 160/110 mmHg they should be managed as hypertension
Antihypertensive pharmacological treatment	This should be given if BP remains above 140/90mmhg	It should be given to all women
Target BP while on anti- hypertensive treatment	A BP of ≤135/85 is desirable	A BP of ≤135/85 is desirable
Continuous monitoring of BP	This should be done every 48hous or more frequently if she is admitted.	It should be done every 15- 30 minutes until it's < 160/110 mmHg, thereafter should be done at least 4 times every 24 hours while the woman is inpatient and dependent on the signs and symptoms.

Dipstick diagnostic test for proteinuria	This is to be repeated If prudent clinically e.g., in the onset of new clinical features or if there's unsureness of the diagnosis	
The blood workups	The full blood count, renal function, and liver function should be checked twice a week	The full blood count, renal function should and liver function be checked thrice a week
Fetal assessment	Fetal auscultation should be offered at each antenatal visit. Ultrasound for fetal assessment should be offered at the diagnosis and thereafter on a two weekly basis if normal. A CTG should be done at	Fetal auscultation should be offered at each ANCI visit. Ultrasound for fetal assessment should be offered at the diagnosis and thereafter on a two weekly basis if normal. A CTG should be done at
	the onset and thereafter only when necessitated clinically	the onset and thereafter only when necessitated clinically

The antihypertensive of choice is labetalol if not suitable/available nifedipine can be used and after methyldopa, if both are not suitable or available.

# Timing of birth

The 2019 NICE guidelines recommend that the maternal and fetal vitals should be on record for timed delivery before 37 weeks in women with PE. The indicators for early delivery include (but are not limited to) any of the enumerated features of severe PE (30).

- Poor control of maternal BP despite the use of 3 or more classes of antihypertensive in appropriate doses.
- Maternal oxygen concentration at less than 90%

- Continued worsening of bloodwork including LFTs, renal function, hemolysis, or thrombocytopenia
- Protracted neurological deficiencies eg severe protracted headache repeated visual field partial blindness or convulsions
- Placenta abruption
- Reversed end-diastolic flow in the umbilical artery Doppler velocimetry, a non-reassuring CTG or stillbirth.

A senior obstetrician, an anesthetist, and the neonatal team should be aware of the birth plan.

# Evaluation of the patient postnatally (including after discharge from critical care)

#### Blood pressure

At Garissa Provincial Hospital, Kenya 2010 it was recommended by Ombonga that clinicians should be aware that 44% of eclampsia occurs postpartum especially in term pregnancies and therefore careful assessment of women with signs and symptoms should be done (46).

In women with pre-eclampsia postnatally and who had no prior antihypertensive treatment, the blood pressure should be monitored; Every 6 hours while admitted, daily between day 3-5 postnatally, and on alternate days until normal if blood pressure was abnormal on days 3-5.

In postnatal women who have preeclampsia and did not have anti-hypertensive treatment it should be started if BP is above 150/100mmHg or higher. The women should also be asked about symptoms of severe PE whenever taking the BP including severe headaches, epigastric pain.

In postnatal women with pre-eclampsia BP should be measured, 6 hourly while admitted and each 1-2 days until 2 weeks after discharge and she is off antihypertensive and hypertension has subsided.

For postnatal women who had been on treatment; should continue on the antihypertensive as had been stated above, the antihypertensive dose should be reviewed if BP falls below 140/90mmHg and the antihypertensive dosage should be decreased if BP is less than 130/80mmHg. For those on methyldopa, it should be discontinued latest 2 days after delivery and another treatment instituted.

The woman should be discharged if ; PE symptoms subside, If BP, while on or off medication is 150/100mmHg or less, and if blood workups are steady or improving(30).

After discharge, all women who have had PE and remain on anti-hypertensive medication should have a postnatal review in 2 weeks and at 6-8 weeks postpartum.

### Hematological and biochemical monitoring

In patients with PE without severe features or after recovery from critical care: the levels of serum creatinine, the platelet count, and the transaminases should be checked 48-72 hours after delivery or recovery, if they are normal, they should not be repeated. If the biochemical markers are out of the reference range postnatally, they should be repeated as clinically indicated until they normalize. Postnatally a urinary reagent strip test should be done 6-8 weeks after birth. In those with proteinuria at 6-8 weeks, postnatally another check should be done at 3 months postnatally to check their renal function, and if they are deranged the patient should be referred to a kidney specialist.

#### 1.2.7 Outcomes in patients with preeclampsia

Looking at the process of achieving an uneventful antepartum, intrapartum, and immediate postpartum period. Better outcomes are expected in situations where there is timely diagnosis and intervention, consistent follow-up on instituted treatment and investigation. If preeclampsia goes undiagnosed and hence untreated or insufficiently treated it may advance to PE with severe features or eclampsia. PE accounts for 76,000 and 500,000 preventable maternal and neonatal deaths globally every year (32). Overall 10%-15 % of maternal mortalities and 25% of stillbirths and neonatal deaths in low and middle-income countries are attributed to PE and eclampsia, and a further 15% experience fetal growth restriction and 20% small for gestation age infants also (1). Data indicate that the rate of PE has is on the rise, with the US having a 25% increase from 1987-2004 according to USNDS(4). In Uganda Nakimuli et al found that PE with severe features affected 54% of patients and Eclampsia affected 43% of patients (5) while a study done at Pumwani maternity hospital (PMH) found that the overall perinatal mortality rate (PMR) was 63/1000 live births while that among patients with pregnancy-induced hypertension (PIH) was 203 and half of the neonates were born prematurely(28).

In Ga-Rankuwa hospital in South Africa, Mwinyoglee J et al while looking at the maternal and fetal outcomes found that out of the 36 maternal mortalities during the study, eclampsia was responsible for 14(38.9%). A case fatality rate of 21.1% and maternal deaths were significantly higher in patients that were not on follow-up, those who were above 30 years, and those who had multiple convulsions(37). This was in keeping with a study done by Kinuthia that showed; antenatal clinic attendance conferred the benefit of better screening, timely diagnosis, early institution of treatment, and management with subsequent better follow-up and appropriate investigation. This resulted in better outcomes among patients who attended ANC(27).

Preeclampsia arises after 20 weeks of pregnancy. Kinuthia noted that patients had a peak ANC attendance at 20-29 weeks similar to the KDHS 2008-2009 which found that most patients first ANC visit was at 5.7 months. Health workers thus have a good chance to check on various signs and symptoms of PE (27). During the study, the bulk

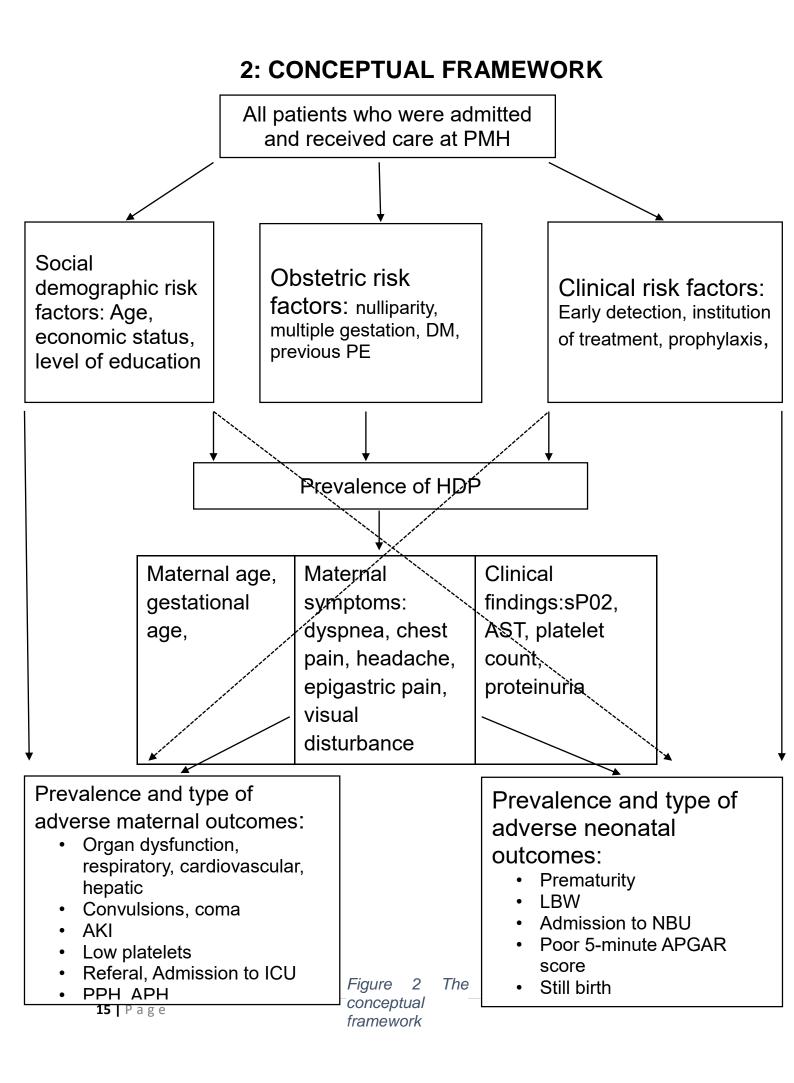
of patients were diagnosed with preeclampsia at a gestational age of 35-39 weeks which was credited to the late development of clinical features associated with PE or due to inadequate follow-up during ANC thus missing the diagnosis. The study showed that 73.3 % had laboratory tests done at diagnosis and 78% had an ultrasound done upon diagnosis of preeclampsia, 97.3% received prescriptions at the point of diagnosis. In this study, it was noted that many of the women who experienced maternal complications were discovered to have PE in the terminal stages of pregnancy, with 70.6% being diagnosed at more than 30 weeks gestation, which could have attributed to the disease development to PE with severe features and eclampsia leading to a surge in maternal complications. Hence large proportions of the study participants were diagnosed with severe preeclampsia, which was associated with poorer newborn outcomes. These results were similar to a study done in Norway over 3 years where severe and early-onset preeclampsia was attributed to significant IUGR and consequently worse perinatal outcomes. PE was linked with a 5% decrease in birth weight, severe PE with a 12% decrease, and in cases where PE was present in early pregnancy duration the birth weight had a 23% reduction from the expected(27). A study in Turkey postulated that perinatal morbidity and mortality are more dependent on gestational age rather than disease dependent on severe PE. However a study by Christian Roberts showed the presence of proteinuria ie preeclampsia is associated more with a small gestation age (22), this study also postulated that elective delivery is averting fetal deaths in preeclampsia.

Preeclampsia affects various organ systems and this is linked to those that are most liable to excessive inflammation and endothelial damage eg CNS, lungs, liver, kidneys, vessels in the whole body and, heart. Others like the placenta and fetus are also affected. Increased involvement of various organs results in higher maternal and perinatal complications. A study by Jussara Mayrink showed that women with preeclampsia had a higher relative risk for longer hospital stay and admission at almost 6 fold higher(47). Immediate maternal complications including eclampsia at a rate of less than 1%(48), antenatal hemorrhage due to placental abruptio recently sighted in a study in 2019 by Sinei at KNH on early trimester bleeding, postpartum hemorrhage, scotomata, pre-term labor, HELLP syndrome, ARDS, AKI and, cerebral edema or even cerebral hemorrhage. Residual maternal complications may include protracted elevation of BP, recurring PE and, kidney disfunction. The likelihood of maternal mortality is linked to the development of drawbacks such as eclampsia, hemorrhage, liver failure or rupture, AKI, pulmonary edema, DIC, and HELLP syndrome, which are parameters used in determining the risk of adverse outcomes using the fullPIERS model(49,50). These drawbacks are usually seen in women who have early-onset PE or women with pre-existing chronic conditions(48). Preeclampsia was also found to be the key cause of gestation-related ICU admissions after obstetric hemorrhage in HCA hospitals in America (12).

In a study by Matter and Sibai adverse outcomes were described in 399 successive women with EC who delivered in their center at Memphis between 1977 and 1998. Leading complications sighted were; placenta abruptio in 10%, neurological deficits

7%, aspiration pneumonia 7%pulmonary edema 7%, cardiopulmonary arrest 4%, ARF 4%, maternal mortality 1%(51).

Wasiche et al at KNH reported maternal complications in 67% of patients with EC, with the most common complications being sepsis 40.4%, pulmonary edema 25.3%, ARF 10.4%, and cerebral hemorrhage 10.4%(37). However, this was different with a study at selected Government hospitals in Addis Ababa on the trends of PE and EC over a 5-year duration that found maternal complications were present in only 36% of preeclampsia/eclampsia cases, which was in line with a similar population study in Nigeria that found maternal complications in 39%(52)



This study will assess all patients who received care at PMH between January 2018 and December 2019 through a review of medical records. To estimate the prevalence of HDP and the risk of adverse obstetric outcomes. Hence the study of all women who were admitted will form the population base for the study of the sample population with HDP. And the prevalence of HDP will be all patients with HDP out of all sampled admissions. Various risk factors have been associated with the development of HDP including maternal age, parity, family history of PE, PE in previous pregnancies, presence of preexisting hypertension, and diabetes. The patients identified with HDP will then be categorized into the various classes of HDP based on patient and clinical characteristics (history, clinical presentation, and examination, investigations). Prevalence of adverse maternal and perinatal outcomes will be all maternal and neonatal adverse outcomes over all women diagnosed with HDP.

Maternal adverse outcomes of interest include-Organ dysfunction, Convulsions, Low platelets, AST>40, AKI, APH, PPH, Death

Perinatal adverse outcomes of interest will include Prematurity, Low birth weight, low APGAR scores at 5 minutes, need for admission to NICU/referral, stillbirths.

Factors that influence the maternal and perinatal outcomes can be social demographic factors eg age, economic status, level of education and obstetric factors eg nulliparity, multiple gestation, the severity of the disease, and clinical factors eg Spo2, platelet count, proteinuria, AST levels at the time of diagnosis, will be noted.

# 2.1 Justification

Preeclampsia is a leading cause of severe long-term disability and death among both women and neonates. In LMIC, nearly one in ten of all maternal deaths are attributed to HDPs.

In Kenya, HDP is identified as the third cause of maternal mortality after hemorrhage and sepsis. The prevalence of preeclampsia and eclampsia in facilities serving lowincome and informal settings is unknown and may be much higher. There is a paucity of information showing the upward trend of HDP (7), and data from the USNDS indicates that the rate of PE in the US has increased by 25% from 1987-2004 (4). A Kenyan confidential inquiry into maternal death in 2014 revealed that 3 out of 20 pregnant or postpartum Kenyan women died from HDP (6).

In this study, we aim to estimate the burden of HDP adverse obstetric outcomes of patients thereof. This will be informative as it will be providing new baseline information on HDP putting into consideration that the last study done in PMH for prevalence was 35 years ago (53). This information will be instrumental in defining the burden of HDP and hence useful in influencing evidence-based policy formulation and resource allocation.

#### 2.2: Research question

What is the prevalence of HDP, and risk of adverse maternal and perinatal outcomes among pregnant and postpartum women who received care at PMH from 1<sup>st</sup> January 2018- 31<sup>st</sup> December 2019?

#### 2.3: Broad objective

To determine the prevalence of HDP, and risk of adverse maternal and perinatal outcomes among pregnant and postpartum women who received HDP care at PMH in January 2018- December 2019.

#### 2.4: Specific objectives:

Among pregnant and postpartum women who received care at Pumwani Maternity Hospital obstetric ward from 1<sup>st</sup> January 2018 to 31<sup>st</sup> December 2019:

- 1. To estimate the prevalence of HDP.
- 2. To determine the prevalence of adverse maternal outcomes among women with HDP.
- 3. To determine the prevalence of adverse perinatal outcomes among women with HDP.

#### 2.5: Secondary objective:

1. To describe the socio-demographic, obstetric factors, and clinical factors associated with adverse maternal and perinatal outcomes.

# CHAPTER 3: METHODOLOGY

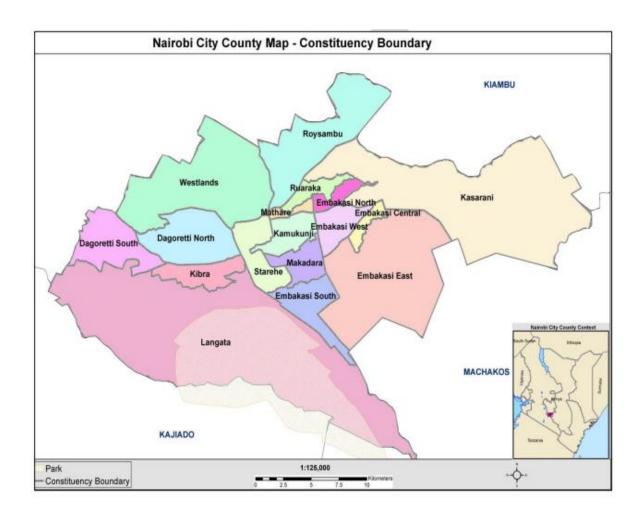
#### 3.1 Study design

This was a descriptive cross-sectional study where records of pregnant and postpartum women admitted at PMH between January 2018 and December 2019 with HDP were reviewed from the time of admission until 3 days after delivery, discharge, or referral for specialized services.

#### 3.2 Study site

This study was conducted at PMH a major referral hospital in Kenya, Eastern Nairobi in the antenatal wards, labor wards, and postnatal wards. PMH was established in 1926, Pumwani provides reproductive and neonatal health care services to patients from Nairobi and adjoining counties. It has an inpatient bed capacity of 350 patients, 144 baby cots, one labor ward, and an antenatal ward and, three postnatal wards, with 2 operating theatres and antenatal clinics running on every working day from 0800hrs to 1400hrs. It has an annual admission of 21,000 to 25,000 patients for delivery. The obstetrics department is staffed with consultants, medical officers, nurses, midwifes, health records officers. Admission runs over 24 hours. It is located in Kamukunji constituency which borders Makadara to the south, Starehe to the East, Mathare to the North, and Embakasi to the west (Figure 3 A map of Nairobi City County), a 20-minute distance from the central business district. Pumwani has a catchment population of about half a million predominantly low-income people. The facility offers free maternity services.

Pumwani was selected for the study because it is the sole and largest purely maternity hospital in the country. Serves as a point of referral for many facilities, it also serves a diverse population ranging from low income in Huruma, Biafra, Califonia areas to lower and middle-income populations of Starehe, Embakasi, Eastleigh neighbourhoods.



#### 3.3 Study population

All pregnant and postpartum women admitted at PMH between January 2018 and December 2019 were the study population for prevalence while those with hypertensive disorders in pregnancy formed the study population of interest for adverse maternal and perinatal outcomes.

# 3.3 Sample size determination

This study was designed to estimate the prevalence of HDP and adverse maternal and perinatal outcomes. We established the sample size using Fisher's as follows:

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

Where:

n - minimum required sample size

Z – standard normal for a 2-sided test at 95% confidence interval (CI) = 1.96

P - The estimated prevalence of the outcome of interest

d - the desired margin of error

# The minimum sample size required to achieve objective 1:

### To estimate the prevalence of hypertensive disorders in pregnancy.

A survey in Kenya reported about 10% of women had HDP (6).

Using the above formula, the required sample size was as follows:

Study population	Outcome of interest	Estimated prevalence (P)	The margin of error (d)	Sample size (n)
All admissions	HDP	10%	2.5%	553

A minimum of 553 records of perinatal women was required to estimate HDP prevalence.

#### The minimum sample size required to achieve objectives 2 and 3:

# To estimate the prevalence of adverse maternal and perinatal outcomes associated with HDP.

A study in Ethiopia found maternal complications occurred in 36% of women admitted with pre-eclampsia or eclampsia (52). Similarly, 25% of stillbirths have been associated with PE and Eclampsia in developing countries (1).

Study population	Outcome of interest	Estimated prevalence (P)	The margin of error (d)	Sample size (n)
HDP	Maternal complications	36%	5%	354
admissions	Neonatal complication:	25%	5%	288
	still births			

A minimum sample of 354 women with HDP was required to estimate the prevalence of both maternal and neonatal complications.

## 3.5 Sampling procedure

A simple random sampling technique was used to sample charts which were included in the study. The admission registers in the study period constituted the sampling frame to randomly select the file numbers which were used to retrieve the charts. A list of all admission numbers were generated to form the sampling frame. The numbers were entered in SPSS statistical software for sampling. A random selection was performed using the 'select' command in SPSS. The selected file numbers were used to retrieve the charts. Any missing charts were noted and replaced.

### 3.5.1 Inclusion criteria

- All women who were admitted for care at PMH between January 2018 and December 2019.
- All women who were admitted for care PMH and had a diagnosis of HDP between January 2018 and December 2019.

### 3.5.2 Exclusion criteria

- Pregnant women admitted at PMH below 20 weeks gestation.
- All women initially meeting inclusion criteria but on review, their files were missing key variables.
- All women who have gestation with diagnosed congenital malformations.

#### 3.5.3 Data collection

Data collection was done by the principal investigator under the guidance of two supervisors from the department of Obstetrics and Gynecology, University of Nairobi and assisted by trained research assistants. The research assistants had medical training qualifications with a specialization in clinical medicine and nursing. The list of file numbers generated from the registers from the random selection was used to retrieve the charts from the health records archives. Patients' charts were reviewed and the relevant information was extracted into a data collection tool. Eligibility criteria was administered at every stage of data collection and any record that did not meet the inclusion criteria was excluded. The excluded charts were recorded and replacement was done at the end of each day. The information extracted from all admission charts included the demographic information, the obstetric characteristics, presence or absence of HDP. Also, information on adverse obstetric outcomes was collected from the women who were admitted with HDP. Files were marked using colored stickers to help in the identification of the files and duplication of patients' records. The investigator ensured completeness and accuracy of the data extracted from the charts by reviewing the questionnaires and making corrections before the charts are returned to the archives.

## Variables

The outcome variable of interest in this study was the prevalence of hypertensive disorders in pregnancy and that of adverse maternal and perinatal outcomes.

#### Socio-demographic variables of interest

Age, Parity, Level of education, marital status, Employment status, Residence.

#### Maternal complications of interest included;

- Organ dysfunction: respiratory, cardiovascular, hepatic
- Convulsions, coma
- AKI
- Low platelets
- Referral, Admission to ICU
- PPH, APH
- Death

The adverse maternal and neonatal outcomes were advised based on previous literature and the fullPIERS model of determining the risk of adverse outcomes. A diagnosis of HDP was made according to the guidelines of the ISSHP as systolic blood pressure  $\geq$  140 mmHg and/or diastolic blood pressure  $\geq$  90 mmHg on at least two occasions 4 hours apart, developing after 20 weeks' gestation, in a previously normotensive woman, combined with significant proteinuria was considered as preeclampsia ( $\geq$  300 mg in 24 h or two readings of at least ++ on dipstick analysis of midstream or catheter urine specimen, if no 24-h collection was available)(31). Chronic hypertension superimposed on PE was defined as the development of significant proteinuria after 20 weeks' gestation in a previously non-proteinuria woman(31).

PE with severe features was defined as any patient with PE who further develops sustained elevated Bp of  $\geq$ 160/110 mmHg and also either, proteinuria of > 0.3gm/2+ dipstick or organ dysfunction evidenced by a derangement in clinical features or investigations done.

Eclampsia was elucidated as the presence of convulsions in a patient with HDP without other neurological complications.

HELLP syndrome was defined as a patient with HDP who developed haemolysis, elevated liver enzymes low platelets.

A patient with HDP was considered to have developed AKI when she had creatinine's >90. Assessed through the U/E/C's results.

Organ dysfunction will include;

- Hepatic dysfunction based on an AST of >40 has been found most sensitive and specific, the following were also be considered ALT, bilirubin albumin, LDH
- Respiratory compromise indicated by dyspnoea, chest pain, pulmonary edema.
- Cardiovascular compromise defined by the presence of chest pains, diagnosed MI, diagnosed cardiac failure.
- Central nervous system GCS<13, reversible ischaemic neurological deficient, TIA, cortical blindness.

Low platelets were be defined by platelet levels  $<150,000 \times 10^9$ /L. A full hemogram was also assessed and severe thrombocytopenia considered when  $<50 \times 10^9$  /L.

Convulsions were defined by the presence of one or more generalized tonic-clonic jerking/ seizures.

Post-partum hemorrhage (PPH) was defined as the loss of >500mls after vaginal birth or >1000mls after caesarean section or any loss that resulted in deterioration of the medical condition of the patient.

Antepartum hemorrhage (APH) was considered when there was bleeding through the genital tract after 28 weeks gestation and before delivery.

The exposure variable of interest was assessed using the number of patients who had hypertensive disorder in pregnancy.

#### Neonatal complications of interest included;

Preterm birth was defined based on WHO criteria as birth before 37 completed weeks and classified into based on gestational age (54):

- Moderate or late preterm delivery between 32 and before 37 completed week's gestation.
- Very preterm as delivery between 28 and less than 32 weeks gestation.
- Extremely preterm as delivery before 28 weeks gestation.

Infants admitted into the neonatal ICU and to the new-born unit due to neonatal asphyxia.

Where asphyxia was defined based on ACOG, AAP guidelines as the presence of:

- Persistent Apgar of 0-3 for longer than 5 minutes.
- Apgar score of less than 7 at 5 minutes after birth.

Intrauterine fetal demise/ stillbirths, perinatal deaths. Which was defined as any neonate born after 28 weeks gestation while dead or if they died within 6 days of delivery.

Low birth weight was be defined based on WHO definition as <2500 grams, and further classification as very low birth weight if <1500g, and extremely low birth weight if <1000g(54).

#### Table 3 Study variables

Objective	Independent variables	Dependent variables
Prevalence of hypertensive disorders in pregnancy	<ul> <li>Level of education</li> <li>Marital status</li> <li>Source of income</li> <li>Place of residence</li> <li>ANC attendance</li> <li>Parity</li> <li>Gestational weeks</li> </ul>	Hypertensive disorders in pregnancy Pre-eclampsia Eclampsia Chronic hypertension HELLP syndrome
Prevalence of adverse maternal outcomes associated with HDP		Maternal outcomes AKI Organ dysfunction Convulsions Admission to ICU Referal Death APH PPH
Prevalence of adverse perinatal outcomes associated with HDP		<ul> <li>Neonatal complications</li> <li>Intrauterine fetal demise</li> <li>LBW</li> <li>Preterm birth</li> <li>Low APGAR score</li> </ul>

#### 3.4.5 Data management and analysis

Data was coded and entered in MS Excel 2016 data entry sheet. Data quality was ensured during data entry and cleaning was done. The entered data was exported into SPSS version 23.0 statistical software for analysis. The study population was described by summarizing socio-demographic and obstetric characteristics into percentages and means or medians for categorical variables and continuous data respectively.

The prevalence of HDP and 95% confidence interval presented was calculated out of the total admissions. Similarly, the prevalence of maternal complications (preeclampsia, eclampsia, chronic hypertension, and HELLP syndrome) and neonatal outcomes (premature birth, stillbirths, and perinatal deaths) was calculated out of all women with HDP and 95% confidence interval presented. Factors associated with HDP, maternal complications, and neonatal outcomes were determined using the chisquare test for categorical variables and a comparison of means using the independent t-test for continuous data. Mann-Whitney U test was used to compare medians for non-normally distributed data. The relative risk was calculated to estimate the likelihood of developing the outcomes associated with each independent variable. All statistical tests were interpreted at a 5% level of significance.

#### Summary based on objectives:

#### Primary Objective 1: Prevalence of hypertensive disorders in pregnancy.

The prevalence of HDP was calculated out of the total admissions and 95% confidence interval presented.

*Primary Objective 2: Prevalence of adverse maternal associated with HDP* Prevalence of maternal complications (Organ dysfunction, Convulsions, Low platelets <150x10<sup>9</sup> /L, AST>40, AKI, APH, PPH, Death) was calculated out of all women with HDP and 95% confidence interval presented.

# *Primary Objective 3: Prevalence of adverse perinatal outcomes associated with HDP.*

Prevalence of adverse perinatal outcomes (premature birth, stillbirths, and perinatal deaths) was calculated out of neonates and 95% confidence interval presented.

# Secondary Objective: Among women with HDP the socio-demographic and obstetric factors, associated with adverse maternal and perinatal outcomes.

Factors associated with HDP, maternal adverse outcomes, and neonatal outcomes were determined using the chi-square test for categorical variables and a comparison of means using the independent t-test for continuous data. Mann-Whitney U test was used to compare medians for non-normally distributed data. The relative risk was

calculated to estimate the risk of developing the outcomes associated with each independent variable. The odds ratio was calculated to estimate the relative risks of developing the outcomes associated with each independent variable. Multiple logistic regression models were used to determine factors independently associated with the outcomes. All statistical tests were interpreted at a 5% level of significance.

#### **Research ethics**

A trained research assistant qualified in the medical field (nurse or clinical officers) at PMH identified the files of women who met the inclusion criteria from the total number of files present covering the two-year duration of the study. This will then be segregated and the required information extracted and analysed maintaining confidentiality.

Ethics approval from Kenyatta National Hospital/University of Nairobi Ethics and Research Committee was sought. Waiver of consent was requested from ERC because data collection was not done directly among patients but from the medical records. No identifiers were used during data collection to ensure confidentiality of the patients' information.

Permission was sought from the administration of PMH to conduct the study at the site.

#### Study limitations

Since the study was be done on files that had some missing information. However, these were set aside and consecutively replaced. There were some missing files as a result of relocation of records, damages due to leakage and limited storage space however with assistance of health records officers we traced most and the missing ones were also replaced consecutively.

The end outcomes ie clinical progress of the patients who were referred out of the facility were missed. In our study a total of 3 patients were referred for more specialized care to KNH due AKI.

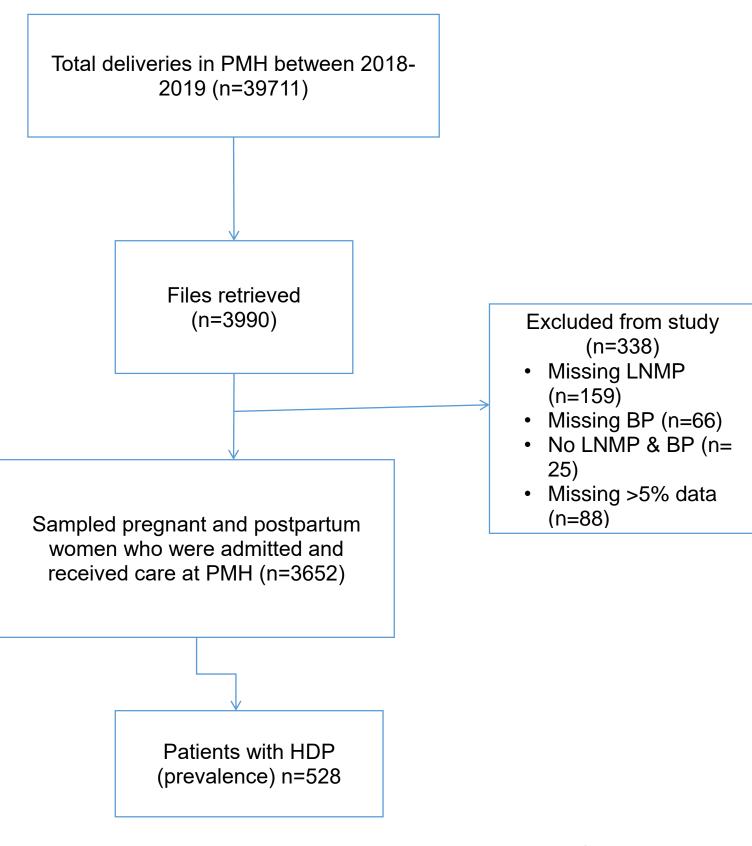
#### Study strengths

The last study of the prevalence of HDP at PMH was done in 1985, thus a new study will help in getting an update of the current prevalence of HDP.

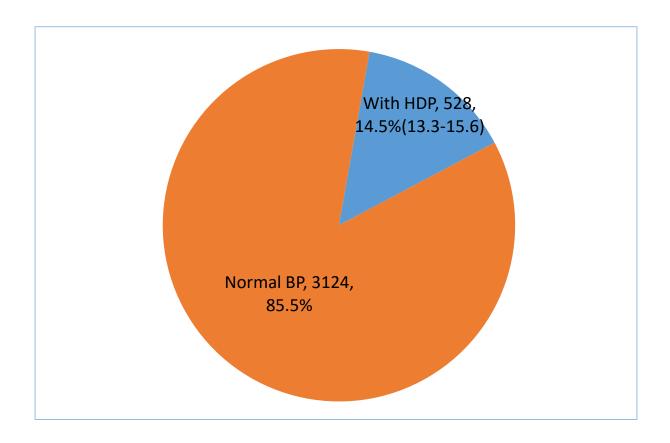
This study was informative and has provided new baseline information on HDP, thus useful in influencing evidence-based policy formulation and resource allocation.

# 4.0 RESULTS

Flow chart of recruitment and identification of women with HDP



A total of thirty-nine thousand seven hundred and eleven (39,711) women delivered at PMH between January 2018 to December 2019 out of whom charts of, three thousand nine hundred and ninety (3990) women who delivered were sampled, three hundred and thirty-eight charts (338) were excluded due to: missing LNMP n=159, missing BP n=66, No LNMP and BP n=25, missing >5% of data n=88. Leaving a total of three thousand six hundred and fifty-two (3652) who were then studied for the prevalence of HDP and that of adverse maternal and perinatal outcomes and, the description of social demographic, obstetric and clinical factors associated with adverse maternal and perinatal outcomes among women with HDP.



#### The prevalence of hypertensive disorders in pregnancy

Figure 5 Pie chart depicting the prevalence of HDP among a sample of 3652 women who delivered at PMH between Jan 2018 and Dec 2019

We calculated the prevalence of HDP from a sample size of 3652 women who delivered between January 2018 and December 2019, where a total of 528 women had HDP giving us a prevalence of 14.5% (13.3-15.6).

#### Prevalence of adverse maternal outcomes among women with HDP

As shown in Table,6 3.2% (95% CI 1.7-4.9%) of the women with HDP had maternal complications. The complications due to postpartum hemorrhage were (47.1%), antepartum hemorrhage (29.4%) and acute renal injury (17.6%).

#### Table 4 Adverse maternal outcomes

Variable	Frequency (%)	95% CI
Maternal complications (n=528)		
Yes	17 (3.2)	1.7 – 4.9
No	511 (96.8)	95.1-98.3
Type of maternal complications		
(n=17)	3 (17.6)	
Acute renal injury	1 (5.9)	
Development of eclampsia	5 (29.4)	
Antepartum hemorrhage	8 (47.1)	
Postpartum hemorrhage		

#### Prevalence adverse perinatal outcomes among women with HDP

As below Table 7, adverse neonatal outcomes were reported in 16.9% (95% CI 13.5-20.1%) of the neonates of women diagnosed with HDP. The complications were neonatal asphyxia (53.9%), preterm birth (24.7%) and intrauterine fetal demise (23.6%).

#### Table 5 Adverse neonatal outcomes

Variable	Frequency (%)	95% CI
Neonatal complications (n=528)		
Yes	89 (16.9)	13.7-20.0
No	439 (83.1)	80.0-86.3
Type of neonatal complications		
(n=89)	21 (23.6)	
Intrauterine fetal demise	2 (2.2)	
Small for gestation age neonates	22 (24.7)	
Preterm birth	48 (53.9)	
Neonatal asphyxia		

#### Social Demographic and obstetric characteristics of the women with HDP

As shown in Table 6 below, the mean age of the women was 27.1 years and ranged between 15 to 44 years. As compared to women who were 35+ years, there was a higher risk of HDP among those aged **between 15 and 24 years [OR 1.7 (95% Cl 1.3-2.4), p=0.001] and 25-34 year-odds [OR 1.4 (95% Cl 1.1-1.7), p=0.002]**. An approximate (22.3%) were not educated, 45.3% had missing records on education level. The majority (89.8%) were married and 77.1% were unemployed. More than two-thirds (67.6%) of the population were living in informal settlements.

ANC attendance was high with **99.2%** of the women having attended antenatal care. Nulliparous were 39.3% while 59.6% of the women were multiparous. The mean gestation age at delivery was 38.5 weeks and ranged from 28 to 42 weeks. Greater than two thirds (69.7%) of the women had spontaneous vaginal delivery (SVD), 159(30.1%) delivered via caesarian section, and 1 woman assisted delivery via vacuum extraction. The mean birth weight for the neonates was 3042.8 kg.

Variable	n= 528
	Frequency (%)
Age	
Mean (SD)	27.1 (5.7)
Min – max	15.0-44.0
Category, n (%)	
15-24	196 (37.1)
25-34	268 (50.8)
35+	64 (12.1)
Highest level of education attained	
None	118 (22.3)
Primary	61 (11.6)
Secondary	68 (12.9)
Post-secondary	42 (8.0)
Not indicated	239 (45.3)
Marital status	
Single	53 (10.0)
Married	474 (89.8)
Divorced/Separated	1 (0.2)
Main source of income	
Salaried job	26 (4.9)
Self-employed	76 (14.4)
Casual work	11 (2.1)
Not-employed	407 (77.1)
Not indicated	8 (1.5)

#### Table 6 Social Demographic and obstetric characteristics of women with HDP

Place of residence	
Slum	357 (67.6)
Non-slum	169 (32.0)
Not indicated	2 (0.4)
Attended ANC	
Yes	524 (99.2)
No	4 (0.8)
Parity	
Nulliparous	197 (37.3)
Multiparous	326 (61.7)
Grand multiparous	4 (0.8)
Not indicated	1 (0.2)
Gestational age at delivery (Weeks)	
Mean (SD)	38.5 (2.6)
Min –max	28.0-42.0
Mode of delivery	
SVD	368 (69.7)
CS	159 (30.1)
Vacuum extraction	1 (0.2)
Mean birth weight (SD)	3042.8 (641.2)
Category, n (%)	
Normal BW (>=2500g)	451(85.4)
LBW (1500-2499g)	68(12.9)
Very LBW (1000-1499g)	7 (1.3)
Extremely LBW (<1000g)	2 (0.4)

#### Factors associated with adverse maternal outcomes in patients with HDP

As shown below in Table 7, none of the socio-demographic factors such as age, level of education, marital status, employment status and residence influenced the occurrence of maternal complications in women with HDP. However, the women with para 3 or more were more likely to report maternal complications compared to para 0, OR 5.0 (95% Cl 1.4-18.3), p=0.015. Similarly, CS deliveries were more likely in women with maternal complication, OR 2.7 (95% Cl 1.0-7.1), p=0.045. However, these were not considered statistically significant.

Variable	Maternal complications		OR (95% CI)	P value
	Yes No			
Mean age (SD)	27.9 (5.8)	27.0 (5.7)	-	0.520
Level of education				
None	3 (50.0)	115 (40.6)	1.1 (0.1-10.6)	0.954
Primary	1 (16.7)	60 (21.2)	0.7 (0-11.2)	0.790
Secondary	1 (16.7)	67 (23.7)	0.6 (0-10.1)	0.731
Post-secondary	1 (16.7)	41 14.5)	1.0	
Marital status				
Single	1 (5.9)	52 (10.2)	1.0	
Married	16 (94.1)	458 (89.6)	1.8 (0.2-14.0)	0.566
Divorced/separated	0	1 (0.2)	-	1.000
Main source of income				
Salaried job	2 (11.8)	24 (4.8)	2.5 (0.5-11.8)	0.240
Self-employed	1 (5.9)	75 (14.9)	0.4 (0.1-3.1)	0.386
Casual work	1 (5.9)	10 (2.0)	3.0 (0.4-25.5)	0.307
Not-employed	13 (76.5)	394 (78.3)	1.0	
Place of residence				
Slum	9 (52.9)	348 (68.4)	0.5 (0.2-1.4)	0.180
Non-slum	8 (47.1)	161 (31.6)	1.0	
Attended ANC				
Yes	17 (100.0)	507 (99.2)	-	1.000
No	0	4 (0.8)		
Parity				
0	4 (23.5)	193 (37.8)	1.0	
1	6 (35.3)	159 (31.2)	1.8 (0.5-6.6)	0.360
2	1 (5.9)	100 (19.6)	0.5 (0.1-4.4)	0.517
3+	6 (35.3)	58 (11.4)	5.0 (1.4-18.3)	0.015
Parirty				
Nulliparous	4(23.5)	193(37.8)	1.0	
Multiparous	13(76.5)	313(61.4)	2.0	0.230
Grand multiparous	0	4(0.8)	-	0.999
Mean gestational age at	37.4 (4.5)	38.6 (2.7)	-	0.077
delivery in weeks (SD)				
Mode of delivery				
SVD	8 (47.1)	360 (70.5)	1.0	
CS	9 (52.9)	150 (29.4)	2.7 (1.0-7.1)	0.045
Vacuum extraction	0	1 (0.2)	-	1.000

#### Table 7 Factors associated with maternal complications in patients with HDP

#### Factors associated with adverse perinatal outcomes in women with HDP

As shown in Table 9, socio-demographic and obstetric factors did not influence neonatal outcomes. However, there were more neonatal complications among the women who delivered at a significantly lower gestational **age of 37.5 weeks** compared to **38.7 weeks** in those without complications (**p**<**0.001**).

Variable	Neonatal complications		OR (95% CI)	P value
	Yes	No		
Mean age (SD)	26.0 (4.9)	27.3 (5.8)	-	0.053
Level of education				
None	18 (36.7)	100 (41.7)	1.1 (0.4-2.9)	0.880
Primary	11 (22.4)	50 (20.8)	1.3 (0.4-3.9)	0.615
Secondary	14 (28.6)	54 (22.5)	1.6 (0.5-4.4)	0.407
Post-secondary	6 (12.2)	36 (15.0)	1.0	
Marital status				
Single	5 (5.6)	48 (10.6)	1.0	
Married	84 (94.4)	390 (88.8)	2.1 (0.8-5.4)	0.134
Divorced/separated	0	1 (0.2)	-	
Main source of income				
Salaried job	4 (4.5)	22 (5.1)	0.9 (0.3-2.6)	0.812
Self-employed	14 (15.7)	62 (14.4)	1.1 (0.6-2.1)	0.796
Casual work	1 (1.1)	10 (2.3)	0.5 (0.1-3.8)	0.489
Not-employed	70 (78.7)	337 (78.2)	1.0	
Place of residence				
Slum	57 (64.0)	300 (68.6)	0.8 (0.5-1.3)	0.396
Non-slum	32 (36.0)	137 (31.4)	1.0	
Attended ANC				
Yes	89 (100.0)	435 (99.1)	-	1.000
No	0	4 (0.9)		
Parity				
0	40 (44.9)	157 (35.8)	1.0	
1	23 (25.8)	142 (32.4)	0.6 (0.4-1.1)	0.113
2	16 (18.0)	85 (19.4)	0.7 (0.4-1.4)	0.352
3+	10 (11.2)	54 (12.3)	0.7 (0.3-1.5)	0.410
Parity				
Nulliparous	40(44.9)	157(35.8)	1.0	
Multiparous	49(55.1)	277(63.2)	0.7(0.4-1.1)	0.121
Grand multiparous	0	4(0.9)	-	0.999
Mean gestational age at	37.5 (4.2)	38.7 (2.4)	-	<0.001
delivery in weeks (SD)				
Mode of delivery				
SVD	55 (61.8)	313 (71.3)	1.0	
CS	34 (38.2)	125 (28.5)	1.5 (1.0-2.5)	0.072
Vacuum extraction	0	1 (0.2)	-	

#### Table 8 Factors associated with neonatal complications in patients with HDP

#### Prevalence of types of HDP

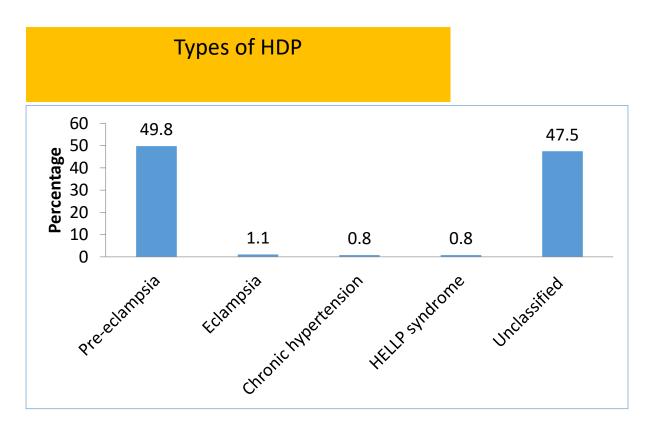


Figure 6 Bar graph showing the prevalence of types of HDP among women with HDP at PMH Jan 2018 to Dec 2019

#### Prevalence of types of HDP

As below Table 9 and figures 4 and 5 above, 528 women had hypertensive disorder of pregnancy (HDP) which translated to 14.5% prevalence among all deliveries at PMH.

The 95% CI ranged between 13.3% and 15.6%. As shown in Table 9 below, (47.5%) of the women had HDP and had not been classified. The most common type of HDP was pre-eclampsia in 49.8% of women.

Variable	Frequency (%)	95% CI
Diagnosis of HDP (n=3652)		
Yes	528 (14.5)	13.3-15.6
No	3124 (85.5)	
Type of HDP (n=528)		
Pre-eclampsia	263 (49.8)	-
Eclampsia	6 (1.1)	
Chronic hypertension	4 (0.8)	

 Table 9 Types of hypertensive disorders of pregnancy (HDP)

HELLP syndrome	4 (0.8)	
Unclassified	251 (47.5)	

#### Maternal complications associated with adverse perinatal outcome

As below Table 10, those with adverse perinatal outcomes had a higher prevalence of HDP (18.8%) compared to those without complications (13.8%), OR 1.4 (95% CI 1.1-1.9), p=0.004. Pre-eclampsia increased the risk of neonatal complications, OR 1.5 (95% CI 1.1-2.0), p=0.024. Maternal complications did not show any significant influence on the occurrence of perinatal complications (p=0.506). However, we didn't consider these statistically significant.

#### Table 10 Maternal complications associated with adverse perinatal outcome

Variable	Neonatal complications		OR (95% CI)	P value
	Yes	No		
HDP				
Present	89 (18.8)	<b>439 (13.8</b> )	1.4 (1.1-1.9)	0.004
Absent	385 (81.2)	2739 (86.2)	1.0	
Type of HDP				
Pre-eclampsia	46 (64.7)	217 (19.8)	1.5 (1.1-2.0)	0.024
Eclampsia	2	4 (1.2)	3.4(0.6-18.4)	0.138
Chronic hypertension	1 (5.9)	3 (0.6)	2.2 (0.2-21.6)	0.474
HELLP syndrome	0 (5.9)	4 (0.6)	-	0.440
Unclassified	40 (23.5)	211 (48.3)	1.3 (0.9-1.8)	0.149
Maternal				
complications	4 (4.5)	13 (3.0)	1.5 (0.5-4.8)	0.506
Present	85 (95.5)	426 (97.0)	1.0	
Absent				

#### DISCUSSION

Hypertensive disorders in pregnancy are an integral part of patient care as they are a leading cause of maternal, fetal and neonatal morbidity and mortality both globally and locally, hence our study aimed at finding the prevalence of (HDP) among pregnant and postpartum women at pumwani maternity hospital (PMH). HDP was diagnosed in 14.5% of the women in this study which was higher than the estimated 10% in pregnancies reported globally (2) and markedly higher than the incidence of 3.7 % found by Bansal in 1985 in the same study site (53). Indicating a marked increase in the disease burden due to HDP in the same study site over the elapsed duration (33 years). This is important for health workers both in clinical practice and in the field of research. A lower prevalence has been reported in various parts of the world such as Australia at 9.8% and India at 7.8% and 5.4% for preeclampsia (3). The prevalence of HDP in this study was comparable to findings by Swati et al in Nigeria who found a prevalence of 17% and Alemayehu et al who found a prevalence of 12.4% in Ethiopia, many studies in Africa report a higher prevalence of HDP and PE (6.35.55). Among those with a diagnosis of HDP, 49.8% had preeclampsia which was in line with a study by Hanson et al, and another by Gorbee. G at al that showed preeclampsia was the most common diagnosis in HDP and similarly a study by Musa Abednego in the same site that found PE affected 50.2% in 2015 (7,28,56). This also correlates with a systematic review and meta-analysis on the burden of HDP in Africa that found that PE was the commonest type of HDP and the prevalence of HDP was higher in Sub Saharan Africa (57). The higher prevalence of HDP could be due to the fact that our study was hospital based as compared to those from other settings, we also had a very good ANC attendance at 99.2 % of patients having attended ANC. As a region the higher prevalence of HDP in Africa in comparison to higher income countries has been attributed to various factors including but not limited to low social economic status, level of education, poor nutrition, higher likelihood for maternal infections, anaemia, variations in study methodology and population structures.

Women with HDP have an increased risk of adverse maternal and perinatal outcomes and preeclampsia is associated with the highest prevalence of complications, affecting 2-8% of pregnancies (7). This study found an overall prevalence of 3.2% of maternal complications in women with HDP. The most common maternal complication was found to be postpartum and antepartum hemorrhage similar to a finding by Sambu at KNH in 2011 (37). Antepartum hemorrhage in the setting of HDP may result from abruptio placenta, which is characterized by per vaginal bleeding after 20 weeks gestation and may be accompanied by abdominal pain and uterine contractions. HDP is a significant risk factor for abruptio and causes a 5 fold likely (58), pathologically caused by premature separation of the placenta secondary to rupture of maternal vessels in the decidua basalis(50). Acute renal injury (AKI) was also prevalent among women diagnosed with HDP. Preeclampsia is a common cause of AKI, and its been found that 15.3% of women with preeclampsia have AKI(11) especially in low resource settings. A history of HDP in a previous pregnancy is a strong predictor, (odds ratio, 2.24:95% CI,1.12-4.17) in a study by Frances et al.(11). Preeclampsia and eclampsia have been shown to affect multiple organs and cause various systemic dysfunctions including renal injury, stroke, cardiac dysfunction or arrest, respiratory compromise coagulopathy, and liver failure(4,37). In addition, previous study findings have associated preeclampsia and eclampsia with direct maternal deaths (1). Our study did not however report any maternal deaths in the period under review.

The prevalence of neonatal complications was 16.9% in women with HDP and neonatal asphyxia contributed to more than a half of the complications. Literature shows that there is an increased risk of perinatal complications associated with HDP. Fetal growth restriction, small for gestation age infants, and preterm births have been attributed to preeclampsia (1). Preterm births affected a substantial proportion of the neonates contributing a quarter of the complications. However, in this study a small proportion of neonates were small for gestation age.

Preeclampsia and/or eclampsia have been linked to higher rate of stillbirths and neonatal deaths in developing countries (1). Intrauterine fetal demise contributed to more than a fifth of the neonatal complications in women with HDP. This was a substantial proportion that could be attributed to the influence of HDP on maternal wellbeing.

Several studies including one by Kinuthia in 2015 (27) brought forward factors associated with maternal and perinatal complications including advanced maternal age, lack of ANC attendance and poor social economic status which were also identified in a study by Sambu as predictors for development of adverse outcomes in pregnancy (37). In our study however we had an excellent ANC attendance at 99.2%, which may be attributed to community outreach programs by the PMH, close proximity to the target population, increased appreciation of the importance of antenatal care during teachings conducted during the ANC visits. ANC attendance has been linked with better pregnancy outcomes (27,37). Our findings showed that multiparous women were at a higher risk of maternal complications and that socio-demographic characteristics of the women did not predict the complications experienced, this is comparable to a study by Gorbee et al 2020 and Sambu 2011(37,56) . Similarly, the neonates with complications were expectedly born earlier and the adverse perinatal outcomes were not associated with the characteristics of the mother. This is as expected as preterm delivery,

#### STUDY LIMITTATIONS

The most outstanding challenge faced was encountering missing files this was partly due to reorganization that was happening at the records office and the transfer of records and also due to the limited space available for records. There had been also a water leak that had damaged some files. This however was mitigated by guidance and cooperation provided in locating the missing files and the fact that we were able to find replacements in the data set.

Another key challenge was incomplete records: the lack of some important either social demographic or crucial patient information, these were then subsequently replaced. However, it was noted as an area that needed improvement by reinforcing the need for complete record keeping to the health care providers.

#### CONCLUSIONS

HDP was found to be common and affected 14.5% of the women delivering at PMH between January 2018 and December 2019. Pre-eclampsia was the most prevalent affecting 49.8% of the patients with HDP, 47.5% of women with HDP were unclassified. This was a marked increase from that of Bansal at the same study site 33 years earlier. This prevalence increase was in tandem with the observed global, regional and local trend of preeclampsia and hypertensive disorders in pregnancy.

The prevalence of adverse maternal outcomes was 3.2% (with the most common being postpartum hemorrhage at 47.1%).

The prevalence of adverse neonatal outcomes was 16.9%, with birth asphyxia at 48% being the most prevalent. No factors were significantly associated with HDP in our setting. Lack of proper classification was identified as a shortcoming.

#### RECOMMENDATIONS

Heightened awareness and precise documentation and classification of HDP is crucial to ensure the provision of quality care, early recognition and treatment, and consequent good maternal and perinatal outcomes.

This can be achieved through incorporating patient centered care.

WHO recommendations on antenatal care for a positive pregnancy experience.

Patient and health care provider education on the importance of preconception care.

Patient and health care provider education on the importance of early antenatal care attendance.

Policy development to facilitate continued patient and health worker education on HDP enhancing early identification and treatment.

Health care providers education on the need for proper documentation and preservation of health records.

Empowering the health care workforce with the right facilities to enhance the early identification and treatment of HDP.

More research on HDP having seen its increased prevalence and hence burden on maternal and neonatal health.

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### **APPENDIX:**

QUESTIONNAIRE

	COLLECTION TOO			
Researc	ch assistant's name	; 		
Date of	admission			
Date of	discharge/ referral			
Study n	umber			
A) Dem	ographic factors			
-	Date of birth		Age y	rears
	he highest level of		, (go )	ouro
	None			Post-secondary
	/arital status			
-	_	Marriad <b>C</b>	Divorced/Separated	d 🖸 Widowed 🗖
	Single		Divorceu/Separatet	
	· —	Self-employed	_	Not-employed
5. F	Place of residence	Slum 🗖	Non-slum 🗖	
B) Obs	tetric characterist	ics		
		Yes 🗋 No 🗖	Г	
	Parity			
		elivery		
		SVD		
	extraction			
0				
C) Hyp	ertensive disorde	r of pregnancy (HD	P)	
11.E	Blood pressure read	lings at admission	Systolic	/ Diastolic
_				
12.V	Vas there a diagnos	sis of HDP? Yes	🗋 No 🗖	
13. lí	f yes in question 11	, what type of HDP?	)	
F	Pre-eclampsia			
E	Eclampsia			
C	Chronic hypertensio	n 🗖		
F	IELLP syndrome			
D) Mate	ernal complication	<u>IS</u>		
A	Acute renal failure			
Ν	Neurological deficits			
C	Development of			
е	clampsia			
C	Death			
A	Antepartum hemorrh	nage 🗖		

Postpartum hemorrhage Admission to ICU	
E) <u>Neonatal outcomes</u>	
14. Apgar score	
15. Birth weight	
16. Complications	
Intrauterine fetal demise	
LBW neonates <2500g	
Small for gestation age r	neonates 🗖
Preterm birth <37/40	
Neonatal asphyxia	
APGAR<7 @ 5 min	



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Dr. Collins Mwaniki Mwangi Reg. No.H58/11249/2018 Dept of Obstetrics and Gynaecology School of Medicine College of Health Sciences University of Nairobi

Dear Dr. Mwangi

KNH-UON ERC Email: uonknh\_erc@uonbi.ac.ke Website: http://www.facebook.com/uonknh.erc Facebook: https://www.facebook.com/uonknh.erc Twitter: @UONKNH\_ERC https://witter.com/UONKNH\_ERC





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25th February 2021

RESEARCH PROPOSAL – PREVALENCE AND RISK OF ADVERSE OUTCOMES OF HYPERTENSIVE DISORDERS IN PREGNANCY AT PUMWANI MATERNITY HOSPITAL IN 2018-2019 (P658/11/2020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and <u>approved</u> your above research proposal. The approval period is 25<sup>th</sup> February 2021 – 24<sup>th</sup> February 2022.

This approval is subject to compliance with the following requirements:

- a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
- e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
- g. Submission of an <u>executive summary</u> report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

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

Yours sincerely,

PROF. M. L. CHINDIA

SECRETARY, KNH-UON ERC

c.c. The Principal, College of Health Sciences, UoN The Senior Director, CS, KNH The Chairperson, KNH- UoN ERC The Assistant Director, Health Information Dept, KNH The Dean, School of Medicine, UoN The Chair, Dept. of Obstetrics and Gynaecology, UoN Supervisors: Dr. Alfred Osoti, Dept.of Obstetrics and Gynaecology, UoN Prof. Omondi Ogutu, Dept.of Obstetrics and Gynaecology,UoN

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### Dummy tables

# Table 11 Social demographic and clinical characteristics of study participants

# Baseline data of study participants

Mean age (SD) Highest level of education	
Highest level of education	
None	
Primary	
Secondary	
Post-secondary	
Marital status	
Single	
Married	
Divorced/separated	
Widowed	
Source of income	
Formal employment	
Self-employment	
Unemployed	
Place of residence	
Slum	
Non-slum	
ANC attendance	
Yes	
No	
Parity	
Nulliparous	
Multipara	

Mean gestational weeks at delivery (SD)	
Mode of delivery	
SVD	
CS	
Vacuum extraction	

5.0 Study timelines Table 12 Study timelines

	S E P	O C T	N O V	D E C	J A N	F E B	M A R	A P R	M A Y	J U N	J U L	AU G	SEP	OC T	NO V	DE C	JAN	FE B	MA R
Conce pt note																			
Propos al Develo pment																			
Propos al presen tation																			
Ethics approv al																			
Data collecti on																			
Result s presen tation																			
Manus cript writing																			
Publis hing																			

# Study Budget

### Table 13 Study budget

Variable	Number	Cost in ksh				
Stationery	5	1000				
Statistician	1	35000				
Research assistant	2	20000				
Airtime	5	5000				
Internet	5	10000				
Transport	5	15000				
Total	25	86000				