# INCIDENCE AND PREDICTORS OF CHRONIC HYPERTENSION FOLLOWING HYPERTENSIVE DISORDERS IN PREGNANCY AT KENYATTA NATIONAL HOSPITAL,

#### (A DESCRIPTIVE PROSPECTIVE COHORT STUDY)

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2019

#### Declaration

This dissertation is my original work and has not been presented elsewhere. This research
project is my original work and has not been presented for academic award in any other
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#### **Certificate of Authenticity**

This is to certify that this thesis is the original work of **Dr. Maryam Badamana**, **H58/75616/2014** in the Department of Obstetrics and Gynecology, College of Health Sciences, University of Nairobi, under the guidance and supervision of Prof. Zahida Qureshi and Dr. Alfred Osoti. This thesis has not been presented in any other university for award of a degree.

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May God bless you all.

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To my parents Prof. Mohamed Badamana and Mrs. Aisha Naji, For their unconditional love and support,

For giving me the best education and making me who I am today

To my siblings Sumayya and Luqman,

For always being there for me and always making it easier for me

To my husband Malik,

My teacher, my partner, my beloved,

Who led me to this path and walked me through it,

Without whom this would not have been possible

To my boys Yusuf and Ammar,

Who have brought so much love and blessings into our lives

And above all to Allah the Almighty,

My source of strength, wisdom, knowledge and understanding

This research is dedicated to you.

#### Section 1.5 Abbreviations

KNH - Kenyatta National Hospital

UON - University of Nairobi

WHO - World Health Organization

HDP - Hypertensive Disorders in Pregnancy

BP - Blood Pressure

ABM - Ambulatory Blood Pressure Measurement

HBPM - Home Blood Pressure Measurement

ISSHP - International Society for the Study of Hypertension in Pregnancy

BMI - Body Mass Index

HTN - Hypertension

HIV - Human Immunodeficiency Virus

ANC - Ante Natal Clinic

PNC - Post Natal Clinic

KNH-UoN Kenyatta National Hospital/University of Nairobi Ethics Research

ERC Committee

FIGO International Federation of Gynecology and Obstetrics

SPSS Statistical Package for the Social Science

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#### Section 1.9 Abstract

# TITLE: INCIDENCE AND RISK FACTORS OF CHRONIC HYPERTENSION FOLLOWING HYPERTENSIVE DISORDERS IN PREGNANCY AT KNH, A PROSPECTIVE DESCRIPTIVE COHORT STUDY.

**Introduction:** Hypertensive disorders in pregnancy complicate up to 10% of pregnancies worldwide, constituting one of the greatest causes of maternal and perinatal morbidity and mortality. In Kenya, studies conducted at Kenyatta National Hospital have noted a prevalence of 5.4% of hypertensive disease and 0.56% for eclampsia. Hypertension in pregnancy usually resolves after delivery. If it persists, it leads to chronic hypertension which in itself is an important risk factor in cardiovascular disease.

**Objective:** To determine the incidence and risk factors of chronic hypertension, and time to resolution of hypertension among patients with gestational hypertension and preeclampsia-eclampsiaseen at KNH up to 12 weeks postpartum.

**Methodology:** This was a prospective descriptive cohort study carried out at Kenyatta National Hospital, Nairobi, Kenya. The study had one hundred and sixteenparticipants with hypertensive disorders in pregnancywho were followed up until 12 weeks postpartum. Data were collected via interviewer-administered questionnaires, serial blood pressure measurements and review of medical records. They were then analyzed using SPSS IBM (Version 21). Categorical variables were subjected to the chi-square test, while continuous variables were compared using Student's t-test. Risk factors for persistence of hypertension underwent bivariate analysis. A p value<0.05 was considered statistically significant.

**Results:** A quarter of the study participants were still hypertensive at the end of puerperium. Among these, 30% developed chronic hypertension. The risk factors associated with development of chronic hypertension among these parturients were higher pre-pregnancy BMI (OR=19.4, 95% CI 2.0-187.9, p=0.02), intimate partner violence(OR=2.5, 95% CI 1.0-6.1, p=0.036), lower gestational age at delivery(OR=2.6, 95% CI 1.1-6.2, p=0.035), lower gestational age at onset of hypertension(OR=2.4, 95% CI 1.1-5.7, p=0.038), family history of hypertension(OR=3.0, 95% CI 1.2-7.5, p=0.015), personal history of diabetes mellitus (OR=4.8, 95% CI 1.5-15.4, p=0.008), and thrombocytopenia (OR=2.8, 95% CI 1.1-7.3, p=0.013). Obesity was the only significant risk factor in both univariate and multivariate analysis. The time to resolution of hypertension was found to be 2 weeks postpartum for majority of the patients (57.8%).

**Conclusion:** Hypertension in pregnancy is a significant risk factor for developing persistent and chronic hypertension after delivery. Timely diagnosis and timely appropriate intervention are the key strategies to reduce the risk of developing future cardiovascular morbidity.

**Recommendations:** Women with hypertensive disorders in pregnancy should be followed up beyond 6 weeks postpartum and should be counseled on the risk of developing chronic hypertension.

#### **Section 2.1 Introduction**

Hypertensive Disorders in Pregnancy (HDP) complicate up to 10% of pregnancies worldwide, constituting one of the greatest causes of maternal morbidity and mortality worldwide. (1)It is also a major cause of perinatal morbidity and mortality globally, especially from preterm delivery.(2)

According to a recent report of the WHO, hypertensive disorders of pregnancy which are associated with about 16% of maternal mortality, are the leading cause of maternal death (after hemorrhage) in sub-Saharan Africa.(3)

In another study, hypertensive disorders in Pregnancy were found to account for nearly 18% of all maternal deaths worldwide, with an estimated 62,000 to 77,000 deaths per year.(4)

In Kenya, studies conducted at KNH have noted a prevalence of 5.4% of hypertensive disease and 0.56% for eclampsia(5).

The International Society for the Study of Hypertension in Pregnancy (ISSHP) classifies hypertensive disorders in pregnancy into 1) chronic hypertension 2) gestational hypertension 3) preeclampsia de novo or superimposed on chronic hypertension 4) white coat hypertension. Hypertension is defined as systolic blood pressure ≥140mmHg or diastolic blood pressure ≥90mmHg. Chronic hypertension is hypertension pre-dating the pregnancy. Gestational hypertension is hypertension after 20 weeks' gestation. Preeclampsia is new onset hypertension after 20 weeks' gestation with new proteinuria ((>0.3g during 24 hours or at least 2+ protein on dipstick testing), other maternal organ dysfunction (renal, liver, neurological or hematological)) or uteroplacental dysfunction. White coat hypertension is BP that is elevated in the office (systolic blood pressure ≥140mmHg or diastolic blood pressure ≥90mmHg) but is consistently normal outside of the office (<135/85mmHg) by ambulatory BP monitoring or home BP monitoring.(6)

High BP in pregnant women is associated with complications like pulmonary edema, strokes, acute kidney injury, disseminated intravascular coagulopathy, and death in the antepartum period. It is also associated with an increased risk of essential hypertension, vascular diseases, end-stage renal disease, and diabetes mellitus later in life.(7)

Hypertension in pregnancy usually resolves within 3 months of delivery. Various factors may increase the risk of persistence of hypertension during the postpartum period and subsequent development of chronic hypertension. These factors include gestational age at diagnosis, gestational age at delivery, maternal age, parity, severe pre-eclampsia, platelet counts and serum creatinine (8)(9)(10)(11).

The aim of this study was to find out the incidence and risk factors of chronic hypertension following hypertensive disorders in pregnancy up to 12 weeks postpartum. This is important as high blood pressures in pregnancy lead to various systemic complications and long term adverse outcomes including chronic hypertension, which in itself is a risk factor for cardiovascular disease (7).

#### Section 2.2 Literature review

#### **Section 2.2.1 Definition of Hypertension**

Hypertension in pregnancy is defined as a sustained systolic blood pressure of ≥140mmHg or a sustained diastolic blood pressure ≥90mmHg, by office (or in-hospital) measurement. Severe hypertension in pregnancy is a sustained systolic blood pressure ≥160mmHg or diastolic blood pressure ≥110mmHg.

#### Section 2.2.2 Measurement of Blood Pressure

Appropriate, standardized technique for blood pressure measurement is critically important. The mercury sphygmomanometer has long been considered the gold standard for measurement of blood pressure, but many different automated devices are also used for this purpose. Blood pressure is obtained after five minutes of rest, with the patient sitting with feet on the ground and legs uncrossed or in a semi-reclining position with her back supported and the arm be supported and at heart level. Measurement of blood pressure in left lateral recumbence, on the left arm, does not differ substantially from blood pressure that is recorded in the sitting position, and may be used if a seated blood pressure is not feasible.(12)

An appropriately sized cuff should be used: width of bladder 40 per cent of circumference and encircling 80 per cent of the upper arm. A large adult cuff should be used in women with an upper-arm circumference of 35 to 44 cm, and a thigh cuff if the upper-arm circumference is 45 to 52 cm. If an auscultatory method is used, the first audible sound (Korotkoff I) is the systolic pressure and the disappearance of sound (Korotkoff V) is the diastolic pressure.(13) However, if sounds are audible with the cuff deflated, which can happen in pregnant women, then Korotkoff IV should be used.(14)

Blood pressure measurements may occur in three types of settings: (1) health care facility; and two types of settings outside the facility: (2) 'ambulatory' blood pressure measurement

(ABM); and (3) home blood pressure measurement (HBPM). Blood pressure can be measured using auscultatory (mercury or aneroid devices) or automated methods.

#### Section 2.2.3 Classification of HDPs

The International Society for the Study of Hypertension in Pregnancy (ISSHP) classifies hypertensive disorders in pregnancy into 1) chronic hypertension 2) gestational hypertension 3) preeclampsia de novo or superimposed on chronic hypertension 4) white coat hypertension. Hypertension is defined as systolic blood pressure ≥140mmHg or diastolic blood pressure ≥90mmHg. Chronic hypertension is hypertension pre-dating the pregnancy. Gestational hypertension is hypertension after 20 weeks' gestation. Preeclampsia is new onset hypertension after 20 weeks' gestation with new proteinuria ((>0.3g during 24 hours or at least 2+ protein on dipstick testing), other maternal organ dysfunction (renal, liver, neurological or hematological)) or uteroplacental dysfunction. White coat hypertension is BP that is elevated in the office (systolic blood pressure ≥140mmHg or diastolic blood pressure ≥90mmHg) but is consistently normal outside of the office (<135/85mmHg) by ambulatory BP monitoring or home BP monitoring.

#### Section 2.2.4 Prevalence of HDPs

HDPs affect about 10% of pregnancies worldwide(1). They account for nearly 18% of all maternal deaths worldwide, with an estimated 62000-77000 deaths per year(4).

According to a recent report of the WHO, HDPs are the leading cause of maternal death (after hemorrhage) in sub-Saharan Africa(3). Studies conducted in Kenya at Kenyatta National Hospital have noted a prevalence of 5.4% of hypertensive disease and 0.56% for eclampsia(5).

A secondary analysis of a retrospective cohort study of women with preeclampsia with severe features done in the USA in 2016 found that 21% of the cohort had persistent hypertension at 6 weeks postpartum (15). A prospective cohort study done by Berks et al in the Netherlands

in 2009 to show resolution of hypertension and proteinuria after preeclampsia found that 39% still had hypertension at 3 months postpartum and 18% at 2 years postpartum (16). In Canada, a retrospective cohort study done in 2010 to determine the postpartum course of gestational hypertension and preeclampsia found that 19% of the cohort still had hypertension at 12 weeks postpartum (17).

A prospective cohort study done in Cameroon in 2014 to determine the postpartum trend in blood pressure levels, renal function and proteinuria in women with severe preeclampsia and eclampsia in sub-Saharan Africa found that 42.6% had persistent hypertension at 6 weeks, 27.8% at 3 months, and 14.8% at 6 months postpartum (18). Olagbuji et al in Nigeria in 2012 found that 25.8% of their cohort had persistent hypertension at 12 weeks postpartum (19).

A prospective cohort study done in Sudan in 2016 on persistent hypertension following preeclampsia found that 35.2% of the patients had persistent hypertension at 6 weeks postpartum (11). Fathy et al in Egypt in 2017 found that 12.1% of women diagnosed with hypertensive disorders in pregnancy had persistent hypertension at 12 weeks postpartum (9).

In Uganda, a prospective cohort study done by Ndayambagye et al in 2010 at Mulago Hospital to determine factors associated with persistent hypertension after puerperium among women with preeclampsia/eclampsia found that 27.7% had persistent hypertension at 6 weeks gestation (10). In 2013, a prospective cohort study done by Nakimuli et al in the same hospital in Uganda found that 34% of the women analyzed had persistent hypertension 3 months post-delivery(8).

#### **Section 2.2.5** Risk factors for chronic hypertension

A retrospective cohort study done in South Korea in 2015 on the risk factors that predict chronic hypertension after delivery in women with a history of hypertensive disorders in pregnancy showed early onset hypertension with end-organ dysfunction, history of smoking and pre pregnancy BMI were independent predictors of progression to chronic hypertension

(20). Limaye et al in the USA in 2016 found factors associated with persistent hypertension to be obesity, severe preeclampsia and women discharged home on blood pressure medication (15).

A prospective cohort study in Cameroon in 2014 to determine the postpartum trend in women with severe preeclampsia and eclampsia in sub-Saharan Africa found that advanced age, higher BMI, low gestational age at delivery, low fetal birth weight, and proteinuria at delivery were the main risk factors for persistent hypertension at 3 months postpartum (18). A similar study done in Nigeria in 2012 found the risk factors to be maternal age ≥35 years, serum creatinine levels, serum uric acid and maternal HIV infection (19).

Fadalallah et al in Sudan in 2016 found the risk factors for persistent hypertension following preeclampsia to be lower platelet counts, lower neonatal weight at delivery and severe preeclampsia (11). In Egypt in 2017, Fathy et al found the risk factors to be older maternal age at diagnosis of hypertensive disorder in pregnancy, lower gestational age at diagnosis, multiparous women, preeclampsia and hypertension with end-organ dysfunction (9).

Studies done in Uganda by Ndayambagye et al (10) and Nakimuli et al (8) at Mulago hospital on hypertension persisting after preeclampsia found the risk factors for persistent hypertension to be serum creatinine, maternal age, gestational age at delivery and parity.

#### Section 2.2.6 Time to resolution of hypertension

In Canada, a retrospective cohort study of women with gestational hypertension or preeclampsia done in 2010 to determine the postpartum course of gestational hypertension and preeclampsia found that hypertension presenting in pregnancy normalized postpartum in 81% of the cohort, in most by 3 months. In those BP normalized, time to normalization was  $5.4 \pm 3.7$  weeks (17). A similar study done in Japan in 2014 to determine the postpartum recovery course in patients with gestational hypertension and preeclampsia found that the

mean interval for normalization of BP was  $41.8 \pm 29.4$  days (median 31.5). 90% of the patients required 77 days to recover from HTN (21).

#### Section 2.3 Conceptual framework

#### Section 2.3.1 Narrative

Hypertensive disorders in pregnancy have been classified into chronic hypertension, gestational hypertension, preeclampsia de novo or superimposed on chronic hypertension and white coat hypertension.

Known risk factors that can increase incidence of chronic hypertension postpartum after hypertensive disorders in pregnancy can be divided into socio-demographic risk factors, obstetric risk factors and medical risk factors.

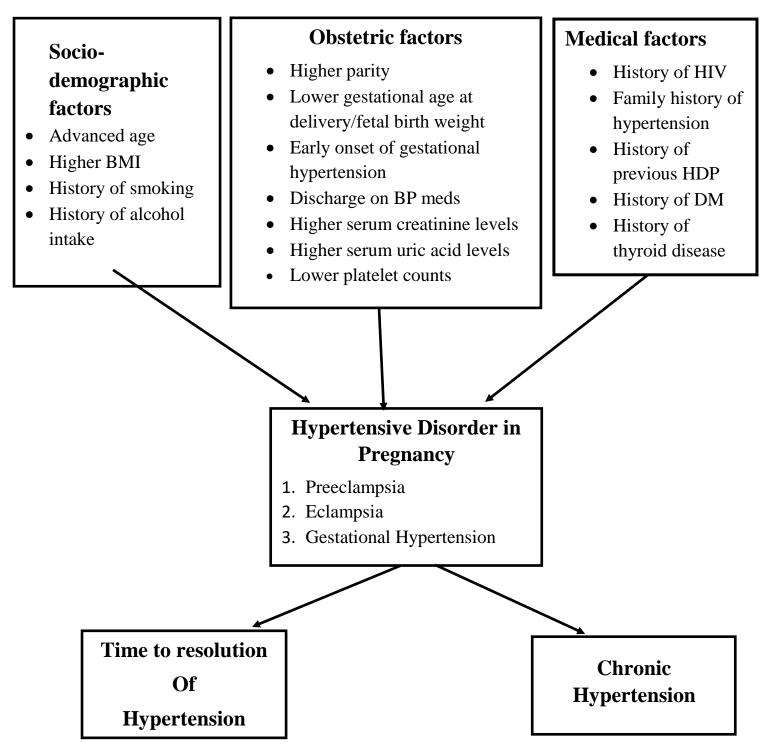
Socio-demographic risk factors that can increase incidence of chronic hypertension include increasing age, marital status, increasing spouse's age, a higher pre-pregnancy BMI, a history of smoking or alcohol intake, and a higher gestational age at delivery.

Obstetric risk factors that can increase incidence of chronic hypertension include a higher parity, higher number of pregnancy, mode of delivery, and a higher baby's birth weight.

Medical risk factors that can increase incidence of chronic hypertension include positive HIV status, a family history of HTN, and a previous history of HDP.

Outcomes expected are either chronic hypertension or normal blood pressure in the postpartum period. For those with normal blood pressure in the postpartum period the time to resolution of hypertension will also be assessed.

Section 2.3.2 Diagrammatic Conceptual framework



#### Figure 1: Conceptual framework

#### **Section 2.4 Justification**

Although extensive research has been conducted on hypertensive disorders in pregnancy in the antepartum period, very little has been done one the postpartum period especially in low resource settings. In this study setting, very little is known on the incidence, risk factors and clinical outcomes chronic hypertension. Postpartum blood pressures are not well monitored since there is no designated service and most patients are lost to follow up soon after delivery. The duration of *time* to resolution of hypertension and persistence of high BPs with the development of chronic hypertension is not documented. It is important for patients with HDP to be followed up in the postpartum period with constant monitoring of BPS especially as this will influence the management of the next pregnancy and long-term outcomes.

#### **Section 3.1** Research questions

What is the incidence, risk factors and time to resolution of chronic hypertension among patients with gestational hypertension and preeclampsia-eclampsia seen at KNH up to 12 weeks postpartum?

#### Section 3.2 Objectives

#### Section 3.2.1 Broad objective

To determine the incidence and risk factors of chronic hypertension, and the time to resolution of hypertension among patients with gestational hypertension and preeclampsia-eclampsia seen at KNH up to 12 weeks postpartum.

#### **Section 3.2.2 Specific Objectives**

Among women with gestational hypertension and preeclampsia-eclampsia who are followed until 12 weeks postpartum,

- 1. To determine the incidence of chronic hypertension
- 2. To determine the risk factors for chronic hypertension
- 3. To describe the time to resolution of hypertension

#### Section 4.0 Study methodology

#### Section 4.1.1 Study design

Descriptive prospective cohort study in which women with gestational hypertension, preeclampsia or eclampsia were followed up for 12 weeks postpartum. Women with chronic hypertension were not recruited into the study.

#### Section 4.1.2 Study site and setting

This study was carried out at the Kenyatta National Hospital (KNH) labor ward, antenatal and post-natal wards (ward GFA, GFB, 1A), antenatal clinic (ANC) and postnatal clinic (PNC) and other clinics. The KNH is the largest public referral and teaching hospital to the University of Nairobi and Kenya Medical Training College.

The hospital receives patients from Nairobi and its environs as well as referrals from all other hospitals in Kenya. The bed capacity is 1800 and is located 2km south west of the Nairobi central business district.

It has an average of 1000 deliveries per month. These deliveries occur amongst mothers of varying socioeconomic status.

Labor ward is run by a registrar and two consultants. Ward rounds are done at 8am and 8pm daily. All patients with hypertensive disorders in pregnancy for admission are first seen in labor ward before being taken to the ANC wards.

Follow up postpartum is done at the Post Natal Clinic at Clinic 18 which is run by a different team of registrars and a consultant every Friday. All pregnant women with HDP are required to be followed up at the PNC in the postpartum period. Those with persistent hypertension at 12 weeks postpartum are referred to the Medical Outpatient Clinic.

#### **Section 4.1.3 Study population**

All patients with gestational hypertension, preeclampsia and eclampsia in KNH not known to have preexisting chronic hypertension.

#### Section 4.1.3a Inclusion criteria

- Patients with gestational hypertension, preeclampsia or eclampsia after 20 weeks' gestation seen at KNH.
- Patients willing to be followed up postpartum.

#### Section 4.1.3b Exclusion criteria

- Patients with no informed consent.
- Patients known to have preexisting chronic hypertension.

#### Section 4.1.4Sample size calculation and sampling procedure

#### **Section 4.1.4a** Sample size determination

Sample size calculation for finite population.

$$n = \frac{Nz^2pq}{E^2(N-1) + z^2pq}$$

n =Desired sample size

N = population size (number of pregnant women with hypertension in pregnancy seen per month at the Kenyatta National Hospital is approximately 50, and for 3 months of the study duration the total will be approximately 150).

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

p =expected true proportion (estimated at 34%, from a study conducted by Nakimuli A. *et. al.* (2013) looking at hypertension persisting after preeclampsia, found 34% of them had persistent hypertension.)

$$q = 1 - p$$

E =desired precision (0.05)

$$n = \frac{150 \times 1.96^2 \times 0.34 \times 0.66}{0.05^2 (150 - 1) + (1.96^2 \times 0.34 \times 0.66)} = 105$$

Sample size increased by 10% to account for those lost to follow up gives 116 participants.

Therefore, total sample size (n) = 116 participants.

#### Section 4.1.4b Sampling procedure

Convenience sampling was done. Patients who were available and willing to participate in the study were considered. The inclusion and exclusion screening enrolment form was used to enroll the patients in the study.

#### Section 4.1.5 Participant recruitment

Potential study participants were recruited by the principal investigator or research assistant in the labour wards and through the antenatal wards and clinic. The participants were identified and chosen for the study if they met the eligible criteria (inclusion and exclusion). Recruitment and enrolment was carried out by the research assistant or principal investigator. Those with elevated blood pressure measurements before 20 weeks' gestation were excluded.

#### **Section 4.1.6 Data collection**

Data was collected through interviewer administered questionnaires. The data collected included socio-demographic characteristics, obstetric and medical factors like age, parity, marital status, spouse's age, pre pregnancy BMI, history of smoking and alcohol intake pre pregnancy, number of pregnancy (gravida), HIV status, mode of delivery, baby's birth weight, family history of hypertension, history of previous hypertensive disorders in pregnancy and gestational age at delivery. The questionnaire was filled on enrolment to the study at first contact. Additional information was obtained from participants' medical records.

Post discharge during the postpartum period, blood pressure measurement was done at KNH or the nearest health facility by a qualified health care worker. The questionnaire had the contact details for each patient to enable follow up in the postpartum period. Patients were called and asked about their BP readings at 2 weeks, 6 weeks and 12 weeks postpartum by the principal investigator or research assistant. The BP measurements were recorded in the

questionnaires. Those with persistent hypertension at 12 weeks postpartum were referred to the medical outpatient clinic for multidisciplinary review and follow up.

#### Section 4.1.7Data Management and Analysis

Quality control measures included developing standard operating procedures (SOPs) and data collection manual to guide data collection. On completing each questionnaire form the principal investigator examined all items for completeness. All incomplete questionnaires were completed by referring back to patient record and in cases where data is missing from records a code was assigned for missing values. Data was entered into databases designed in SPSS IBM (version 21). Quality assurance measures was implemented through designing a customized database using the study questionnaire structure with data stored in numeric coded format, and text for open ended questions. The design was intended to minimize data entry errors. In addition, range and consistency checks were built into the database to identify implausible values due to possible data collection errors. Data cleaning and analysis was then conducted. In cases where data entry errors were noted cleaning involved validating entries by referring back to the study questionnaire using the unique study identifier contained in each questionnaire. Any inconsistency between the questionnaire and data contained in the database was resolved by checking patient records and re-entering the data contained in the records.

All data including questionnaires and electronic databases were archived in a secure lockable cabinet and retained until the end of the study and after publication of the study findings.

The characteristics of participants with persistent hypertension and women in whom hypertension resolved within 12 weeks' months after delivery were compared. Categorical variables were compared using the chi-square test. The mean of numerical variables e.g. age of participants in the persistent hypertension group and the group with resolved hypertension

were compared using Student's t-test. To assess risk factors for persistence of hypertension, bivariable analysis was performed to compute risk ratios and 95% confidence intervals. Multivariable logistic regression models were used to determine the risk factors that are significantly associated with persistent hypertension at 12 weeks postpartum. In these regressions all factors that showed significant association with persistence of hypertension in the univariate analysis were included as explanatory factors in a logistic regression containing binary variable indicating hypertension persistence as the dependent variable. Risk ratios were reported along with 95% CI derived from the multivariable model. Associations with p values less than 0.05 were considered statistically significant.

#### Section 4.2 Research ethics

#### **Section 4.2.1Participants**

#### Section 4.2.1a Ethical approval

This protocol and the template informed consent form found in the appendix, and any subsequent modifications to this form, were reviewed and approved by the Kenyatta National Hospital/University of Nairobi Ethics Research Committee (KNH-UoN ERC) prior to initiation of the study, with respect to scientific content and compliance with applicable research and human participants' regulations (Protocol number P649/09/2018).

This protocol, the informed consent form, and any other requested documents, as well as any subsequent modifications, were also reviewed and approved by the Ethical Review Committee.

Safety and progress reports were submitted to the KNH-UoN ERC, after study completion. The reports included the total participants enrolled in the study, the number of participants that completed the study, all changes in the research activity, and all other problems that were not anticipated that involves risks to human participants or others.

#### Section 4.2.1b Risk to Subjects

We ensured the participants privacy and confidentiality was maintained at all times. However, it is possible that others knew of the participant's involvement in the study, we believe there will be no stigma related to this and hence no harm

#### Section 4.2.2 Benefits of the study

The participants benefitted by receiving close monitoring throughout the study period. They also benefitted by receiving health education on neonatal care. The information learnt from this study may benefit others in the future.

#### Section 4.3 Strengths of the study

- This is the first local study evaluating the incidence and predictors of chronic hypertension following hypertensive disorders in pregnancy, it will therefore form a baseline for other studies in this area.
- The study had high retention of participants who were recruited in the antenatal period and followed up until 12 weeks postpartum, unlike other similar studies which only followed them up to 6 weeks postpartum.

#### Section 4.4 Limitations of the study

- The blood pressure measurements should have been done by the same person and the same machine at each visit for all the study participants. We were not able to standardize the measurements in this way in our study. As in routine practice, blood pressure measurements were done by different people and machines.
- In the postpartum period the patient's blood pressure measurements were taken at 2 weeks, 6 weeks and 12 weeks postpartum as in the usual postnatal visits at Kenyatta National Hospital. It would have been more accurate to take them more frequently to determine time to resolution of hypertension.

#### Section 5.0 Results

The study period extended from 2<sup>nd</sup> January 2019 to 30<sup>th</sup>May 2019.

Table 1 summarizes the patients and demographic characteristics of the participants.

Table 1: Sociodemographic characteristics of study participants

Variable	Frequency n (%)
	n=116
Age (Mean=30, SD=5.9)	
18-25	25 (22)
26-35	69 (59)
36-45	22 (19)
Marital status	
Married	88 (76)
Single	28 (24)
Spouse's age ( <i>Mean=35.6</i> , <i>SD=6.7</i> )	
18-25	5 (6)
26-35	38 (43)
36-45	40 (45)
>45	5 (6)
History of smoking	
Yes	5 (4)
No	111 (96)
History of alcohol intake	
Yes	31 (27)
No	85 (73)
Intimate partner violence	
Yes	33 (28)
No	83 (72)

Table 2 shows the clinical characteristics of the study participants.

Table 2: Clinical characteristics of study participants

Variable	Frequency n (%)
	n=116
Hypertensive disorder	
Gestational hypertension	5 (4)
Mild preeclampsia	9 (8)
Severe preeclampsia	80 (69)
Eclampsia	22 (19)
Pre-pregnancy BMI	
<18.5	3 (3)
18.5-24.9	73 (63)
25.0-29.9	35 (30)
>=30.0	5 (4)
Gestation at delivery	
≤36	62 (53)
>36	54 (47)
Gestational age at onset of HTN	
≤28	40 (34)
>28	76 (66)
Number of pregnancy (gravida)	
≤3	72 (62)
>3	44 (38)
Mode of delivery	
Caesarian Section	79 (68)
Spontaneous vertex delivery	37 (32)
Baby's birth weight	
≤2000	46 (40)
>2000	70 (60)

**BMI-Body Mass Index, HTN-Hypertension** 

A total of one hundred and sixteen participants (n= 116) were recruited into this study. The mean age of the women was 30.0 (SD=5.9) years, median age was 29.0 (IQR=8) years.

## Section 5.1 Incidence of chronic hypertension following gestational hypertension and preeclampsia-eclampsia

The incidence of chronic hypertension was found to be 25.9% at 6 weeks and 7.8% at 12 weeks.

Table 3: Incidence of chronic hypertension following gestational hypertension and preeclampsia-eclampsia at Kenyatta National Hospital

Weeks	Frequency n (%)	Cumulative
postpartum	n=116	incidence
6 weeks		
Yes	30 (25.9)	30/116
No	86 (74.1)	
12 weeks		
Yes	9 (7.8)	9/116
No	107 (92.2)	

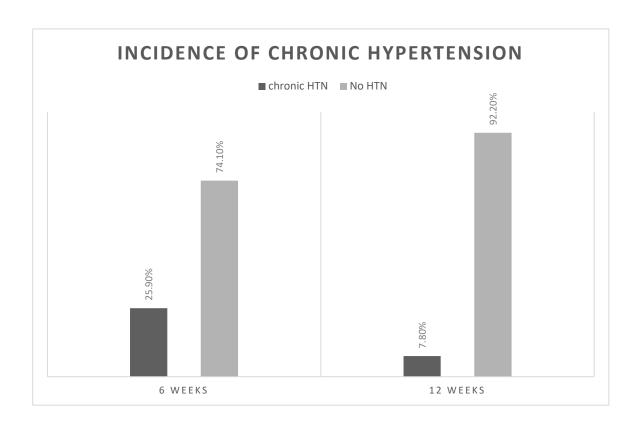


Figure 2: Incidence of chronic hypertension following gestational hypertension and preeclampsia-eclampsia at Kenyatta National Hospital

### Section 5.2 Risk factors for chronic hypertension among the study participants

This section presents the results of risk factors for chronic hypertension.

#### Section 5.2.1 Hypertension related risk factors for chronic hypertension

Table 4 summarizes the hypertension related risk factors for chronic hypertension following gestational hypertension and preeclampsia-eclampsia at Kenyatta National Hospital.

Table 4: Hypertension related risk factors for chronic hypertension among the study participants

Variable	<b>Chronic Hypertension</b>		Total	OR (95% CI)	<b>p-</b>
	Yes	No	n=116		value
	n (%)	n (%)			
Type of hypertension					
Gestational hypertension	1 (3)	4 (5)	5 (4)		Ref
Mild preeclampsia	1 (3)	8 (9)	9 (8)	0.5 (0.02-10.3)	1.000
Severe preeclampsia	20 (67)	60 (70)	80 (69)	1.3 (0.14-12.6)	1.000
Eclampsia	8 (27)	14 (16)	22 (19)	2.3 (0.22-24.1)	0.636
Severity of hypertension					
Mild preeclampsia	1 (3)	8 (10)	9 (8)	0.3 (0.04-2.8)	0.441
Severe preeclampsia	28 (97)	74 (90)	102 (92)		

Out of the 116 study participants, 5 had gestational hypertension, 9 had mild preeclampsia, 80 had severe preeclampsia and 22 had eclampsia. In severity of hypertension eclampsia was grouped as a severe form of preeclampsia. Type of hypertension and severity of hypertension were not found to be significant risk factors for chronic hypertension in this study.

#### Section 5.2.2 Sociodemographic risk factors for chronic hypertension.

The risk factors for chronic hypertension are as shown by the table below.

Table 5: Sociodemographic risk factors for chronic hypertensionamong the study participants

Variable	Chronic Hypertension Yes No		Total	OR (95% CI)	p-
			n=116		value
	n (%)	n (%)			
Age of the patient					
≤35	22 (73)	72 (84)	94 (81)	0.5 (0.2-1.4)	0.211
>35	8 (27)	14 (16)	22 (19)		
Marital status					
Married	26 (87)	62 (72)	88 (76)	2.5 (0.8-7.9)	0.108
Single	4 (13)	24 (28)	28 (24)		
Spouse's age					
≤35	9 (35)	34 (55)	43 (49)	0.4 (0.2-1.1)	0.083
>35	17 (65)	28 (45)	45 (51)		
Pre-pregnancy BMI					
≤24.9	13 (43)	63 (73)	73 (66)		Ref
25.0-29.9	13 (43)	22 (26)	35 (30)	2.9 (1.2-7.1)	0.021
>=30.0	4 (14)	1 (1)	5 (4)	19.4 (2.0-187.9)	0.006
History of smoking					
Yes	1 (3)	4 (5)	5 (4)	0.7 (0.1-6.6)	1.000
No	29 (97)	82 (95)	111 (96)		
History of alcohol intake					
Yes	8 (27)	23 (27)	31 (27)	0.9 (0.4-2.5)	0.993
No	22 (73)	63 (73)	85 (73)		
Intimate partner violence					
Yes	13 (43)	20 (23)	33 (28)	2.5 (1.0-6.1)	0.036
No	17 (57)	66 (77)	83 (72)		

**BMI-Body Mass Index** 

The sociodemographic risk factors found to be of significance were pre-pregnancy BMI (p=0.006, p=0.021) and those with a history of intimate partner violence (p=0.036). Those

with a higher pre-pregnancy BMI had a higher chance of getting chronic hypertension. Those with a BMI >25 i.e. overweight were 2.9 times more likely to get chronic hypertension (OR=2.9, 95% CI 1.2-7.1) and those with a BMI  $\geq$ 30 i.e. obese were 19.4 times more likely to get chronic hypertension (OR=19.4, 95% CI 2.0-187.9). Those with a history of intimate partner violence were 2.5 times more likely to get chronic hypertension (OR=2.5, 95% CI 1.0-6.1).

Section 5.2.3 Obstetric risk factors for chronic hypertension.

Table 6: Obstetric risk factors for chronic hypertensionamong the study participants

Variable	<b>Chronic Hypertension</b>		Total	OR (95% CI)	p-value
	Yes	No	n=116		
	n (%)	n (%)			
Number of pregnancy					
(gravida)					
≤1	2 (7)	5 (6)	7 (6)	1.2 (0.2-6.3)	1.000
>1	28 (93)	81 (94)	109 (94)		
Baby's birth weight					
≤2000	15 (50)	31 (36)	46 (40)	1.8 (0.8-4.1)	0.179
>2000	15 (50)	55 (64)	70 (60)		
Gestational age at delivery					
≤36	21 (70)	41 (48)	62 (53)	2.6 (1.1-6.2)	0.035
>36	9 (30)	45 (52)	54 (47)		
Gestational age at onset of					
HTN					
≤28	15 (50)	25 (29)	40 (35)	2.4 (1.1-5.7)	0.038
>28	15 (50)	61 (71)	76 (65)		

**HTN-Hypertension** 

The obstetric factors found to be of significance for chronic hypertension were gestational age at delivery (p=0.035) and gestational age at onset of HTN (p=0.038). Those with a lower

gestational age at delivery were 2.6 times more likely to get chronic hypertension (OR=2.6, 95% CI 1.1-6.2) and those with a lower gestational age at onset of HTN were 2.4 times more likely to get chronic hypertension (OR=2.4, 95% CI 1.1-5.7).

#### Section 5.2.4 Medical risk factors for chronic hypertension

Table 7: Medical risk factors for chronic hypertensionamong the study participants

Variable	Chronic H	ypertension	Total	OR (95% CI)	p-value
	Yes No		n=116		
	n (%)	n (%)			
HIV status					
Positive	2 (7)	1 (1)	3 (3)	6.1 (0.5-69.6)	0.164
Negative	28 (93)	85 (99)	113 (97)		
Family history of HTN					
Present	22 (73)	41 (48)	63 (54)	3.0 (1.2-7.5)	0.015
Absent	8 (27)	45 (52)	53 (46)		
History of previous HDP					
Present	11 (39)	22 (27)	33 (30)	1.7 (0.7-4.3)	0.242
Absent	17 (61)	59 (73)	76 (70)		
History of DM					
Present	8 (27)	6 (7)	14 (12)	4.8 (1.5-15.4)	0.008
Absent	22 (73)	80 (93)	102 (88)		
History of Thyroid disease					
Present	3 (10)	6 (7)	9 (8)	1.5 (0.3-6.3)	0.693
Absent	27 (90)	80 (93)	107 (92)		

HIV-Human Immunodeficiency Virus, HTN-Hypertension, HDP-Hypertensive Disorder in Pregnancy, DM-Diabetes Mellitus.

In participants with history of previous hypertensive disorders in pregnancy, primigravidae were excluded. Medical risk factors found to be of significance were family history of hypertension (p=0.015), and history of diabetes mellitus (p=0.008). Those with a family

history of hypertension were 3 times more likely to get chronic HTN (OR=3.0, 95% CI 1.2-7.5) and those with a history of diabetes mellitus were 4.8 times more likely to get chronic HTN (OR=4.8, 95% CI 1.5-15.4).

Section 5.2.5 Binomial logistic regression of the risk factors

Table 8: Binomial logistic regression of risk factors

Risk factor	В	Wald	Sig.	OR	95% C.I. for OR	
					Lower	Upper
Intimate partner violence (Yes)	.637	1.581	.209	1.890	.701	5.099
Pre-pregnancy BMI (<=24.9)	-1.092	5.089	.024	.336	.130	.867
Gestational age at delivery (<=36)	.680	1.823	.177	1.974	.736	5.297
Family history of HTN (Present)	.601	1.384	.239	1.824	.670	4.964
History of DM (Present)	1.263	3.710	.054	3.537	.978	12.793
Lowest platelet count (<=150)	.725	1.642	.200	2.064	.681	6.253
Constant	-1.744	8.685	.003	.175		

A binomial logistic regression was performed to ascertain the effects of intimate partner violence, pre-pregnancy BMI, gestational age at delivery, family history of hypertension, history of DM, and lowest platelet count on the likelihood that participants have chronic hypertension. The pre-pregnancy BMI of less than or equal than 24.9 was the only variable that was statistically significant, with the resulting Odds Ratio of 0.3 indicating they were less likely to have chronic hypertension than those above the pre-pregnancy BMI of 24.9.

#### Section 5.2.6 Biochemical risk factors for chronic hypertension

Table 9: Biochemical risk factors for chronic hypertensionamong the study participants

Variable	Chi	ronic	Total	OR	p-value
	Hypertension		n=116	(95% CI)	
	Yes	No	-		
	n (%)	n (%)			
Serum creatinine levels					
≤80	0 (0)	8 (9)	8 (7)	-	0.110
>80	30 (100)	78 (91)	108 (93)		
Serum uric acid levels					
≤375	13 (43)	52 (60)	65 (56)	0.5 (0.2-1.2)	0.104
>375	17 (57)	34 (40)	51 (44)		
Hemoglobin level					
≤11.0	16 (53)	32 (37)	48 (41)	1.9 (0.8-4.5)	0.123
>11.0	14 (47)	54 (63)	68 (59)		
Platelet count					
≤150	10 (33)	13 (15)	23 (20)	2.8 (1.1-7.3)	0.013
>150	20 (67)	73 (85)	93 (80)		

These were laboratory tests done by the participants during the antepartum period. Biochemical risk factors found to be of significance were platelet count (p=0.013). Those with a lower platelet count were 2.8 times more likely to get chronic hypertension (OR=2.8, 95% CI 1.1-7.3).

#### Section 5.3 Time to resolution of hypertension

This section presents the results of the time to resolution of hypertension.

Table 10: Time to resolution of hypertension following gestational hypertension and preeclampsia-eclampsia at Kenyatta National Hospital

Time postpartum	Frequency n (%)
0 weeks	9 (7.8)
2 weeks	67 (57.8)
6 weeks	17 (14.7)
12 weeks	23 (19.8)

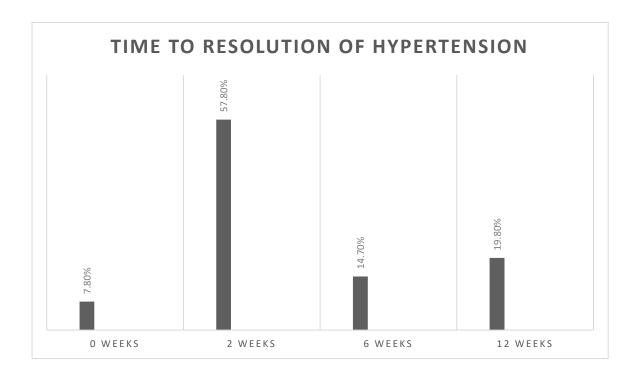


Figure 3: Time to resolution of hypertension following gestational hypertension and preeclampsia-eclampsia at Kenyatta National Hospital

In our findings for time to resolution of hypertension, majority of the participants (57.8%) had resolved hypertension by 2 weeks postpartum.

#### Section 6.1 Discussion

Hypertensive disorders in pregnancy complicate up to 10% of pregnancies worldwide, constituting one of the greatest causes of maternal and perinatal morbidity and mortality. In Kenya, studies conducted at Kenyatta National Hospital have noted a prevalence of 5.4% of hypertensive disease and 0.56% for eclampsia. Hypertension in pregnancy usually resolves after delivery. If it persists, it leads to chronic hypertension which in itself is an important risk factor in cardiovascular disease.

There has been very limited research and follow up in the postpartum period as compared to the antepartum period, especially in low resource settings. There is also limited data on the incidence, risk factors and clinical outcomes of chronic hypertension after hypertensive disease in pregnancy. In our setting, there has been inconsistent postpartum management and follow up of raised blood pressures with most patients being lost to follow up soon after delivery. Our study sought to answer these questions and to expose areas in which improvement can be made in our management of these patients.

This was a descriptive prospective cohort study to determine the incidence and predictors of chronic hypertension following gestational hypertension and preeclampsia-eclampsia at Kenyatta National Hospital and the time to resolution of hypertension in these patients. Data was collected from 116 participants from 2<sup>nd</sup> January 2019 to 30<sup>th</sup> May 2019.Participants were investigated for the presence of established potential risk factors and blood pressure measurements were recorded up to 12 weeks postpartum.

We found that 30 out of the 116 participants (25.9%) had persistent hypertension at 6 weeks postpartum, and 9 out of the 116 participants (7.8%) had persistent hypertension at 12 weeks postpartum. The predictors/risk factors for chronic hypertension were a higher pre-pregnancy BMI, history of intimate partner violence, lowergestational age at delivery, lower gestational age at onset of hypertension, family history of hypertension, history of diabetes mellitus and

lower platelet counts ( $\leq$ 150,000). On binomial logistic regression obesity was the only significant risk factor with those with a pre-pregnancy body mass index  $\geq$ 25 more likely to have chronic hypertension. On time to resolution of hypertension, majority of the participants (57.8%) had resolved hypertension by 2 weeks postpartum.

Our incidence for chronic hypertension was 25.9% at 6 weeks postpartum (30/116) and 7.8% at 12 weeks postpartum (9/116). These findings were similar to Podymow et al(17) who had an incidence of 19% at 12 weeks postpartum, and Hesham Fathy et al(9) who had an incidence of 12.1% at 12 weeks postpartum. Fadalallah et al(11) had an incidence of 35.2% at 6 weeks but their study was looking at persistent hypertension following preeclampsia only while ours included gestational hypertension and mild preeclampsia. That could explain our lower incidence in comparison.

Our study found the risk factors for chronic hypertension to be a higher pre-pregnancy BMI, a history of intimate partner violence, lower gestational age at delivery, lower gestational age at onset of hypertension, family history of hypertension, a history of diabetes mellitus and lower platelet counts. Some similar comparative studies were Fadalallah et al(11) who also found lower platelet counts to be a risk factor, Hwang et al(20) and Kaze et al(18) found higher BMI to be a risk factor while Kaze et al(18) and Nakimuli et al(8) also found lower gestational age at delivery to be a risk factor.

For time to resolution of hypertension, our study found that majority (57.8%) of the participants had resolved hypertension by 2 weeks postpartum. Comparative studies were Podymow et al(17) who had a time to normalization of  $5.4 \pm 3.7$  weeks and Mikami et al(21) who had a time to resolution of  $41.8 \pm 29.4$  days. The differences in our results may be related to differences in our study populations including sociodemographic and clinical characteristics and maybe racial differences.

Our findings suggested that clinicians can easily determine the risk factors of chronic hypertension in patients with hypertensive disorders in pregnancy, and ensure regular BP monitoring for these patients especially in the postpartum period. Patients with risk factors can be counselled on lifestyle modification in order to reduce their risk of developing chronic hypertension, especially as our study showed that obesity is a significant risk factor for chronic hypertension. For those with persistent hypertension, early involvement of a multidisciplinary team including cardiologists and nephrologists would help in earlier diagnosis of complications and improved management of the patients.

#### Section 6.2 Conclusion

Our study found that a quarter of the study participants were still hypertensive at 6 weeks postpartum. Among these, 30% were still hypertensive at 12 weeks postpartum. The risk factors for chronic hypertension were pre-pregnancy BMI, intimate partner violence, gestational age at delivery, gestational age at onset of hypertension, family history of hypertension, history of diabetes mellitus and platelet counts. Obesity was the only significant risk factor on both univariate and multivariate analysis. The majority of the participants (57.8%) had resolved hypertension by 2 weeks postpartum.

#### **Section 6.3 Recommendations**

- It is important to identify risk factors for chronic hypertension in all women with hypertensive disorders in pregnancy so as to identify those at higher risk and to follow them up more closely.
- Obesity has been shown to be an important risk factor for chronic hypertension following hypertensive disorders in pregnancy. It is therefore important to counsel obese women in pregnancy on lifestyle modification so as to reduce their chances of developing chronic hypertension.

• Close follow up of patients with hypertensive disorders in pregnancy during the postpartum period is important so as to ensure early diagnosis of chronic hypertension and timely referral to a multidisciplinary team.

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Section 8.0

**APPENDICES** 

Section 8.1

**APPENDIX I: CONSENT FORM** 

Date (date/month/year):

Study Title:: INCIDENCE AND PREDICTORS OF CHRONIC HYPERTENSION

FOLLOWING HYPERTENSIVE DISEASE IN PREGNANCY AT KENYATTA

NATIONAL HOSPITAL, A DESCRIPTIVE PROSPECTIVE COHORT STUDY

**Principal Investigator:** 

Dr. Maryam Badamana (MBChB)

Department of Obstetrics and Gynecology, University of Nairobi.

**Telephone Number: 0724-699628** 

Investigator's Statement:

I am requesting you to kindly participate in this research study. The purpose of this

consent form is to provide you with the information you will need to help you decide

whether to participate in the study. This process is called 'Informed Consent'. Please read

this consent information carefully and ask any questions or seek clarification on any

matter concerning the study with which you are uncertain. You are free to ask any

questions about the study. The investigator will be available to answer any questions that

arise during the study and afterwards.

**Introduction:** 

Hypertension in pregnancy usually resolves after delivery. If it persists, it leads to chronic

hypertension which in itself is an important risk factor in cardiovascular disease.

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Therefore, it is important to monitor blood pressures during pregnancy and in the postpartum period.

Preeclampsia and eclampsia in pregnancy are managed supportively and definitively. Supportive management includes use of oxygen, respiratory support and IV fluids. Definitive management involves use of anti hypertensives, magnesium sulphate and other anti convulsants where necessary. This management is instituted by the clinicians managing the patient in the hospital.

Known predictors of chronic hypertension postpartum include sociodemographic factors, obstetric factors and medical factors. We would like to determine which of these factors cause chronic hypertension following hypertensive disorders in pregnancy.

#### Benefits:

As a participant you will benefit from the study by receiving closer monitoring of your blood pressure during pregnancy and in the postpartum period. You will benefit by receiving health education and advice during your pregnancy. You will be able to access the principal investigator at any time during the study period. Your participation in the study may benefit others in future from the information we find in this study.

#### Risks:

Uncontrolled hypertension can lead to complications like heart attack and stroke. If at any time you experience headache, blurring of vision or epigastric pain please inform the principal investigator.

We will ensure that your privacy and confidentiality is maintained at all times. We will ensure that all your medical records and information is kept safely.

#### Voluntariness:

The study participation will be fully voluntary. There will be no financial rewards to you for participating in the study. One is free to participate or withdraw from the study at any point. Refusal to participate will not compromise you or your child's care in any way.

#### Confidentiality:

All the information obtained from you will be held in strict confidentiality. Any information that may identify you or your child will not be published or discussed with any unauthorized persons. No specific information regarding you, your child or your family will be released to any person without your written permission. Your research number will be used in place of your names.

#### Access of health records

You may apply for access to your own records, or may authorize third parties such as lawyers, employers, or insurance companies to do so on your behalf. The Principal Investigator can be contacted if access to health records is required.

#### Sharing of results

Study staff will protect your personal information closely so no one will be able to connect your responses and any other information that identifies you. Federal or state laws may require us to show information to university or government officials (or sponsors), who are responsible for monitoring the safety of this study. Directly identifying information (e.g. names, addresses) will be safeguarded and maintained under controlled conditions. You will not be identified in any publication from this study.

#### Study procedure

You have been picked for this study because you have preeclampsia or eclampsia in pregnancy. We will require you to answer some questions for us as honestly and truthfully as possible so as to help us fill our study questionnaire. We will also need to take your blood pressure measurements. You will be required to give us your contact details so that we can follow you up in the postpartum period. We will need to contact you at two weeks, six weeks and twelve weeks postpartum to find out your blood pressure measurement which can be taken at your nearest health facility. The blood pressure measurement will be recorded in the questionnaire you filled earlier. If your blood pressure is consistently elevated in the postpartum period, we will refer you to a health facility for further management as it will require longer follow up.

#### Intervention:

Your blood pressure measurements during pregnancy and during the postpartum period will be recorded and kept safely with your records. We will also ask you to complete a questionnaire that will help in our study.

#### Problems or Questions:

If you ever have any questions about the study or about the use of the results you can contact the principal investigator, Dr. Maryam Badamana by calling 0724-699628. If you have any questions on your rights as a research participant, you can contact the Kenyatta National Hospital Ethics and Research Committee (KNH- ESRC) by calling 2726300 Ext. 44355.

#### Consent Form: Participant's Statement:

I having received adequate information regarding the study research, risks, benefits hereby AGREE / DISAGREE

(Cross out as appropriate) to participate in the study. I understand that my participation is fully voluntary and that I am free to withdraw at any time. I have been given adequate opportunity to ask questions and seek clarification on the study and these have been addressed satisfactorily.

Parent's name:	Signature/thumb print:
Date	
Witness name:	Signature/thumbprint:
Date:	
Ι	declare that I have adequately
explained to the above participant, the	study procedure, risks and benefits and given him
/her time to ask questions and seek cla	arification regarding the study. I have answered all
the questions raised to the best of my a	bility.
Interviewer's name and Signature:	Date:

#### **Problems or Questions:**

If you ever have any questions about the study or about the use of the results you can contact the principal investigator, Dr. Maryam Badamana by calling 0724-699628. If you have any questions on your rights as a research participant, you can contact the Kenyatta National Hospital Ethics and Research Committee (KNH- ERC) by calling 2726300 Ext.44355.

Section 8.2 APPENDIX 2: CONSENT FORM IN KISWAHILI

**FOMU YA RIDHAA** 

Tarehe (siku/mwezi/mwaka):

**Study Title: INCIDENCE** AND **PREDICTORS OF CHRONIC** 

HYPERTENSION FOLLOWING HYPERTENSIVE DISEASE IN PREGNANCY

AT KENYATTA NATIONAL HOSPITAL, A PROSPECTIVE COHORT STUDY

Mtafiti Mkuu:

Dkt. Maryam Badamana (MBChB)

Idara ya Uzazi na Afya ya kina mama, Chuo kikuu cha Nairobi.

Nambari ya simu: 0724-699628

Taarifa ya mtafiti:

Ninakuomba kushiriki kwenye utafiti huu. Lengo la fomu hii ya idhini ni kukupa habari

utakayohitaji ili ikusaidie kuamua ikiwa utashiriki kwenye utafiti. Utaratibu huu unaitwa

'Idhini ya kujulishwa'. Tafadhali soma ujumbe wa idhini hii kwa uangalifu na uulize

maswali yoyote au ufafanuzi kwa mambo yoyote yanayohusisha utafiti ambayo hauna

uhakika nayo. Uko huru kuuliza ma swali yoyote kuhusu utafiti. Mtafiti atakuweko kujibu

maswali yatakayotokea wakati wa utafiti na baadaye.

**Utangulizi:** 

Shinikizo la damu katika ujauzito kawaida huamua baada ya kujifungua. Ikiendelea,

husababisha shinikizo la damu sugu ambayo yenyewe ni sababu muhimu ya ugonjwa wa

moyo. Kwa hiyo, ni muhimu kufuatilia shinikizo la damu wakati wa ujauzito na katika

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kipindi cha baada ya kujifungua.

Magonjwa ya shinikizo la damu katika mimba yanatibiwa kwa njia tofauti kulingana na muuguzi anayemhudumia mgonjwa hospitalini. Matibabu haya yanaweza kuwa kama madawa ya kupunguza shinikizo la damu, na madawa ya kukuepusha na kupata kifafa.

Maambukizi yanajulikana ya ugonjwa wa shinikizo la damu baada ya kujifungua yanajumuisha sababu za kijamii, sababu za kiuzazi na mambo ya matibabu. Tungependa kuamua ni sababu gani ya hizi zinazosababisha shinikizo la damu kubwa baada ya matatizo ya shinikizo la damu katika ujauzito.

#### Faida:

Kama mshiriki utafaidika kutokana na utafiti kwa kupata malezi ya kufwatiliwa shinikizo la damu katika mimba yako na baada ya kujifungua.Utafaidika kwa kupokea elimu na ushauri wa afya wakati wa ujauzito. Utaweza kumfikia mtafiti mkuu wakati wowote kwa wakati wa utafiti. Kushiriki kwako kwenye utafiti kwaweza wafaidi wengine wakati wa usoni kutokana na habari tutakoyopata kwenye utafiti huu.

#### Hatari:

Shinikizo la damu isiyoweza kudhibitiwa inaweza kusababisha matatizo kama vile mashambulizi ya moyo na kiharusi. Ikiwa wakati wowote unahisi kuumwa na kichwa, kutoona vizuri au kiungulia, tafadhali muarifu mhusika mkuu wa utafiti huu.

Tutahakikisha kuwa usiri wako utahifadhiwa wakati wote. Tutahakikisha kuwa rekodi za matibabu yako yote yatahifadhiwa vizuri.

#### Kujitolea:

Kujihusisha katika utafiti utakua wa kujitolea. Hakuta kuwa na malipo ya kifedha kwa kushiriki kwenye utafiti huu. Mtu ako huru kushiriki au kujiondoa kwenye uta fiti kwa wakati wowote. Kukataa kushiriki hakutaathiri malezi yako au ya mwanao hata.

#### Usiri:

Habari yoyote itakayotolewa kwako itawekwa kwa usiri wa hali ya juu. Habari yoyote ya kukutambulisha wewe au mwanao haitachapishwa au kujadiliwa na watu wasiona kibali. Hakuna habari maalum kukuhusu, kuhusu mwanao au mtu wa familia yako itapeanwa kwa mtu mwingine bila ruhusa yako iliyoandikwa. Nambari yako ya utafiti itatumika badala ya jina lako.

#### Kupata rekodi za kimatibabu

Unaweza kuomba ku weza kufikia rekodi zako au kuruhusu watu wengine kama vile mawakili, waajiri au kampuni za fidia kufunya hivyo kwa niaba yako. Mtafiti mkuu anaweza fikiwa ikiwa rekodi zako zahitaji kufikiwa.

#### Kujulisha wengine matokeo

Wafanyakazi wa utafiti watalinda habari sana habari yako ya kibinafsi ilimtu yeyote asije akajua akaunganisha majibu yako na habari inayoweza kukutambulisha. Sheria za serikali zatuhitaji kuonyesha habari kwa wawakilikilishi wa serikali (wafadhili) au chuo kikuu ambao wana jukumu la kufuatilia usalama wa utafiti huu. Habari inayotambulisha moja kwa moja (majina, anwani) zitalindwa na kuwekwa katika hali salama. Hautatambulishwa na chapisho lolote kutoka na utafiti huu.

#### Utaratibu wa kujifunza

Umechaguliwa kwa ajili ya utafiti huu kwa sababu una preeclampsia au eclampsia wakati wa ujauzito. Tutakuhitaji kujibu maswali fulani kwa uaminifu na ukweli iwezekanavyo ili kutusaidia kujaza maswali ya utafiti. Tunahitaji pia kuchukua kipimo chako cha shinikizo la damu. Utatakiwa kutupa maelezo yako ya kuwasiliana ili tuweze kukufuata katika kipindi cha baada ya kujifungua. Tutahitaji kuwasiliana na wewe wiki mbili, wiki sita na wiki kumi na mbili baada ya kujifungua ili kujua kipimo chako cha shinikizo la damu ambacho kinaweza kuchukuliwa kwenye kituo chako cha afya cha karibu. Upimaji wa shinikizo la damu utaandikishwa katika fomu ya maswali uliojaza awali. Ikiwa shinikizo la damu lako limeongezeka mara kwa mara katika kipindi cha baada ya kujifungua tutakuelekeza kwenye kituo cha afya kwa ajili ya usimamizi zaidi kama itahitaji ufuatiliaji mrefu.

#### **Tutakachofanya**

Shindikizo la damu yako itapimwa katika wakati wa mimba na baada ya kujifungua. Rekodi zako zote zitawekwa vizuri. Tutakuomba utusaidie kujaza dodoso ya utafiti wetu.

#### Shida au Maswali:

Ikiwa una maswali kuhusu utafiti au matumizi ya majibu waweza asiliana na mtafiti, Dkt. Maryam Badamana kwa kupiga 0724-699628. Ikiwa una maswali kuhusu haki yako kam mshiriki waweza wasiliana na kamati ya madili na tafiti ya hospitali kuu ya (KNH- ERC) kwakupiga 2726300 Ext. 44355.

Fomu ya Idhini: Taarifaya Mshiriki:	
Mimi	Nimepewa habari ya kutosha kuhusiana
na utafiti , hatari, faida, NINAKUBAI	LI/SIKUBALI (weka alama inavyostahili).
Kushiriki kwenye utafiti. Ninaelewa kwaml	ba kushiriki kwangu ni kwa kujitolea na niko
huru kujiondoa wakati wowote. Nimepewa	a nafasi ya kutosha ya kuuliza ma swali na
kuuliza ufafanuzi wa utafiti na nimeelezewa	haya nikatosheka.
Jina la mshiriki:	Sahihi/alamayakidole:
Tarehe	
Jina la mshahidi:	Sahihi/alamayakidole:
Tarehe:	
Mimi_	Natangaza yakwamba nimemwelezea
mshiriki aliye hapo juu yakutosha, taratibu	za utafiti, hatari na faida na nimempa wakati
wakuuliza naswali nakuuliza ufafanuzi kuh	usu utafiti. Nimejibu maswali yake yote kwa
uwezo wangu wote.	
Jina la anayeuliza ma swali na sahihi:	Tarehe:
Shida au Maswali:	

Ikiwa una maswali kuhusu utafiti au matumizi ya majibu waweza asiliana na mtafiti, Dkt.

Maryam Badamana kwa kupiga 0724-699628. Ikiwa una maswali kuhusu haki yako kam

mshiriki waweza wasiliana na kamati ya madili na tafiti ya hospitali kuu ya (KNH- ERC) kwakupiga2726300 Ext. 44355.

## Section 8.3 APPENDIX 3: INCLUSION AND EXCLUSION SCREENING ENROLMENT FORM

Study Title: INCIDENCE AND PREDICTORS OF CHRONIC HYPERTENSION FOLLOWING HYPERTENSIVE DISEASE IN PREGNANCY AT KENYATTA NATIONAL HOSPITAL, A PROSPECTIVE COHORT STUDY

Date: (date/month/year):
Enrolment identification number:
Inclusion Criteria: Answers MUST be 'yes' for these questions.
Patients with gestational hypertension, preeclampsia or eclampsia after 20 weeks
gestation
Patients willing to be followed up postpartum
Exclusion criteria: If any answer is 'Yes' exclude from enrolment
Patients with no informed consent.
Patients who are unwilling to be followed up.
Patients known to have preexisting chronic hypertension.
Patients too sick to give informed consent.

#### Section 8.4 APPENDIX 4: DATA COLLECTION TOOL

# Study Title: INCIDENCE AND PREDICTORS OF CHRONIC HYPERTENSION FOLLOWING HYPERTENSIVE DISEASE IN PREGNANCY AT KENYATTA NATIONAL HOSPITAL

BASELINE	QUESTIONNAIRE		
Indicate all	times using the 24-ho	ur clock, and d	lates in this format date/month/year.
DATE			
Patient ident	ification number:		
Date of Sign	ed Informed Consent:	/_	
Copy given	to patient: Yes / No		
Part 1: Hyp	ertensive disorder in ]	pregnancy	
Gesta	ational hypertension		
Mild	preeclampsia		
Seve	re preeclampsia		
Eclar	mpsia		
Part 2: Soci	o demographic factor	s	
1. Age of m	nother (years)		
2. Marital S	Status		
Single		Widowed	
Married		Separated	

Di	vorced $\square$	
3.	Spouse's age (years)	
4.	Pre-pregnancy Body Mass Index	
5.	Discharge Body Mass Index	
6.	History of smoking	
	Yes	
	No	
7.	History of alcohol intake	
	Yes	
	No	
8.	Intimate partner violence	
	Yes	
	No	
Pa	rt 3: Obstetric factors	
1.	Parity	
2.	Number of pregnancy (gravida)	
3.	Mode of delivery	

Caesarian Section

### Spontaneous vertex delivery

4.	Baby's birth weight
5.	Gestational age at delivery
6.	Gestational age at onset of hypertension
7.	Outcome of delivery
	Live birth
	Still birth
8.	Discharged on blood pressure medication
	Yes
	No
Pa	rt 4: Medical factors
1.	Human Immunodeficiency Virus status
	Positive
	Negative
2.	Family history of hypertension
	Present
	Absent
3.	History of previous hypertensive disorder in pregnancy

		Present				
		Absent				
4.	History o	f Diabetes Mellitus				
		Present				
		Absent				
5.	History o	f thyroid disease				
		Present				
		Absent				
6.	Others					
Pa	Part 5: Peri-partum blood pressure measurements and laboratory results					
	1. At 2 v	weeks postpartum				
	At 6 v	weeks postpartum				
	At 12	weeks postpartum				
	2. Highe	est blood pressure recor	rded			
	3. Highe	est serum creatinine				
	4. Highe	est serum uric acid				
	5. Lowe	st haemoglobin level				
	6. Lowe	st platelet counts				